



explain why such standards should be used in this proposed action.

j. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

Executive Order 12898 (59 FR 7629) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. The EPA determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The EPA has assessed the overall protectiveness of modifying the Charleston ODMDS against the criteria established pursuant to the MPRSA to ensure that any adverse impact to the environment will be mitigated to the greatest extent practicable. We welcome comments on this proposed action related to this Executive Order.

List of Subjects in 40 CFR Part 228

Environmental protection, Water pollution control.

Authority: This action is issued under the authority of Section 102 of the Marine Protection, Research, and Sanctuaries Act, as amended, 33 U.S.C. 1401, 1411, 1412.

Dated: June 22, 2016.

Heather McTeer Toney,
Regional Administrator, Region 4.

For the reasons set out in the preamble, the EPA proposes to amend chapter I, title 40 of the Code of Federal Register as follows:

PART 228—CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING

■ 1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

■ 2. Section 228.15 is amended by revising paragraphs (h)(5)(i) through (iii) and (vi) to read as follows:

§ 228.15 Dumping sites designated on a final basis.

* * * * *
(h) * * *

(5) * * *
(i) *Location:* 32°36.280' N., 79°43.662' W.; 32°21.514' N., 79°46.576' W.; 32°20.515' N., 79°45.068' W.; 32°20.515' N., 79°42.152' W.

(ii) *Size:* Approximately 7.4 square nautical miles in size.

(iii) *Depth:* Ranges from approximately 30 to 45 feet (9 to 13.5 meters).

* * * * *
(vi) *Restrictions:* (A) Disposal shall be limited to dredged material from the Charleston, South Carolina, area;

(B) Disposal shall be limited to dredged material determined to be suitable for ocean disposal according to 40 CFR 227.13;

(C) Disposal shall be managed by the restrictions and requirements contained in the currently-approved Site Management and Monitoring Plan (SMMP);

(D) Monitoring, as specified in the SMMP, is required.

* * * * *
[FR Doc. 2016-16584 Filed 7-12-16; 8:45 am]
BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 75

RIN 0991-AC06

Health and Human Services Grants Regulation

AGENCY: Department of Health and Human Services; Office of the Assistant Secretary for Financial Resources, Division of Grants, Office of Grants Policy, Oversight, and Evaluation.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking (NPRM) proposes changes to the Department of Health and Human Services' (HHS) adoption of the Office of Management and Budget's (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Uniform Administrative Requirements") published on December 19, 2014 (79 FR 75871) and the technical amendments published by HHS on January 20, 2016 (81 FR 3004). HHS codified the OMB language, with noted modifications as explained in the preamble to the December promulgation, in 45 CFR part 75. The HHS-specific modifications to the Uniform Administrative Requirements adopted prior regulatory language that was not in conflict with OMB's language, and provided additional

guidance to the regulated community. Unlike all of the other modifications to the Uniform Administrative Requirements, these proposed changes, although based on existing law or HHS policy, were not previously codified in regulation. This NPRM seeks comments on these important proposed regulatory changes.

DATES: To be assured consideration, comments must be received at the address provided below, no later than 5 p.m. on August 12, 2016.

ADDRESSES: In commenting, please refer to file code 0991-AC06. Because of staff and resource limitations, comments must be submitted electronically to www.regulations.gov. Follow the "Submit a comment" instructions.

FOR FURTHER INFORMATION CONTACT: Dr. Audrey Clarke at HHS at 202-720-1908.

SUPPLEMENTARY INFORMATION:
Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. We post all comments received before the end of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view the public comments.

Background

This NPRM proposes changes to the HHS's adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published on December 19, 2014 (79 FR 75871) and the technical amendments published by HHS on January 20, 2016 (81 FR 3004). HHS codified the OMB language, with noted modifications, in 45 CFR part 75. Unlike all of the other modifications to the Uniform Administrative Requirements, these proposed changes, although based on existing law or HHS policy, were not previously codified in regulation. This NPRM seeks comments for these important regulatory changes.

In order to give full effect to other important government-wide initiatives, HHS is proposing further amendments at this time, which HHS intends to finalize as soon as possible. HHS proposes several additional changes to the codification of 2 CFR part 200 in 45 CFR part 75. First, HHS proposes to add language to 45 CFR 75.102, clarifying that the audit requirements and cost principles applicable to contracts and compacts awarded pursuant to the Indian Self Determination and Education Assistance Act (ISDEAA) are

governed by subparts E and F including § 75.505 Sanctions, enforceable through § 75.371 Remedies for noncompliance, and that certain other sections and subparts of these regulations do not apply to ISDEAA contracts and compacts.

Notably, the ISDEAA itself specifies that contracts and compacts awarded pursuant to the ISDEAA are subject to the Single Audit Act and OMB Circulars A–133, A–87, and A–122 and that ISDEAA contracts are not subject to federal grant and cooperative agreement requirements. 25 U.S.C. 450c(f), 458aaa–5(c). In order to clarify how the Uniform Administrative Requirements interact with the prior-enacted Federal statute, and to minimize confusion regarding applicability, HHS has determined that this clarification is required. This will additionally ensure that Indian tribes and tribal organizations are fully apprised of their rights and responsibilities. Although HHS considers this amendment to be a requirement of existing statute and regulation, HHS proposes this change with notice and an opportunity for comment to ensure that the regulated community is aware of this clarification.

In addition, HHS proposes to add language to clarify the meaning of disallowed cost as used in 25 U.S.C. 450j–1(f) to reflect that the meaning must adhere to the audit requirements of 45 CFR part 75, subpart F. Because subpart F applies to ISDEAA contracts and compacts, and the ISDEAA contains a stringent time limitation on certain claims pursuant to the Single Audit Act Amendments of 1996 (31 U.S.C. 7501–7507), HHS proposes to clarify that the scope of the time limitation applies only to cost disallowances arising under such Act, and not to other claims or disallowances identified through other audits or investigations. Without the addition of this clarifying language a different interpretation of the time limitation (which has been adopted in a few isolated judicial and administrative cases) would place additional administrative burdens on the Indian Health Service and entities holding ISDEAA contracts and compacts by compelling the government and the entities to perform burdensome and intrusive program compliance reviews in addition to the annual single audit required by the Single Audit Act. HHS believes the proposed language avoids imposing unreasonable burdens on the government and tribes and limits the need for yearly program compliance reviews.

Second, HHS proposes two changes to 45 CFR 75.300. First, HHS is codifying a prohibition in the provision of

services of discrimination on the basis of age, disability, sex, race, color, national origin, religion, sexual orientation, or gender identity. This provision codifies for all HHS service grants what is already applicable for all HHS service contracts, as required by the HHS Acquisition Regulation (HHSAR) 352.237–74. The HHSAR provision makes explicit HHS's non-discrimination policy when obligating appropriations for solicitations, contracts and orders that deliver service under HHS's programs directly to the public. In order to ensure that this same provision applies equally to grants, HHS proposes an addition to make this explicit in the grants context.

This provision does not apply to funding under the Temporary Assistance for Needy Families Program (TANF) (title IV–A of the Social Security Act, 42 U.S.C. 601–619). The TANF statute, 42 U.S.C. 608(d), already identifies the nondiscrimination provisions that can be applied to TANF.

In addition, HHS is codifying its implementation of the decisions in *U.S. v. Windsor*, 570 U.S. ____ (2013), 133 S.Ct. 2675 and *Obergefell v. Hodges*, 576 U.S. ____ (2015), 135 S.Ct. 2584. The HHS codification of its interpretation of these Supreme Court decisions ensures that same-sex spouses, marriages, and households are treated the same as opposite-sex spouses, marriages, and households in terms of determining beneficiary eligibility or participation in grant-related activities.

Because these two codifications are being proposed for consistency with law and current HHS policy, HHS believes that they are non-controversial, but nonetheless requests public comment. Third, HHS is proposing to clarify the language currently codified in 45 CFR part 75 regarding the applicability to states of certain payment provisions. Because the current language applies the provisions of Treasury—State Cash Management Improvement Act agreements and default procedures codified at 31 CFR part 205 and TM 4A–2000, and such agreements may not contain specific provisions addressed by 45 CFR 75.305, HHS seeks to modify the language to ensure clarity. In doing so, to the extent that the governing provisions are silent as to the payment provisions described in the Uniform Administrative Requirements, there should be no effect on states, as they had been subject to these same provisions pursuant to 45 CFR 92.21. However, HHS proposes the clarification so that all states are aware of the necessity to, for example, expend refunds and rebates prior to drawing down additional grant funds.

Fourth, HHS is proposing to amend 45 CFR 75.365, related to restrictions on public access to records, in order to implement the President's Executive Order 13,642 (May 9, 2013), and corresponding law. See, e.g., <http://www.whitehouse.gov/the-press-office/2013/05/09/executive-order-making-open-and-machine-readable-new-default-government->, and Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act of 2014, Public Law 113–76, Div. H, Sec. 527. HHS proposes to codify permissive authority for HHS awarding agencies to require public access to manuscripts, publications, and data produced under an award, consistent with applicable law.

Fifth, HHS is proposing to amend 45 CFR 75.414(c) to add a provision to restrict indirect cost rates for certain grants. It is long-standing HHS policy to restrict training grants to a maximum eight percent indirect cost rate. HHS proposes additionally to impose this same limitation on foreign organizations and foreign public entities, which typically do not negotiate indirect cost rates. In the proposed rule, American University, Beirut, and the World Health Organization are exempted specifically from the indirect cost rate limitation because they are eligible for negotiated facilities and administration (F&A) cost reimbursement. This restriction on indirect costs, as indicated by 45 CFR 75.101, flows down to subawards and subrecipients.

Finally, HHS proposes a new selected item of cost for codification in the cost principles as 45 CFR 75.477, regarding shared responsibility payments. As HHS has already announced in policy for the Ryan White HIV/AIDS Program, any payments or assessments imposed on an individual or individuals pursuant to 26 U.S.C. 5000A(b) as a result of any failure to maintain minimum essential coverage as required by 26 U.S.C. 5000A(a), are not allowable costs under a grant. See HAB Policy Notice 13–04, at 2–3; <http://hab.hrsa.gov/manageyourgrant/pinspals/pcn1304privateinsurance.pdf>. Because this is a sound public policy requirement for all grants, not just the Ryan White HIV/AIDS Program grants, HHS proposes to codify this provision in the Uniform Administrative Requirements. Furthermore, HHS proposes to adopt the same stance with regard to payments for failure to offer health coverage to employees. Because the provision codified at 26 U.S.C. 4980H has not yet been enforced against any employers, HHS has not had the need previously to announce a stance on this issue. HHS does so now, and seeks comments from the public.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320 Appendix A.1), HHS reviewed this NPRM and determined that there are no new collections of information contained therein.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires that an agency provide a final regulatory flexibility analysis or to certify that the rule will not have a significant economic impact on a substantial number of small entities. This NPRM aligns 45 CFR part 75 with various regulatory and statutory provisions, implements Supreme Court decisions, and codifies long-standing policies thus clarifying and enhancing the provisions in HHS's interim final guidance issued December 19, 2014, and amended on January 20, 2016. In order to ensure that the public receives the most value, it is essential that HHS grant programs function as effectively and efficiently as possible, and that there is a high level of accountability to prevent waste, fraud, and abuse. The proposed additions provide enhanced direction for the public and will not have a significant economic impact beyond HHS's current regulations.

Executive Order 12866 Determination

Pursuant to Executive Order 12866, HHS has designated this NPRM to be economically non-significant. This rule is not being treated as a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. HHS has determined that this NPRM will not result in expenditures by State, local, and tribal governments, or by the private sector, of \$100 million or more in any one year. Accordingly, HHS has not prepared a budgetary impact

statement or specifically addressed the regulatory alternatives considered.

Executive Order 13132 Determination

HHS has determined that this NPRM does not have any Federalism implications, as required by Executive Order 13132.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

List of Subjects in 45 CFR Part 75

Accounting, Administrative practice and procedure, Cost principles, Grant programs, Grant programs—health, Grants administration, Hospitals, Indians, Nonprofit organizations reporting and recordkeeping requirements, and State and local governments.

For the reasons set forth in the preamble, part 75 of title 45 of the Code of Federal Regulations is proposed to be amended as follows:

■ 1. The authority citation for 45 CFR part 75 continues to read as follows:

Authority: 5 U.S.C. 301.

■ 2. Amend § 75.101 by adding paragraph (f) to read as follows:

§ 75.101 Applicability.

* * * * *

(f) Section 75.300(c) does not apply to the Temporary Assistance for Needy Families Program (title IV–A of the Social Security Act, 42 U.S.C. 601–619).

■ 3. Amend § 75.102 by adding paragraph (e) to read as follows:

§ 75.102 Exceptions.

* * * * *

(e)(1) Indian tribes and tribal organizations carrying out a compact or contract under the ISDEAA must comply with Subpart E, Cost Principles, and Subpart F, Audit Requirements, including § 75.505 Sanctions, enforceable through § 75.371 Remedies for noncompliance. References to cost principles and audit requirements in the ISDEAA and its implementing regulations, including OMB Circulars A–87, A–122, and A–133 (which were superseded by 2 CFR 200), shall be deemed to be references to subparts E and F. Except for statutorily mandated grants added to a funding agreement in accordance with 42 CFR part 137, subpart F, certain sections of this part, applicable to grants and cooperative agreements, do not apply to ISDEAA contracts and compacts, including 45 CFR 75.111, 75.112, and 75.113 and subparts C and D.

(2) Cost disallowances to which the limitation on remedies under 25 U.S.C. 450j–1(f) applies shall include only

disallowed costs that are identified through a Single Agency Audit conducted pursuant to the Single Audit Act and subject to the requirements of subpart F, and shall not include claims or disallowances identified through other audits or investigations.

■ 4. Amend § 75.300 by adding paragraphs (c) and (d) to read as follows:

§ 75.300 Statutory and national policy requirements.

* * * * *

(c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as age, disability, sex, race, color, national origin, religion, gender identity, or sexual orientation. Recipients must comply with this public policy requirement in the administration of programs supported by HHS awards.

(d) In accordance with the Supreme Court decisions in *United States v. Windsor* and in *Obergefell v. Hodges*, all recipients must treat as valid the marriages of same-sex couples. This does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under state law as something other than a marriage.

■ 5. Revise § 75.305(a) to read as follows:

§ 75.305 Payment.

(a)(1) For states, payments are governed by Treasury-State CMIA agreements and default procedures codified at 31 CFR part 205 and TFM 4A–2000 Overall Disbursing Rules for All Federal Agencies.

(2) To the extent that Treasury-State CMIA agreements and default procedures do not address expenditure of program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds, such funds must be expended before requesting additional cash payments.

* * * * *

■ 6. Revise § 75.365 to read as follows:

§ 75.365 Restrictions on public access to records.

Consistent with section 75.322 of this part, HHS awarding agencies may require recipients to permit public access to manuscripts, publications, and data produced under an award. However, no HHS awarding agency may place restrictions on the non-Federal entity that limit public access to the records of the non-Federal entity pertinent to a Federal award identified

in sections 75.361 through 75.364, except for protected personally identifiable information (PII) or when the HHS awarding agency can demonstrate that such records will be kept confidential and would have been exempted from disclosure pursuant to the Freedom of Information Act (5 U.S.C. 552) or controlled unclassified information pursuant to Executive Order 13556 if the records had belonged to the HHS awarding agency. The Freedom of Information Act (5 U.S.C. 552) (FOIA) does not apply to those records that remain under a non-Federal entity's control except as required under § 75.322. Unless required by Federal, state, local, or tribal statute, non-Federal entities are not required to permit public access to their records identified in sections 75.361 through 75.364. The non-Federal entity's records provided to a Federal agency generally will be subject to FOIA and applicable exemptions.

■ 7. In § 75.414(c)(1) add paragraphs (c)(1)(i) through (iii):

§ 75.414 Indirect (F&A) costs.

* * * * *

(c)(1) * * *

(i) indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000;

(ii) indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000; and,

(iii) negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

* * * * *

■ 8. Add § 75.477 to read as follows:

§ 75.477 Shared responsibility payments.

(a) *Payments for failure to maintain minimum essential health coverage.* Any payments or assessments imposed on an individual or individuals pursuant to 26 U.S.C. 5000A(b) as a result of any failure to maintain minimum essential coverage as required by 26 U.S.C. 5000A(a) are not allowable expenses under Federal awards from an HHS awarding agency.

(b) *Payments for failure to offer health coverage to employees.* Any payments or assessments imposed on an employer pursuant to 26 U.S.C. 4980H as a result of the employer's failure to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan are not allowable expenses under Federal awards from an HHS awarding agency.

[FR Doc. 2016-15014 Filed 7-12-16; 8:45 am]

BILLING CODE 4150-24-P



report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 10, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it

extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 28, 2016.

Heather McTeer Toney,
Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Z—Mississippi

■ 2. Section 52.1270(e) is amended by adding a new entry “110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM_{2.5} NAAQS” at the end of the table to read as follows:

§ 52.1270 Identification of plan.

* * * * *
(e) * * *

EPA APPROVED MISSISSIPPI NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual PM _{2.5} NAAQS.	Mississippi	12/11/2015	12/12/2016, [Insert citation of publication in Federal Register].	With the exception of sections: 110(a)(2)(C) and (J) concerning PSD permitting requirements; 110(a)(2)(D)(i)(I) and (II) (prongs 1 through 4) concerning interstate transport requirements and the state board majority requirements respecting significant portion of income of section 110(a)(2)(E)(ii).

[FR Doc. 2016–29593 Filed 12–9–16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 75

RIN 0991–AC06

Health and Human Services Grants Regulation

AGENCY: Division of Grants, Office of Grants Policy, Oversight, and Evaluation, Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule makes changes to the Department of Health and Human Services’ (HHS) adoption of the Office of Management and Budget’s (OMB) (“Uniform Administrative Requirements”) published on December 19, 2014 and the technical amendments published by HHS on January 20, 2016. HHS codified the OMB language, with noted modifications as explained in the preamble to the December promulgation. The HHS-specific

modifications to the Uniform Administrative Requirements adopted prior regulatory language that was not in conflict with OMB’s language, and provided additional guidance to the regulated community. Unlike all of the other modifications to the Uniform Administrative Requirements, these additional changes, although based on existing law or HHS policy, were not previously codified in regulation. HHS sought comment on these proposed changes in a notice of proposed rulemaking published on July 13, 2016. This final rule implements these regulatory changes. It also corrects one typographical error that was recently discovered in the most recent promulgation of the Uniform Administrative Requirements.

DATES: This rule is effective on January 11, 2017.

FOR FURTHER INFORMATION CONTACT: Quadira Dantro, MSHS, CRA at (202) 260–6825.

SUPPLEMENTARY INFORMATION:

Background

This final rule makes changes to the HHS’s adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published on December

19, 2014 (79 FR 75871) and the technical amendments published by HHS on January 20, 2016 (81 FR 3004). HHS codified the OMB language, with noted modifications, in 45 CFR part 75. Unlike all of the other modifications to the Uniform Administrative Requirements, these additional changes, although based on existing law or HHS policy, were not previously codified in regulation. This final rule implements these regulatory changes.

HHS received 24 relevant comments on the notice of proposed rulemaking, half of which were strongly supportive of the proposed rule. HHS addresses all of the comments below.

A. Nondiscrimination Provisions

Comment: HHS received twelve comments on these provisions, all of which were strongly supportive of the codification of the nondiscrimination provisions in HHS awards and the recognition of same-sex marriages. Several of these supportive comments also provided additional areas for consideration specifically regarding the definition of discrimination on the basis of sex. Collectively, the comments indicated that HHS should define discrimination on the basis of sex explicitly to include discrimination on

the basis of sex stereotyping, gender identity, sexual orientation, pregnancy, intersex traits, and the presence of atypical sex characteristics.

Response: HHS appreciates the comments received, and thanks commenters for their positive reactions and helpful suggestions. For the time being, HHS does not believe it is necessary to add additional categories to the list of non-merit based factors. We note that the determination whether a factor is merit-based for purposes of applying the prohibition will depend on the nature of the particular grant at issue. HHS has therefore decided not to amend the nondiscrimination language proposed in 45 CFR 75.300.

Comment: One comment urged HHS and its partner federal agencies to broadly construe age discrimination protections to support young people as well as older Americans. The comment noted that while many age discrimination laws are enacted with older adults in mind, it is important to recognize the stigmatization of young people and adolescents, particularly in the healthcare arena.

Response: HHS agrees that young people and adolescents should have access to health care and services free from discrimination. No alterations of the regulatory text are necessary to implement these protections. We note that, while employment laws enforced by the Equal Employment Opportunity Commission apply to applicants and employees forty or older, youth have additional rights under other federal, state, or local laws. The Age Discrimination Act of 1975 (Age Act), for instance, prohibits discrimination against young people and older Americans on the basis of age in federally funded programs and activities. In some cases, the Age Act permits age distinctions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective. State and local discrimination laws may offer broader protection.

Comment: One commenter indicated that HHS should specify that the nondiscrimination provisions included in § 75.300(c) flow down to subawards.

Response: HHS notes that the provisions of 45 CFR part 75 already address the flow down of requirements. 45 CFR 75.101(b)(1) stating that the terms and conditions of Federal awards flow down to subawards to subrecipients unless a particular section of this part or the terms and conditions of the Federal award specifically indicate otherwise.

Comment: Several commenters noted that the provisions of § 75.300(c) do not

apply to funding under the Temporary Assistance for Needy Families Program (TANF) (title IV–A of the Social Security Act, 42, U.S.C. 601–619). These commenters suggested that HHS should provide additional guidance to TANF grantees on nondiscrimination.

Response: HHS appreciates the importance of continued education on the full scope of nondiscrimination obligations. The Administration for Children and Families shares this commitment.

B. Indirect Cost Rates

Comment: HHS received three comments regarding the proposed eight percent cap on indirect cost rates for foreign organizations. Notably, HHS did not receive any comments that objected to the imposition of the same eight percent cost cap on indirect cost rates for training grants. The comments received suggested that the proposed provision was in conflict with § 75.414(f), and that HHS should instead adopt a ten percent cap on indirect cost rates for these organizations.

Response: A non-Federal entity that has never received an indirect cost rate that is a foreign organization or foreign public entity, or that would conduct a training grant, would be limited to the eight percent modified total direct cost rate as articulated in § 75.414(c)(3). Commenters indicated that this limitation conflicts with § 75.414(f), which would permit an entity that had never received an indirect cost rate to charge a de minimis rate of ten percent.

HHS agrees that this is inconsistent, and has added clarifying language to paragraph (f) to ensure that there is no conflict.

C. Indian Self Determination and Education Assistance Act

Comment: HHS received numerous comments, both through the regulations.gov portal and separately through the HHS Office of Intergovernmental and External Affairs, on the proposed language clarifying that applicability of certain provisions of the Uniform Administrative Requirements to contracts and compacts awarded pursuant to the Indian Self Determination and Education Assistance Act (ISDEAA). The comments received requested additional tribal consultation on these issues.

Response: The Department is in the process of conducting this tribal consultation, and will proceed as appropriate after that consultation has concluded. The regulatory language from the notice of proposed rulemaking is not included in this final rule.

D. Other Issues

HHS received no comments on the portions of the notice of proposed rulemaking suggesting changes to the proposed language regarding same-sex spouses, marriages, and households, payment provisions as applied to states, public access to records, or shared responsibility payments. Consequently, HHS is finalizing the regulatory language without modification. In addition, HHS is amending one provision to correct a typographical error that was inadvertently included in the most recent promulgation of the Uniform Administrative Requirements, so that the HHS promulgation matches the OMB guidance as intended.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320 Appendix A.1), HHS reviewed this final rule and determined that there are no new collections of information contained therein.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires that an agency provide a final regulatory flexibility analysis or to certify that the rule will not have a significant economic impact on a substantial number of small entities. This final rule aligns 45 CFR part 75 with various regulatory and statutory provisions, implements Supreme Court decisions, and codifies long-standing policies thus clarifying and enhancing the provisions in HHS's interim final guidance issued December 19, 2014, and amended on January 20, 2016. In order to ensure that the public receives the most value, it is essential that HHS grant programs function as effectively and efficiently as possible, and that there is a high level of accountability to prevent waste, fraud, and abuse. The additions provide enhanced direction for the public and will not have a significant economic impact beyond HHS's current regulations.

Executive Order 12866 Determination

Pursuant to Executive Order 12866, HHS has designated this final rule to be economically non-significant. This rule is not being treated as a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies

prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. HHS has determined that this final rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of \$100 million or more in any one year. Accordingly, HHS has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

Executive Order 13132 Determination

HHS has determined that this final rule does not have any Federalism implications, as required by Executive Order 13132.

List of Subjects in 45 CFR Part 75

Accounting, Administrative practice and procedure, Cost principles, Grant programs, Grant programs—health, Grants administration, Hospitals, Indians, Nonprofit organizations reporting and recordkeeping requirements, State and local governments.

Dated: November 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

For the reasons set forth in the preamble, part 75 of title 45 of the Code of Federal Regulations is amended as follows:

PART 75—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR HHS AWARDS

■ 1. The authority citation for 45 CFR part 75 continues to read as follows:

Authority: 5 U.S.C. 301.

■ 2. Amend § 75.101 by adding paragraph (f) to read as follows:

§ 75.101 Applicability.

* * * * *
(f) Section 75.300(c) does not apply to the Temporary Assistance for Needy Families Program (title IV–A of the Social Security Act, 42 U.S.C. 601–619).

§ 75.110 [Amended]

■ 3. Amend § 75.110(a) by removing “75.355” and adding, in its place, “75.335”.

■ 4. Amend § 75.300 by adding paragraphs (c) and (d) to read as follows:

§ 75.300 Statutory and national policy requirements.

* * * * *
(c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as age, disability, sex, race, color, national origin, religion, gender identity, or sexual orientation. Recipients must comply with this public policy requirement in the administration of programs supported by HHS awards.

(d) In accordance with the Supreme Court decisions in *United States v. Windsor* and in *Obergefell v. Hodges*, all recipients must treat as valid the marriages of same-sex couples. This does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under state law as something other than a marriage.

■ 5. Revise § 75.305(a) to read as follows:

§ 75.305 Payment.

(a)(1) For states, payments are governed by Treasury-State CMAA agreements and default procedures codified at 31 CFR part 205 and TFM 4A–2000 Overall Disbursing Rules for All Federal Agencies.

(2) To the extent that Treasury-State CMAA agreements and default procedures do not address expenditure of program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds, such funds must be expended before requesting additional cash payments.

■ 6. Revise § 75.365 to read as follows:

§ 75.365 Restrictions on public access to records.

Consistent with § 75.322, HHS awarding agencies may require recipients to permit public access to manuscripts, publications, and data produced under an award. However, no HHS awarding agency may place restrictions on the non-Federal entity that limit public access to the records of the non-Federal entity pertinent to a Federal award identified in §§ 75.361 through 75.364, except for protected personally identifiable information (PII) or when the HHS awarding agency can demonstrate that such records will be kept confidential and would have been exempted from disclosure pursuant to the Freedom of Information Act (5

U.S.C. 552) or controlled unclassified information pursuant to Executive Order 13556 if the records had belonged to the HHS awarding agency. The Freedom of Information Act (5 U.S.C. 552) (FOIA) does not apply to those records that remain under a non-Federal entity’s control except as required under § 75.322. Unless required by Federal, state, local, or tribal statute, non-Federal entities are not required to permit public access to their records identified in §§ 75.361 through 75.364. The non-Federal entity’s records provided to a Federal agency generally will be subject to FOIA and applicable exemptions.

■ 7. In § 75.414, add paragraphs (c)(1)(i) through (iii) and revise the first sentence of paragraph (f) to read as follows:

§ 75.414 Indirect (F&A) costs.

* * * * *
(c) * * *
(1) * * *

(i) Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000;

(ii) Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000; and,

(iii) Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

* * * * *
(f) In addition to the procedures outlined in the appendices in paragraph (e) of this section, any non-Federal entity that has never received a negotiated indirect cost rate, except for those non-Federal entities described in paragraphs (c)(1)(i) and (ii) and section (D)(1)(b) of appendix VII to this part, may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely.* * *

■ 8. Add § 75.477 to read as follows:

§ 75.477 Shared responsibility payments.

(a) *Payments for failure to maintain minimum essential health coverage.* Any payments or assessments imposed on an individual or individuals pursuant to 26 U.S.C. 5000A(b) as a result of any failure to maintain minimum essential coverage as required by 26 U.S.C. 5000A(a) are not allowable

expenses under Federal awards from an HHS awarding agency.

(b) *Payments for failure to offer health coverage to employees.* Any payments or assessments imposed on an employer pursuant to 26 U.S.C. 4980H as a result of the employer's failure to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan are not allowable expenses under Federal awards from an HHS awarding agency.

[FR Doc. 2016-29752 Filed 12-9-16; 8:45 am]

BILLING CODE 4150-24-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151130999-6225-01]

RIN 0648-XF069

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; approval of quota transfer.

SUMMARY: NMFS announces its approval of a transfer of 2016 commercial bluefish quota from the State of

Maryland to the State of New York. The approval of the transfer complies with the Atlantic Bluefish Fishery Management Plan quota transfer provision. This announcement also informs the public of the revised commercial quotas for Maryland and New York.

DATES: Effective December 9, 2016 through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Reid Lichwell, Fishery Management Specialist, (978) 281-9112.

SUPPLEMENTARY INFORMATION:

Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.162.

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan published in the *Federal Register* on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the Administrator, Greater Atlantic Region, NMFS (Regional Administrator), can request approval of a transfer of bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must first

approve any such transfer based on the criteria in § 648.162(e).

Maryland and New York have requested the transfer of 50,000 lb (22,680 kg) of bluefish commercial quota from Maryland to New York. Both states have certified that the transfer meets all pertinent state requirements. This quota transfer was requested by New York to ensure that its 2016 quota would not be exceeded. The Regional Administrator has approved this quota transfer based on his determination that the criteria set forth in § 648.162(e)(1)(i) through (iii) have been met. The revised bluefish quotas for calendar year 2016 are: Maryland, 96,631 lb (43,831 kg); and New York, 927,289 lb (420,611 kg). These quota adjustments revise the quotas specified in the final rule implementing the 2016-2018 Atlantic Bluefish Specifications published on August 4, 2016 (81 FR 51370), and reflect all subsequent commercial bluefish quota transfers completed to date. For information of previous transfers for fishing year 2016 visit: <http://go.usa.gov/xZT8H>.

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 7, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016-29720 Filed 12-9-16; 8:45 am]

BILLING CODE 3510-22-P



States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 5, 2019.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR part 721 is corrected as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. In § 721.11107, revise paragraph (a)(2)(ii) to read as follows:

§ 721.11107 Alkanediol, 2,2-bis (substituted alky)-polymer with substituted alkane, heteromonocycles, alkenoate (generic).

(a) * * *
(2) * * *

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (e) (concentration set 0.1 percent), (f), (g)(1)(i), (ii), (iv), (vii), (ix), (respiratory sensitization), (g)(2)(i), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

* * * * *

[FR Doc. 2019–24945 Filed 11–18–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 75

Notification of Nonenforcement of Health and Human Services Grants Regulation

AGENCY: Office of the Secretary, HHS.

ACTION: Notification of exercise of enforcement discretion.

SUMMARY: This notification is to inform the public that the U.S. Department of Health and Human Services (HHS) has determined that the rulemaking that resulted in the regulatory provisions promulgated on Dec. 12, 2016, regarding HHS’s grant regulations, raises significant concerns about compliance with the Regulatory Flexibility Act. The provisions will not be enforced pending

a repromulgation that complies with the Act.

DATES: November 19, 2019.

FOR FURTHER INFORMATION CONTACT: Richard Brundage at (202) 401–6107.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services has determined that the rulemaking which promulgated or amended 45 CFR 75.101(f), 75.110(a), 75.300(c) and (d), 75.305(a), 75.365, 75.414(c) and (f), and 75.477, published at 81 FR 89393 (Dec. 12, 2016), raises significant concerns about compliance with the requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The Department has accordingly determined to exercise its enforcement discretion not to enforce the regulations until they have been repromulgated with a proper RFA analysis.

I. Statutory Background

The RFA generally requires that when an agency issues a proposed rule, or a final rule (after publishing a proposed rule) pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. The RFA is a “[p]urely procedural” statute, but “set[s] out precise, specific steps an agency must take.” *Nat’l Telephone Co-op Ass’n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) (internal quotation marks omitted). Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA);¹ (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)–(6).² The requirement does not apply if the head of the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” *Id.* section 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of

¹ Depending on the industry, SBA considers businesses to be small by virtue of having less than between \$7.5 million and \$38.5 million in average annual revenue.

² The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue.

publication of the proposed or final rule, “along with a statement providing the factual basis for such certification.” *Id.* The RFA also requires the agency to provide the certification and the statement with the factual justification to the SBA Chief Counsel for Advocacy. *Id.*

If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA’s waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).³ In addition, the RFA provides for judicial review of an agency’s compliance with its provisions under some circumstances, which can result in a court ordering the agency to take corrective action by remanding the rule to the agency and deferring enforcement of the rule against small entities. *Id.* section 611(a)(4).

II. Absence of RFA Analysis or Certification

The rulemaking that promulgated and amended 45 CFR 75.101(f), 75.110(a), 75.300(c) and (d), 75.305(a), 75.365, 75.414(c) and (f), and 75.477, published at 81 FR 89393 (Dec. 12, 2016), raises significant concerns about compliance with the requirements of the RFA, 5 U.S.C. 601 *et seq.* The Department neither performed the RFA analysis described in 5 U.S.C. 602–604, nor expressly certified that the rules “will not . . . have a significant economic impact on a substantial number of small entities” and provided a statement with the factual basis for such certification as provided for by section 605(b). *See* 81 FR 89393 (Dec. 12, 2016). The rulemaking simply declared that it would “not have a significant economic

³ Section 608(b) provides that except as provided in section 605(b), an agency head may not waive the requirements of section 604 for final rules. An agency head may delay the completion of the requirements of section 604 of the title for a period of not more than one hundred and eighty days after the date of publication in the **Federal Register** of a final rule by publishing in the **Federal Register**, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of the title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of the title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency. 5 U.S.C. 608(b).

impact beyond HHS's current regulations," without even mentioning small entities or grappling with the obvious interests of such entities that should have been protected by the RFA process. The Department is accordingly exercising its enforcement discretion and as such, these regulatory provisions will not be enforced, pending repromulgation.

The Department failed to make the certification, and provide the factual statement, described by the statute.

Where an agency engaged in notice and comment rulemaking pursuant to section 553 does not perform a RFA analysis, the head of the agency normally must certify that a rule will not have a significant impact on small entities, and the agency must ordinarily provide a statement that lays out the facts that support the certification. The agency's **Federal Register** publication must, thus, include a certification under section 605(b) that discusses the impact of a rule on a substantial number of small entities and "a statement providing the factual basis for such certification." While this is not a high bar, the Government must, at a minimum, show that it made a reasonable, good faith effort to consider at least some facts relevant to small entities impacted by the rule. *Compare North Carolina Fisheries Ass'n, Inc. v. Daley*, 16 F. Supp. 2d 647, 651–53 (E.D. Va. 1997) (finding that certification was noncompliant because it did not discuss any facts regarding the impact on small entities in the time period subject to the rule), *with Nat. Women, Infants and Children Grocers Ass'n v. Food and Nutrition Serv.*, 416 F. Supp. 2d 92, 108–09 (D.D.C. 2006) (holding that certification complied because it explained that the challenged rule applied to the states, which had varying market conditions), and *Cactus Corner, LLC v. U.S. Dep't of Agric.*, 346 F. Supp. 2d 1075 (E.D. Cal. 2004) (finding that certification complied because it defined and discussed the small wholesalers impacted by the rule and made predictions about the likely impact of the rule).

In the preamble to the December 12, 2016 final rules, the Department stated it had an obligation under the RFA to "provide a final regulatory flexibility analysis or to certify that the rule[s] will not have a significant economic impact on a substantial number of small entities." 81 FR at 89394. It then listed a subset of the regulatory changes: Aligning the grants regulation at part 75 "with various regulatory and statutory provisions," implementing Supreme Court decisions, and codifying long-standing policies. Without explaining

whether or how these regulatory changes might apply to small entities, the Department simply concluded that, "[i]n order to ensure that the public receives the most value, it is essential that HHS grant programs function as effectively and efficiently as possible, and that there is a high level of accountability to prevent waste, fraud, and abuse. The additions provide enhanced direction for the public and will not have a significant economic impact beyond HHS's current regulations." See 81 FR at 89394.⁴

This statement in the **Federal Register** raises serious questions about compliance with the RFA's requirement that the agency head must certify that the rules will not have a significant economic effect on a substantial number of small entities. The statement fails to mention the economic impact on small entities in particular or to even acknowledge that the regulation would apply to small entities. Furthermore, there is nothing in the final rules that provides a factual basis for any inference that the rules would not have a significant economic impact on a substantial number of small entities. Indeed, if anything, there are indications that the rulemaking likely did have a significant economic impact on a substantial number of small entities. The absence of a factual basis for a required section 605 certification, too, would be inconsistent with the requirements of the RFA. See 5 U.S.C. 605(b).

The rules were not submitted to the SBA Chief Counsel for Advocacy.

When a certification is required, the RFA further requires that the agency "provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration." 5 U.S.C. 605(b). The Chief Counsel for Advocacy of the SBA maintains records of the proposed and final rules submitted to it pursuant to the RFA. The Office of the Chief Counsel has informed the Department's General Counsel that it does not have a record of having received the rules pursuant to the RFA.

The rules may have affected a significant number of small entities.

The provisions in the final rules may have affected a significant number of small entities, which underscores why Congress prohibited agency heads from waiving the requirement to conduct an otherwise required regulatory impact analysis except in the narrow

circumstance where an agency can provide the factual basis for a certification by the agency head that there is no significant economic impact on a substantial number of small entities.⁵ For example, § 75.477(b) precludes a grantee from including as allowable costs those payments that it may make to the Internal Revenue Service in lieu of providing minimum essential coverage (MEC) to its employees. While nearly all large employers offer their employees MEC, in 2015, among companies with 50 to 199 employees, around 8 percent did not. The 8 percent equates to approximately 14,000 small businesses. See <http://files.kff.org/attachment/report-2015-employer-health-benefits-survey> at 44; <https://www.sba.gov/advocacy/firm-size-data> (2014). Moreover, if an entity (including governmental or non-profit entities) with at least 50 full-time employees failed to meet the MEC requirements, it could be assessed a penalty equal to the number of its full-time employees for the year (minus up to 30 employees) times \$2,000 if at least one full-time employee purchased health coverage with premium tax credits through the health insurance exchange. Any reasonable certification under section 605(b) necessarily would have had to reflect the potential impact on those 14,000 small businesses from this single provision.

A similar showing would have been sensible to perform with respect to the other regulatory provisions contained in the rulemaking that culminated in the December 12, 2016 final rules. Indeed, the data that existed at the time of the rulemaking revealed that various provisions could, in fact, affect a significant number of small entities. For example, § 75.414(c) limits reimbursement for indirect costs on training grants to eight percent. The proposed rule (see 81 FR 45270 (July 13, 2016)) indicated that the amendment to paragraph (c) reflected HHS's longstanding policy. However, under the Richardson Waiver (see 36 FR 2532 (Feb. 5, 1971)), such policy, absent rulemaking, is not binding. Thus, there was no valid, binding limit on reimbursement of indirect costs prior to the issuance of this rule, and no corresponding showing of the economic implications for small entities, including non-profits, of this new

⁴ The RFA discussion in the preamble to the proposed rule was virtually identical. See Health and Human Services Grants Regulation, 81 FR 45270, 45272 (July 13, 2016).

⁵ Even in the case of an emergency, the agency must conduct a regulatory flexibility analysis. Congress simply gave the agency an additional 180 days to conduct the analysis in case of an emergency, underscoring how important Congress considered the regulatory flexibility analysis to be. See 5 U.S.C. 608(b).

limitation on overhead reimbursement. A proper RFA analysis likely should have considered the effect that moving from a nonbinding policy to binding rule would have on small entities. *Cf. Am. Federation of Labor v. Chertoff*, 552 F. Supp. 2d 999, 1013 (N.D. Cal. 2007) (noting “serious questions [about] whether DHS violated the RFA” when it refused to conduct a final flexibility analysis about a rule that “as good as mandates costly compliance with a new 90-day timeframe”). There was also no showing concerning § 75.300(c) and (d), which may impose compliance costs on recipients by subjecting the recipients to conflicting statutory and non-statutory requirements.

The regulatory provisions promulgated in the final rules will not be enforced pending rulemaking.

As described above, unless waived pursuant to section 605(b), the RFA generally requires an agency to prepare a final regulatory flexibility analysis. See 5 U.S.C. 604(a), 611(a). The preparation of such analysis may be delayed by up to 180 days after the publication of the final rule in cases of emergency. See 5 U.S.C. 608(b). Moreover, flawed RFA analyses have been the basis for judicial review of rulemakings.

Because the Department has serious concerns about whether the RFA analysis performed here complied with the RFA, the Department is announcing that it will not enforce the regulatory provisions, pending repromulgation of the Rule. The majority of the Department’s grantees are small entities,⁶ and the RFA process undertaken with respect to this Rule raises significant concerns about whether their interests were protected in the manner the statute prescribes. Rather than apply a nonenforcement policy only to small entities, however, the Department is exercising its discretion to not enforce the rules with respect to any grantees until the rules have been properly re-promulgated with an impact analysis that hews to the requirements of the RFA. Applying these rules differently to agency grantees depending on size would be unfair, create increased compliance costs for all entities as they seek to determine whether they are or are not still subject to the rules, and impose additional administrative burdens on the Department disproportionate to the benefit of enforcement.

Accordingly, the regulatory actions, promulgated through the December 12, 2016 final rules, 81 FR 89393, namely,

the additions of 45 CFR 75.101(f), 75.300(c) and (d), 75.414(c)(1)(i) through (iii), and 75.477, and the amendments to 45 CFR 75.110(a), 75.305(a), 75.365, and 75.414(f), will not be enforced pending repromulgation.⁷

Dated: November 1, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–24384 Filed 11–18–19; 8:45 am]

BILLING CODE 4150–24–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 74, 78, and 101

[GN Docket No. 82–334; WT Docket No. 00–19, RM–9418; FCC 02–218; and WT Docket No. 94–148, FCC 96–51]

Establishment of a Spectrum Utilization Policy for the Fixed and Mobile Services’ Use of Certain Bands Between 947 MHz and 40 GHz; Streamline Processing of Microwave Applications in the Wireless Telecommunications Services and Telecommunications Industry Association Petition for Rulemaking; Terrestrial Microwave Fixed Radio Services

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: The Federal Communications Commission (FCC/Commission) is correcting final rules that had typographical errors that were published in three separate reports in the *Federal Register*. In those documents, the Commission used table 8 MHz maximum authorized bandwidth channels that had an error in various rules. This document corrects the errors.

DATES: Effective November 19, 2019.

FOR FURTHER INFORMATION CONTACT:

Stephen Buenzow of the Wireless Telecommunications Bureau, Broadband Division at (717) 338–2647 or Stephen.Buenzow@fcc.gov.

SUPPLEMENTARY INFORMATION: The Commission’s documents GN Docket No. 82–334, published March 9, 1987 (52 FR 7136, pages 7142 and 7144); WT Docket No. 00–19, RM–9418, FCC 02–218, published May 28, 1996 (61 FR 26677, as amended at 62 FR 4924, Feb. 3, 1997, page 4925); and WT Docket No. 94–148, FCC 96–51, published May 28,

1996 (61 FR 26677, pages 26708, 26712, and 26725) contained typographical errors. The correcting amendments in this document fix those errors. The Commission is also correcting an error in a footnote and table—*Table 3—Paired Frequencies (MHz), [12.5 kHz bandwidth]*. The corrected rules are §§ 74.602(i)(2), 78.18(a)(5)(ii), 101.115(b)(2), 101.147(b)(2) and 101.803(e)(2).

List of Subjects

47 CFR Part 74

Communications equipment, Radio, Television.

47 CFR Part 78

Cable television, television, Communications equipment, Radio.

47 CFR Part 101

Communications equipment, Radio.

Accordingly, 47 CFR parts 74, 78, and 101 are corrected by making the following correcting amendments:

PART 74—EXPERIMENTAL RADIO, AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

■ 1. The authority citation for part 74 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 307, 309, 310, 336, and 554.

■ 2. In § 74.602, amend the table in paragraph (i)(2) by revising the entry for “6446.0” to read as follows:

§ 74.602 Frequency assignment.

* * * * *

(i) * * *

(2) * * *

Transmit (or receive MHz)		Receive (or transmit) (MHz)	
*	*	*	*
	6446.0		6496.0
*	*	*	*
* * * * *			

PART 78—CABLE TELEVISION RELAY SERVICE

■ 3. The authority citation for part 78 continues to read as follows:


Authority: 47 U.S.C. 152, 153, 154, 301, 303, 307, 308, 309.

■ 4. In § 78.18, amend paragraph (a)(5)(ii) by revising entry for “6446.0” to read as follows:

⁷ Elsewhere in this issue of the *Federal Register*, the Department publishes a notice of proposed rulemaking to begin the process of repromulgating, as appropriate, these rules.

⁶ See, e.g., <https://taggs.hhs.gov/ReportsGrants/GrantsByRecipClass>.

§ 601. Definitions, 5 USCA § 601

 KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 601

§ 601. Definitions

Effective: March 29, 1996

[Currentness](#)

For purposes of this chapter--

- (1) the term “agency” means an agency as defined in [section 551\(1\)](#) of this title;

- (2) the term “rule” means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to [section 553\(b\)](#) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term “rule” does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;

- (3) the term “small business” has the same meaning as the term “small business concern” under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

- (4) the term “small organization” means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

- (5) the term “small governmental jurisdiction” means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;

- (6) the term “small entity” shall have the same meaning as the terms “small business”, “small organization” and “small governmental jurisdiction” defined in paragraphs (3), (4) and (5) of this section; and

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(7) the term “collection of information”--

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either--

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States; or

(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and

(B) shall not include a collection of information described under [section 3518\(c\)\(1\) of title 44, United States Code](#).

(8) **Recordkeeping requirement.**--The term “recordkeeping requirement” means a requirement imposed by an agency on persons to maintain specified records.

CREDIT(S)

(Added [Pub.L. 96-354](#), § 3(a), Sept. 19, 1980, 94 Stat. 1165; amended [Pub.L. 104-121, Title II, § 241\(a\)\(2\)](#), Mar. 29, 1996, 110 Stat. 864.)

EXECUTIVE ORDERS

[EXECUTIVE ORDER NO. 12291](#)

[Ex. Ord. No. 12291](#), Feb. 17, 1981, 46 F.R. 13193, which established requirements for agencies to follow in promulgating regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, was revoked by [Ex. Ord. No. 12866](#), Sept. 30, 1993, 58 F.R. 51735, set out as a note under this section.

[EXECUTIVE ORDER NO. 12498](#)

[Ex. Ord. No. 12498](#), Jan. 4, 1985, 50 F.R. 1036, which established a regulatory planning process by which to develop and publish a regulatory program for each year, was revoked by [Ex. Ord. No. 12866](#), § 11, Sept. 30, 1993, 58 F.R. 51735, set out as a note under this section.

[EXECUTIVE ORDER NO. 12606](#)

[Ex. Ord. No. 12606](#), Sept. 2, 1987, 52 F.R. 34188, relating to family considerations in policy formulation and implementation, was revoked by [Ex. Ord. No. 13045](#), Apr. 21, 1997, 62 F.R. 19885, set out as a note under [section 4321 of Title 42](#), The Public Health and Welfare.

[EXECUTIVE ORDER NO. 12612](#)

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Ex. Ord. No. 12612, Oct. 26, 1987, 52 F.R. 41685, relating to federalism considerations in policy formulation and implementation, was revoked by Ex. Ord. No. 13083, May 14, 1998, 63 F.R. 27651, formerly set out as a note under this section, and subsequently also revoked by Ex. Ord. No. 13132, Aug. 4, 1999, 64 F.R. 43255, set out as a note under this section. [Ex. Ord. No. 13083 was suspended by Ex. Ord. No. 13095, Aug. 5, 1998, 63 F.R. 42565, also formerly set out as a note under this section. Both Ex.Ords. 13083 and 13095 were also revoked by Ex. Ord. No. 13132.]

EXECUTIVE ORDER NO. 12630

<Mar. 15, 1988, 53 F.R. 8859>

Governmental Actions and Interference with Constitutionally Protected Property Rights

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to ensure that government actions are undertaken on a well-reasoned basis with due regard for fiscal accountability, for the financial impact of the obligations imposed on the Federal government by the Just Compensation Clause of the Fifth Amendment, and for the Constitution, it is hereby ordered as follows:

Section 1. Purpose. (a) The Fifth Amendment of the United States Constitution provides that private property shall not be taken for public use without just compensation. Government historically has used the formal exercise of the power of eminent domain, which provides orderly processes for paying just compensation, to acquire private property for public use. Recent Supreme Court decisions, however, in reaffirming the fundamental protection of private property rights provided by the Fifth Amendment and in assessing the nature of governmental actions that have an impact on constitutionally protected property rights, have also reaffirmed that governmental actions that do not formally invoke the condemnation power, including regulations, may result in a taking for which just compensation is required.

(b) Responsible fiscal management and fundamental principles of good government require that government decision-makers evaluate carefully the effect of their administrative, regulatory, and legislative actions on constitutionally protected property rights. Executive departments and agencies should review their actions carefully to prevent unnecessary takings and should account in decision-making for those takings that are necessitated by statutory mandate.

(c) The purpose of this Order is to assist Federal departments and agencies in undertaking such reviews and in proposing, planning, and implementing actions with due regard for the constitutional protections provided by the Fifth Amendment and to reduce the risk of undue or inadvertent burdens on the public fisc resulting from lawful governmental action. In furtherance of the purpose of this Order, the Attorney General shall, consistent with the principles stated herein and in consultation with the Executive departments and agencies, promulgate Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings to which each Executive department or agency shall refer in making the evaluations required by this Order or in otherwise taking any action that is the subject of this Order. The Guidelines shall be promulgated no later than May 1, 1988, and shall be disseminated to all units of each Executive department and agency no later than July 1, 1988. The Attorney General shall, as necessary, update these guidelines to reflect fundamental changes in takings law occurring as a result of Supreme Court decisions.

Sec. 2. Definitions. For the purpose of this Order: (a) “Policies that have takings implications” refers to Federal regulations, proposed Federal regulations, proposed Federal legislation, comments on proposed Federal legislation, or other Federal policy statements that, if implemented or enacted, could effect a taking, such as rules and regulations that propose or implement licensing, permitting, or other condition requirements or limitations on private property use, or that require dedications or exactions from owners of private property. “Policies that have takings implications” does not include:

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- (1) Actions abolishing regulations, discontinuing governmental programs, or modifying regulations in a manner that lessens interference with the use of private property;
 - (2) Actions taken with respect to properties held in trust by the United States or in preparation for or during treaty negotiations with foreign nations;
 - (3) Law enforcement actions involving seizure, for violations of law, of property for forfeiture or as evidence in criminal proceedings;
 - (4) Studies or similar efforts or planning activities;
 - (5) Communications between Federal agencies or departments and State or local land-use planning agencies regarding planned or proposed State or local actions regulating private property regardless of whether such communications are initiated by a Federal agency or department or are undertaken in response to an invitation by the State or local authority;
 - (6) The placement of military facilities or military activities involving the use of Federal property alone; or
 - (7) Any military or foreign affairs functions (including procurement functions thereunder) but not including the U.S. Army Corps of Engineers civil works program.
- (b) Private property refers to all property protected by the Just Compensation Clause of the Fifth Amendment.
- (c) “Actions” refers to proposed Federal regulations, proposed Federal legislation, comments on proposed Federal legislation, applications of Federal regulations to specific property, or Federal governmental actions physically invading or occupying private property, or other policy statements or actions related to Federal regulation or direct physical invasion or occupancy, but does not include:
- (1) Actions in which the power of eminent domain is formally exercised;
 - (2) Actions taken with respect to properties held in trust by the United States or in preparation for or during treaty negotiations with foreign nations;
 - (3) Law enforcement actions involving seizure, for violations of law, of property for forfeiture or as evidence in criminal proceedings;
 - (4) Studies or similar efforts or planning activities;
 - (5) Communications between Federal agencies or departments and State or local land-use planning agencies regarding planned or proposed State or local actions regulating private property regardless of whether such communications are initiated by a Federal agency or department or are undertaken in response to an invitation by the State or local authority;
 - (6) The placement of military facilities or military activities involving the use of Federal property alone; or
 - (7) Any military or foreign affairs functions (including procurement functions thereunder), but not including the U.S. Army Corps of Engineers civil works program.

Sec. 3. General Principles. In formulating or implementing policies that have takings implications, each Executive department and agency shall be guided by the following general principles:

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- (a) Governmental officials should be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning and carrying out governmental actions so that they do not result in the imposition of unanticipated or undue additional burdens on the public fisc.
- (b) Actions undertaken by governmental officials that result in a physical invasion or occupancy of private property, and regulations imposed on private property that substantially affect its value or use, may constitute a taking of property. Further, governmental action may amount to a taking even though the action results in less than a complete deprivation of all use or value, or of all separate and distinct interests in the same private property and even if the action constituting a taking is temporary in nature.
- (c) Government officials whose actions are taken specifically for purposes of protecting public health and safety are ordinarily given broader latitude by courts before their actions are considered to be takings. However, the mere assertion of a public health and safety purpose is insufficient to avoid a taking. Actions to which this Order applies asserted to be for the protection of public health and safety, therefore, should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose.
- (d) While normal governmental processes do not ordinarily effect takings, undue delays in decision-making during which private property use is interfered with carry a risk of being held to be takings. Additionally, a delay in processing may increase significantly the size of compensation due if a taking is later found to have occurred.
- (e) The Just Compensation Clause is self-actuating, requiring that compensation be paid whenever governmental action results in a taking of private property regardless of whether the underlying authority for the action contemplated a taking or authorized the payment of compensation. Accordingly, governmental actions that may have a significant impact on the use or value of private property should be scrutinized to avoid undue or unplanned burdens on the public fisc.

Sec. 4. Department and Agency Action. In addition to the fundamental principles set forth in Section 3, Executive departments and agencies shall adhere, to the extent permitted by law, to the following criteria when implementing policies that have takings implications:

- (a) When an Executive department or agency requires a private party to obtain a permit in order to undertake a specific use of, or action with respect to, private property, any conditions imposed on the granting of a permit shall:
- (1) Serve the same purpose that would have been served by a prohibition of the use or action; and
 - (2) Substantially advance that purpose.
- (b) When a proposed action would place a restriction on a use of private property, the restriction imposed on the use shall not be disproportionate to the extent to which the use contributes to the overall problem that the restriction is imposed to redress.
- (c) When a proposed action involves a permitting process or any other decision-making process that will interfere with, or otherwise prohibit, the use of private property pending the completion of the process, the duration of the process shall be kept to the minimum necessary.
- (d) Before undertaking any proposed action regulating private property use for the protection of public health or safety, the Executive department or agency involved shall, in internal deliberative documents and any submissions to the Director of the Office of Management and Budget that are required:

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- (1) Identify clearly, with as much specificity as possible, the public health or safety risk created by the private property use that is the subject of the proposed action;
- (2) Establish that such proposed action substantially advances the purpose of protecting public health and safety against the specifically identified risk;
- (3) Establish to the extent possible that the restrictions imposed on the private property are not disproportionate to the extent to which the use contributes to the overall risk; and
- (4) Estimate, to the extent possible, the potential cost to the government in the event that a court later determines that the action constituted a taking.

In instances in which there is an immediate threat to health and safety that constitutes an emergency requiring immediate response, this analysis may be done upon completion of the emergency action.

Sec. 5. Executive Department and Agency Implementation. (a) The head of each Executive department and agency shall designate an official to be responsible for ensuring compliance with this Order with respect to the actions of that department or agency.

(b) Executive departments and agencies shall, to the extent permitted by law, identify the takings implications of proposed regulatory actions and address the merits of those actions in light of the identified takings implications, if any, in all required submissions made to the Office of Management and Budget. Significant takings implications should also be identified and discussed in notices of proposed rule-making and messages transmitting legislative proposals to the Congress, stating the departments' and agencies' conclusions on the takings issues.

(c) Executive departments and agencies shall identify each existing Federal rule and regulation against which a takings award has been made or against which a takings claim is pending including the amount of each claim or award. A "takings" award has been made or a "takings" claim pending if the award was made, or the pending claim brought, pursuant to the Just Compensation Clause of the Fifth Amendment. An itemized compilation of all such awards made in Fiscal Years 1985, 1986, and 1987 and all such pending claims shall be submitted to the Director, Office of Management and Budget, on or before May 16, 1988.

(d) Each Executive department and agency shall submit annually to the Director, Office of Management and Budget, and to the Attorney General an itemized compilation of all awards of just compensation entered against the United States for takings, including awards of interest as well as monies paid pursuant to the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, 42 U.S.C. 4601 [section 4601 et seq. of Title 42, The Public Health and Welfare].

(e)(1) The Director, Office of Management and Budget, and the Attorney General shall each, to the extent permitted by law, take action to ensure that the policies of the Executive departments and agencies are consistent with the principles, criteria, and requirements stated in Sections 1 through 5 of this Order, and the Office of Management and Budget shall take action to ensure that all takings awards levied against agencies are properly accounted for in agency budget submissions.

(2) In addition to the guidelines required by Section 1 of this Order, the Attorney General shall, in consultation with each Executive department and agency to which this Order applies, promulgate such supplemental guidelines as may be appropriate to the specific obligations of that department or agency.

Sec. 6. Judicial Review. This Order is intended only to improve the internal management of the Executive branch and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

RONALD REAGAN

[For Executive Order No. 13406 of June 23, 2006, *Protecting the Property Rights of the American People*, see Ex. Ord. No. 13406, June 23, 2006, 71 F.R. 36973, set out under this section.]

EXECUTIVE ORDER NO. 12803

Ex. Ord. No. 12803, Apr. 30, 1992, 57 F.R. 19063, relating to Infrastructure Privatization, is set out in a note under 31 U.S.C.A. § 501.

EXECUTIVE ORDER NO. 12861

<Sept. 11, 1993, 58 F.R. 48255>

Elimination of One-Half of Executive Branch Internal Regulations

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code [section 301 of Title 3, The President], and section 1111 of title 31, United States Code [section 1111 of Title 31, Money and Finance], and to cut 50 percent of the executive branch's internal regulations in order to streamline and improve customer service to the American people, it is hereby ordered as follows:

Section 1. Regulatory Reductions. Each executive department and agency shall undertake to eliminate not less than 50 percent of its civilian internal management regulations that are not required by law within 3 years of the effective date of this order. An agency internal management regulation, for the purposes of this order, means an agency directive or regulation that pertains to its organization, management, or personnel matters. Reductions in agency internal management regulations shall be concentrated in areas that will result in the greatest improvement in productivity, streamlining of operations, and improvement in customer service.

Sec. 2. Coverage. This order applies to all executive branch departments and agencies.

Sec. 3. Implementation. The Director of the Office of Management and Budget shall issue instructions regarding the implementation of this order, including exemptions necessary for the delivery of essential services and compliance with applicable law.

Sec. 4. Independent Agencies. All independent regulatory commissions and agencies are requested to comply with the provisions of this order.

WILLIAM J. CLINTON

EXECUTIVE ORDER NO. 12866

<Sept. 30, 1993, 58 F.R. 51735>

Regulatory Planning and Review

[Ex. Ord. No. 13258, Feb. 26, 2002, 67 F.R. 9385 and Ex. Ord. No. 13422, Jan. 18, 2007, 72 F.R. 2763, which amended Ex. Ord. No. 12866 were revoked by section 1 of Ex. Ord. No. 13497, January 30, 2009, which is set as a note under this section

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following this note. The revocation of [Ex. Ord. No. 13258](#), Feb. 26, 2002, 67 F.R. 9385 and [Ex. Ord. No. 13422](#), Jan. 18, 2007, 72 F.R. 2763, by section 1 of [Ex. Ord. No. 13497](#), January 30, 2009, was executed by undoing the amendments made by Ex. Ords. No. 13258 and 13422 to [Ex. Ord. No. 12866](#) .]

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

- (1)** Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.
- (2)** Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.
- (3)** Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.
- (4)** In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

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(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) The Agencies. Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) The Office of Management and Budget. Coordinated review of agency rulemaking is necessary to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, the Vice President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations, as provided by this Executive order.

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(c) The Vice President. The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order. In fulfilling their responsibilities under this Executive order, the President and the Vice President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President and the Vice President may, from time to time, consult.

Sec. 3. Definitions. For purposes of this Executive order: **(a)** “Advisors” refers to such regulatory policy advisors to the President as the President and Vice President may from time to time consult, including, among others: **(1)** the Director of OMB; **(2)** the Chair (or another member) of the Council of Economic Advisers; **(3)** the Assistant to the President for Economic Policy; **(4)** the Assistant to the President for Domestic Policy; **(5)** the Assistant to the President for National Security Affairs; **(6)** the Assistant to the President for Science and Technology; **(7)** the Assistant to the President for Intergovernmental Affairs; **(8)** the Assistant to the President and Staff Secretary; **(9)** the Assistant to the President and Chief of Staff to the Vice President; **(10)** the Assistant to the President and Counsel to the President; **(11)** the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and **(12)** the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) “Agency,” unless otherwise indicated, means any authority of the United States that is an “agency” under [44 U.S.C. 3502\(1\)](#), other than those considered to be independent regulatory agencies, as defined in [44 U.S.C. 3502\(10\)](#).

(c) “Director” means the Director of OMB.

(d) “Regulation” or “rule” means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of [5 U.S.C. 556, 557](#);

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) “Regulatory action” means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) “Significant regulatory action” means any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

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(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Sec. 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law: **(a) Agencies' Policy Meeting.** Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.

(b) Unified Regulatory Agenda. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in [44 U.S.C. 3502\(10\)](#). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under [5 U.S.C. 602](#) and [41 U.S.C. 402](#) into these agendas.

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in [44 U.S.C. 3502\(10\)](#). **(1)** As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

- (A)** A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;
 - (B)** A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;
 - (C)** A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;
 - (D)** A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;
 - (E)** The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and
 - (F)** The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.
- (2)** Each agency shall forward its Plan to OIRA by June 1st of each year.
- (3)** Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, the Advisors, and the Vice President.
- (4)** An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

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(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies, the Advisors, and the Vice President.

(6) The Vice President, with the Advisors' assistance, may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) Regulatory Working Group. Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, the Advisors, and the Vice President. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Vice President on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: **(a)** Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of

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regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) Agency Responsibilities. (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

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(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there

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has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

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Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

During the Vice Presidential and Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Vice President shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Vice President, as provided under section 7 of this order. Upon receipt of this request, the Vice President shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. Agency Authority. Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law.

Sec. 10. Judicial Review. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. [Executive Orders Nos. 12291](#) and [12498](#); all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

WILLIAM CLINTON

[For provisions supplementing, but not superseding, the provisions of this Executive Order, see [Ex.Ord. No. 13132](#), Aug. 4, 1999, 64 F.R. 43255, set out as a note under this section.]

[[Ex. Ord. No. 13497](#) of Jan. 30, 2009, "Revocation of Certain Executive Orders Concerning Regulatory Planning and Review", provided:

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[“By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered that:

“**Section 1.** [Executive Order 13258](#) of February 26, 2002, and [Executive Order 13422](#) of January 18, 2007, concerning regulatory planning and review, which amended [Executive Order 12866](#) of September 30, 1993 [set out as a note under 5 U.S.C.A. § 601], are revoked.

“**Sec. 2.** The Director of the Office of Management and Budget and the heads of executive departments and agencies shall promptly rescind any orders, rules, regulations, guidelines, or policies implementing or enforcing [Executive Order 13258](#) or [Executive Order 13422](#), to the extent consistent with law.

“**Sec. 3.** This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

[The revocation of [Ex. Ord. No. 13258](#), Feb. 26, 2002, 67 F.R. 9385 and [Ex. Ord. No. 13422](#), Jan. 18, 2007, 72 F.R. 2763, which amended [Ex. Ord. No. 12866](#), by section 1 of [Ex. Ord. No. 13497](#), January 30, 2009, was executed by undoing the amendments made by Ex. Ords. No. 13258 and 13422 to [Ex. Ord. No. 12866](#) .]

EXECUTIVE ORDER NO. 12875

[Ex. Ord. No. 12875](#), Oct. 26, 1993, 58 F.R. 58093, relating to enhancing the intergovernmental partnership, was revoked by [Ex. Ord. No. 13083](#), May 14, 1998, 63 F.R. 27651, formerly set out as a note under this section, and also subsequently revoked by [Ex.Ord. No. 13132](#), Aug. 4, 1999, 64 F.R. 43255, set out as a note under this section. [[Ex. Ord. No. 13083](#) was suspended by [Ex. Ord. No. 13095](#), Aug. 5, 1998, 63 F.R. 42565, also formerly set out as a note under this section. Both Ex. Ords. 13083 and 13095 were also revoked by [Ex. Ord. No. 13132](#).]

EXECUTIVE ORDER NO. 12878

[Ex. Ord. No. 12878](#), Nov. 5, 1993, 58 F.R. 59343, as amended by [Ex. Ord. No. 12887](#), Dec. 23, 1993, 58 F.R. 68713, relating to the bipartisan commission on entitlement reform, was deleted by the Law Revision Counsel.

EXECUTIVE ORDER NO. 13083

[Ex. Ord. No. 13083](#), May 14, 1998, 63 F.R. 27651, relating to federalism considerations in policy formulation and implementation, was suspended by [Ex. Ord. No. 13095](#), Aug. 5, 1998, 63 F.R. 42565, formerly set out as a note under this section, and subsequently revoked by [Ex. Ord. No. 13132](#), Aug. 4, 1999, 64 F.R. 43255, set out as a note under this section. [[Ex. Ord. No. 13095](#) was also revoked by [Ex. Ord. No. 13132](#).]

EXECUTIVE ORDER NO. 13095

[Ex. Ord. No. 13095](#), Aug. 5, 1998, 63 F.R. 42565, formerly set out as a note under this section, which had suspended [Ex. Ord. No. 13083](#), May 14, 1998, 63 F.R. 27651, also formerly set out as a note under this section, was revoked by [Ex. Ord. No. 13132](#), Aug. 4, 1999, 64 F.R. 43255, set out as a note under this section. [[Ex. Ord. No. 13083](#) was also revoked by [Ex. Ord. No. 13132](#).]

EXECUTIVE ORDER NO. 13107

<Dec. 10, 1998, 63 F.R. 68991>

Implementation of Human Rights Treaties

By the authority vested in me as President by the Constitution and the laws of the United States of America, and bearing in mind the obligations of the United States pursuant to the International Covenant on Civil and Political Rights (ICCPR), the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT), the Convention on the Elimination of All Forms of Racial Discrimination (CERD), and other relevant treaties concerned with the protection and promotion of human rights to which the United States is now or may become a party in the future, it is hereby ordered as follows:

Section 1. Implementation of Human Rights Obligations.

(a) It shall be the policy and practice of the Government of the United States, being committed to the protection and promotion of human rights and fundamental freedoms, fully to respect and implement its obligations under the international human rights treaties to which it is a party, including the ICCPR, the CAT, and the CERD.

(b) It shall also be the policy and practice of the Government of the United States to promote respect for international human rights, both in our relationships with all other countries and by working with and strengthening the various international mechanisms for the promotion of human rights, including, inter alia, those of the United Nations, the International Labor Organization, and the Organization of American States.

Sec. 2. Responsibility of Executive Departments and Agencies.(a) All executive departments and agencies (as defined in 5 U.S.C. 101-105, including boards and commissions, and hereinafter referred to collectively as “agency” or “agencies”) shall maintain a current awareness of United States international human rights obligations that are relevant to their functions and shall perform such functions so as to respect and implement those obligations fully. The head of each agency shall designate a single contact officer who will be responsible for overall coordination of the implementation of this order. Under this order, all such agencies shall retain their established institutional roles in the implementation, interpretation, and enforcement of Federal law and policy.

(b) The heads of agencies shall have lead responsibility, in coordination with other appropriate agencies, for questions concerning implementation of human rights obligations that fall within their respective operating and program responsibilities and authorities or, to the extent that matters do not fall within the operating and program responsibilities and authorities of any agency, that most closely relate to their general areas of concern.

Sec. 3. Human Rights Inquiries and Complaints. Each agency shall take lead responsibility, in coordination with other appropriate agencies, for responding to inquiries, requests for information, and complaints about violations of human rights obligations that fall within its areas of responsibility or, if the matter does not fall within its areas of responsibility, referring it to the appropriate agency for response.

Sec. 4. Interagency Working Group on Human Rights Treaties. (a) There is hereby established an Interagency Working Group on Human Rights Treaties for the purpose of providing guidance, oversight, and coordination with respect to questions concerning the adherence to and implementation of human rights obligations and related matters.

(b) The designee of the Assistant to the President for National Security Affairs shall chair the Interagency Working Group, which shall consist of appropriate policy and legal representatives at the Assistant Secretary level from the Department of State,

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the Department of Justice, the Department of Labor, the Department of Defense, the Joint Chiefs of Staff, and other agencies as the chair deems appropriate. The principal members may designate alternates to attend meetings in their stead.

(c) The principal functions of the Interagency Working Group shall include:

(i) coordinating the interagency review of any significant issues concerning the implementation of this order and analysis and recommendations in connection with pursuing the ratification of human rights treaties, as such questions may from time to time arise;

(ii) coordinating the preparation of reports that are to be submitted by the United States in fulfillment of treaty obligations;

(iii) coordinating the responses of the United States Government to complaints against it concerning alleged human rights violations submitted to the United Nations, the Organization of American States, and other international organizations;

(iv) developing effective mechanisms to ensure that legislation proposed by the Administration is reviewed for conformity with international human rights obligations and that these obligations are taken into account in reviewing legislation under consideration by the Congress as well;

(v) developing recommended proposals and mechanisms for improving the monitoring of the actions by the various States, Commonwealths, and territories of the United States and, where appropriate, of Native Americans and Federally recognized Indian tribes, including the review of State, Commonwealth, and territorial laws for their conformity with relevant treaties, the provision of relevant information for reports and other monitoring purposes, and the promotion of effective remedial mechanisms;

(vi) developing plans for public outreach and education concerning the provisions of the ICCPR, CAT, CERD, and other relevant treaties, and human rights-related provisions of domestic law;

(vii) coordinating and directing an annual review of United States reservations, declarations, and understandings to human rights treaties, and matters as to which there have been nontrivial complaints or allegations of inconsistency with or breach of international human rights obligations, in order to determine whether there should be consideration of any modification of relevant reservations, declarations, and understandings to human rights treaties, or United States practices or laws. The results and recommendations of this review shall be reviewed by the head of each participating agency;

(viii) making such other recommendations as it shall deem appropriate to the President, through the Assistant to the President for National Security Affairs, concerning United States adherence to or implementation of human rights treaties and related matters; and

(ix) coordinating such other significant tasks in connection with human rights treaties or international human rights institutions, including the Inter-American Commission on Human Rights and the Special Rapporteurs and complaints procedures established by the United Nations Human Rights Commission.

(d) The work of the Interagency Working Group shall not supplant the work of other interagency entities, including the President's Committee on the International Labor Organization, that address international human rights issues.

Sec. 5. Cooperation Among Executive Departments and Agencies. All agencies shall cooperate in carrying out the provisions of this order. The Interagency Working Group shall facilitate such cooperative measures.

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Sec. 6. Judicial Review, Scope, and Administration. (a) Nothing in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

(b) This order does not supersede Federal statutes and does not impose any justiciable obligations on the executive branch.

(c) The term “treaty obligations” shall mean treaty obligations as approved by the Senate pursuant to [Article II, section 2, clause 2 of the United States Constitution](#).

(d) To the maximum extent practicable and subject to the availability of appropriations, agencies shall carry out the provisions of this order.

WILLIAM J. CLINTON

EXECUTIVE ORDER NO. 13132

<Aug. 4, 1999, 64 F.R. 43255>

Federalism

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies, and to further the policies of the Unfunded Mandates Reform Act [Pub.L. 104-4, Mar. 22, 1995, 109 Stat. 48; see Tables for classification], it is hereby ordered as follows:

Section 1. Definitions. For purposes of this order:

(a) “Policies that have federalism implications” refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

(b) “State” or “States” refer to the States of the United States of America, individually or collectively, and, where relevant, to State governments, including units of local government and other political subdivisions established by the States.

(c) “Agency” means any authority of the United States that is an “agency” under [44 U.S.C. 3502\(1\)](#), other than those considered to be independent regulatory agencies, as defined in [44 U.S.C. 3502\(5\)](#).

(d) “State and local officials” means elected officials of State and local governments or their representative national organizations.

Sec. 2. Fundamental Federalism Principles. In formulating and implementing policies that have federalism implications, agencies shall be guided by the following fundamental federalism principles:

(a) Federalism is rooted in the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people.

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- (b) The people of the States created the national government and delegated to it enumerated governmental powers. All other sovereign powers, save those expressly prohibited the States by the Constitution, are reserved to the States or to the people.
- (c) The constitutional relationship among sovereign governments, State and national, is inherent in the very structure of the Constitution and is formalized in and protected by the Tenth Amendment to the Constitution.
- (d) The people of the States are free, subject only to restrictions in the Constitution itself or in constitutionally authorized Acts of Congress, to define the moral, political, and legal character of their lives.
- (e) The Framers recognized that the States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy.
- (f) The nature of our constitutional system encourages a healthy diversity in the public policies adopted by the people of the several States according to their own conditions, needs, and desires. In the search for enlightened public policy, individual States and communities are free to experiment with a variety of approaches to public issues. One-size-fits-all approaches to public policy problems can inhibit the creation of effective solutions to those problems.
- (g) Acts of the national government--whether legislative, executive, or judicial in nature--that exceed the enumerated powers of that government under the Constitution violate the principle of federalism established by the Framers.
- (h) Policies of the national government should recognize the responsibility of--and should encourage opportunities for--individuals, families, neighborhoods, local governments, and private associations to achieve their personal, social, and economic objectives through cooperative effort.
- (i) The national government should be deferential to the States when taking action that affects the policymaking discretion of the States and should act only with the greatest caution where State or local governments have identified uncertainties regarding the constitutional or statutory authority of the national government.

Sec. 3. Federalism Policymaking Criteria. In addition to adhering to the fundamental federalism principles set forth in section 2, agencies shall adhere, to the extent permitted by law, to the following criteria when formulating and implementing policies that have federalism implications:

- (a) There shall be strict adherence to constitutional principles. Agencies shall closely examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and shall carefully assess the necessity for such action. To the extent practicable, State and local officials shall be consulted before any such action is implemented. [Executive Order 12372](#) of July 14, 1982 (“Intergovernmental Review of Federal Programs”) [31 U.S.C.A. § 6506 note] remains in effect for the programs and activities to which it is applicable.
- (b) National action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Where there are significant uncertainties as to whether national action is authorized or appropriate, agencies shall consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means.
- (c) With respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible. Intrusive Federal oversight of State administration is neither necessary nor desirable.
- (d) When undertaking to formulate and implement policies that have federalism implications, agencies shall:

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- (1) encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States;
- (2) where possible, defer to the States to establish standards;
- (3) in determining whether to establish uniform national standards, consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority; and
- (4) where national standards are required by Federal statutes, consult with appropriate State and local officials in developing those standards.

Sec. 4. Special Requirements for Preemption. Agencies, in taking action that preempts State law, shall act in strict accordance with governing law.

- (a) Agencies shall construe, in regulations and otherwise, a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.
- (b) Where a Federal statute does not preempt State law (as addressed in subsection (a) of this section), agencies shall construe any authorization in the statute for the issuance of regulations as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt State law.
- (c) Any regulatory preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.
- (d) When an agency foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.
- (e) When an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.

Sec. 5. Special Requirements for Legislative Proposals. Agencies shall not submit to the Congress legislation that would:

- (a) directly regulate the States in ways that would either interfere with functions essential to the States' separate and independent existence or be inconsistent with the fundamental federalism principles in section 2;
- (b) attach to Federal grants conditions that are not reasonably related to the purpose of the grant; or
- (c) preempt State law, unless preemption is consistent with the fundamental federalism principles set forth in section 2, and unless a clearly legitimate national purpose, consistent with the federalism policymaking criteria set forth in section 3, cannot otherwise be met.

Sec. 6. Consultation.

- (a) Each agency shall have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. Within 90 days after the effective date of this order, the

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head of each agency shall designate an official with principal responsibility for the agency's implementation of this order and that designated official shall submit to the Office of Management and Budget a description of the agency's consultation process.

(b) To the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute, unless:

(1) funds necessary to pay the direct costs incurred by the State and local governments in complying with the regulation are provided by the Federal Government; or

(2) the agency, prior to the formal promulgation of the regulation,

(A) consulted with State and local officials early in the process of developing the proposed regulation;

(B) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and

(C) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.

(c) To the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation,

(1) consulted with State and local officials early in the process of developing the proposed regulation;

(2) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and

(3) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.

Sec. 7. Increasing Flexibility for State and Local Waivers.

(a) Agencies shall review the processes under which State and local governments apply for waivers of statutory and regulatory requirements and take appropriate steps to streamline those processes.

(b) Each agency shall, to the extent practicable and permitted by law, consider any application by a State for a waiver of statutory or regulatory requirements in connection with any program administered by that agency with a general view toward increasing opportunities for utilizing flexible policy approaches at the State or local level in cases in which the proposed waiver is consistent with applicable Federal policy objectives and is otherwise appropriate.

(c) Each agency shall, to the extent practicable and permitted by law, render a decision upon a complete application for a waiver within 120 days of receipt of such application by the agency. If the application for a waiver is not granted, the agency shall provide the applicant with timely written notice of the decision and the reasons therefor.

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(d) This section applies only to statutory or regulatory requirements that are discretionary and subject to waiver by the agency.

Sec. 8. Accountability.

(a) In transmitting any draft final regulation that has federalism implications to the Office of Management and Budget pursuant to [Executive Order 12866](#) of September 30, 1993 [set out as a note under this section], each agency shall include a certification from the official designated to ensure compliance with this order stating that the requirements of this order have been met in a meaningful and timely manner.

(b) In transmitting proposed legislation that has federalism implications to the Office of Management and Budget, each agency shall include a certification from the official designated to ensure compliance with this order that all relevant requirements of this order have been met.

(c) Within 180 days after the effective date of this order, the Director of the Office of Management and Budget and the Assistant to the President for Intergovernmental Affairs shall confer with State and local officials to ensure that this order is being properly and effectively implemented.

Sec. 9. Independent Agencies. Independent regulatory agencies are encouraged to comply with the provisions of this order.

Sec. 10. General Provisions.

(a) This order shall supplement but not supersede the requirements contained in [Executive Order 12372](#) (“Intergovernmental Review of Federal Programs”) [[31 U.S.C.A. § 6506](#) note], [Executive Order 12866](#) (“Regulatory Planning and Review”) [set out as a note under this section], [Executive Order 12988](#) (“Civil Justice Reform”) [[28 U.S.C.A. § 519](#) note], and OMB Circular A-19.

(b) [Executive Order 12612](#) (“Federalism”), [Executive Order 12875](#) (“Enhancing the Intergovernmental Partnership”), [Executive Order 13083](#) (“Federalism”), and [Executive Order 13095](#) (“Suspension of [Executive Order 13083](#)”) [all formerly set out as notes under this section] are revoked.

(c) This order shall be effective 90 days after the date of this order.

Sec. 11. Judicial Review. This order is intended only to improve the internal management of the executive branch, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

EXECUTIVE ORDER NO. 13198

<Jan. 29, 2001, [66 F.R. 8497](#), as amended [Ex. Ord. No. 13831](#), § 2, May 3, 2018, [83 F.R. 20715](#)>

Agency Responsibilities with Respect to Faith-Based and Community Initiatives

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to help the Federal Government coordinate a national effort to expand opportunities for faith-based and other community organizations and to strengthen their capacity to better meet social needs in America's communities, it is hereby ordered as follows:

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Section 1. Establishment of Executive Department Centers for Faith and Opportunity Initiatives. (a) The Attorney General, the Secretary of Education, the Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of Housing and Urban Development shall each establish within their respective departments a Center for Faith and Opportunity Initiatives (Center).

(b) Each executive department Center shall be supervised by a Director, appointed by the department head in consultation with the White House Faith and Opportunity Initiative (White House OFBCI).

(c) Each department shall provide its Center with appropriate staff, administrative support, and other resources to meet its responsibilities under this order.

(d) Each department's Center shall begin operations no later than 45 days from the date of this order.

Sec. 2. Purpose of Executive Department Centers for Faith and Opportunity Initiatives. The purpose of the executive department Centers will be to coordinate department efforts to eliminate regulatory, contracting, and other programmatic obstacles to the participation of faith-based and other community organizations in the provision of social services.

Sec. 3. Responsibilities of Executive Department Centers for Faith and Opportunity Initiatives. Each Center shall, to the extent permitted by law: (a) conduct, in coordination with the White House Faith and Opportunity Initiative, a department-wide audit to identify all existing barriers to the participation of faith-based and other community organizations in the delivery of social services by the department, including but not limited to regulations, rules, orders, procurement, and other internal policies and practices, and outreach activities that either facially discriminate against or otherwise discourage or disadvantage the participation of faith-based and other community organizations in Federal programs;

(b) coordinate a comprehensive departmental effort to incorporate faith-based and other community organizations in department programs and initiatives to the greatest extent possible;

(c) propose initiatives to remove barriers identified pursuant to section 3(a) of this order, including but not limited to reform of regulations, procurement, and other internal policies and practices, and outreach activities;

(d) propose the development of innovative pilot and demonstration programs to increase the participation of faith-based and other community organizations in Federal as well as State and local initiatives; and

(e) develop and coordinate department outreach efforts to disseminate information more effectively to faith-based and other community organizations with respect to programming changes, contracting opportunities, and other department initiatives, including but not limited to Web and Internet resources.

Sec. 4. Additional Responsibilities of the Department of Health and Human Services and the Department of Labor Centers. In addition to those responsibilities described in section 3 of this order, the Department of Health and Human Services and the Department of Labor Centers shall, to the extent permitted by law: (a) conduct a comprehensive review of policies and practices affecting existing funding streams governed by so-called "Charitable Choice" legislation to assess the department's compliance with the requirements of Charitable Choice; and (b) promote and ensure compliance with existing Charitable Choice legislation by the department, as well as its partners in State and local government, and their contractors.

Sec. 5. Reporting Requirements. (a) Report. Not later than 180 days after the date of this order and annually thereafter, each of the five executive department Centers described in section 1 of this order shall prepare and submit a report to the White House Faith and Opportunity Initiative.

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(b) Contents. The report shall include a description of the department's efforts in carrying out its responsibilities under this order, including but not limited to:

(1) a comprehensive analysis of the barriers to the full participation of faith-based and other community organizations in the delivery of social services identified pursuant to section 3(a) of this order and the proposed strategies to eliminate those barriers; and

(2) a summary of the technical assistance and other information that will be available to faith-based and other community organizations regarding the program activities of the department and the preparation of applications or proposals for grants, cooperative agreements, contracts, and procurement.

(c) Performance Indicators. The first report, filed 180 days after the date of this order, shall include annual performance indicators and measurable objectives for department action. Each report filed thereafter shall measure the department's performance against the objectives set forth in the initial report.

Sec. 6. Responsibilities of All Executive Departments and Agencies. All executive departments and agencies (agencies) shall: **(a)** designate an agency employee to serve as the liaison and point of contact with the White House Faith and Opportunity Initiative; and

(b) cooperate with the White House Faith and Opportunity Initiative and provide such information, support, and assistance to the White House Faith and Opportunity Initiative as it may request, to the extent permitted by law.

Sec. 7. Administration and Judicial Review. **(a)** The agencies' actions directed by this Executive Order shall be carried out subject to the availability of appropriations and to the extent permitted by law.

(b) This order does not create any right or benefit, substantive or procedural, enforceable at law or equity against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13272

<Aug. 13, 2002, 67 F.R. 53461>

Proper Consideration of Small Entities in Agency Rulemaking

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. General Requirements. Each agency shall establish procedures and policies to promote compliance with the Regulatory Flexibility Act, as amended (5 U.S.C. 601 et seq.) (the "Act"). Agencies shall thoroughly review draft rules to assess and take appropriate account of the potential impact on small businesses, small governmental jurisdictions, and small organizations, as provided by the Act. The Chief Counsel for Advocacy of the Small Business Administration (Advocacy) shall remain available to advise agencies in performing that review consistent with the provisions of the Act.

Sec. 2. Responsibilities of Advocacy. Consistent with the requirements of the Act, other applicable law, and [Executive Order 12866](#) of September 30, 1993, as amended, Advocacy [set out as a note under this section]:

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(a) shall notify agency heads from time to time of the requirements of the Act, including by issuing notifications with respect to the basic requirements of the Act within 90 days of the date of this order;

(b) shall provide training to agencies on compliance with the Act; and

(c) may provide comment on draft rules to the agency that has proposed or intends to propose the rules and to the Office of Information and Regulatory Affairs of the Office of Management and Budget (OIRA).

Sec. 3. Responsibilities of Federal Agencies. Consistent with the requirements of the Act and applicable law, agencies shall:

(a) Within 180 days of the date of this order, issue written procedures and policies, consistent with the Act, to ensure that the potential impacts of agencies' draft rules on small businesses, small governmental jurisdictions, and small organizations are properly considered during the rulemaking process. Agency heads shall submit, no later than 90 days from the date of this order, their written procedures and policies to Advocacy for comment. Prior to issuing final procedures and policies, agencies shall consider any such comments received within 60 days from the date of the submission of the agencies' procedures and policies to Advocacy. Except to the extent otherwise specifically provided by statute or Executive Order, agencies shall make the final procedures and policies available to the public through the Internet or other easily accessible means;

(b) Notify Advocacy of any draft rules that may have a significant economic impact on a substantial number of small entities under the Act. Such notifications shall be made (i) when the agency submits a draft rule to OIRA under [Executive Order 12866](#) if that order requires such submission, or (ii) if no submission to OIRA is so required, at a reasonable time prior to publication of the rule by the agency; and

(c) Give every appropriate consideration to any comments provided by Advocacy regarding a draft rule. Consistent with applicable law and appropriate protection of executive deliberations and legal privileges, an agency shall include, in any explanation or discussion accompanying publication in the Federal Register of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule that preceded the final rule; provided, however, that such inclusion is not required if the head of the agency certifies that the public interest is not served thereby.

Agencies and Advocacy may, to the extent permitted by law, engage in an exchange of data and research, as appropriate, to foster the purposes of the Act.

Sec. 4. Definitions. Terms defined in section 601 of title 5, United States Code, including the term “agency,” shall have the same meaning in this order.

Sec. 5. Preservation of Authority. Nothing in this order shall be construed to impair or affect the authority of the Administrator of the Small Business Administration to supervise the Small Business Administration as provided in the first sentence of section 2(b)(1) of Public Law 85-09536 ([15 U.S.C. 633\(b\)\(1\)](#)).

Sec. 6. Reporting. For the purpose of promoting compliance with this order, Advocacy shall submit a report not less than annually to the Director of the Office of Management and Budget on the extent of compliance with this order by agencies.

Sec. 7. Confidentiality. Consistent with existing law, Advocacy may publicly disclose information that it receives from the agencies in the course of carrying out this order only to the extent that such information already has been lawfully and publicly disclosed by OIRA or the relevant rulemaking agency.

Sec. 8. Judicial Review. This order is intended only to improve the internal management of the Federal Government. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13279

<Dec. 12, 2002, [67 F.R. 77141](#), as amended [Ex. Ord. No. 13403](#), § 2, May 12, 2006, [71 F.R. 28543](#); [Ex. Ord. No. 13559](#), § 1, Nov. 17, 2010, [75 FR 71319](#); [Ex. Ord. No. 13831](#), § 2, May 3, 2018, [83 F.R. 20715](#)>

Equal Protection of the Laws for Faith-Based and Other Neighborhood Organizations

By the authority vested in me as President by the Constitution and the laws of the United States of America, including [section 121\(a\) of title 40, United States Code](#), and [section 301 of title 3, United States Code](#), and in order to guide Federal agencies in formulating and developing policies with implications for faith-based organizations and other neighborhood organizations, to ensure equal protection of the laws for faith-based and community organizations, to further the national effort to expand opportunities for, and strengthen the capacity of, faith-based and other neighborhood organizations so that they may better meet social needs in America's communities, and to ensure the economical and efficient administration and completion of Government contracts, it is hereby ordered as follows:

Section 1. Definitions. For purposes of this order:

(a) “Federal financial assistance” means assistance that non-Federal entities receive or administer in the form of grants, contracts, loans, loan guarantees, property, cooperative agreements, food commodities, direct appropriations, or other assistance, but does not include a tax credit, deduction, or exemption.

(b) “Social service program” means a program that is administered by the Federal Government, or by a State or local government using Federal financial assistance, and that provides services directed at reducing poverty, improving opportunities for low-income children, revitalizing low-income communities, empowering low-income families and low-income individuals to become self-sufficient, or otherwise helping people in need. Such programs include, but are not limited to, the following:

(i) child care services, protective services for children and adults, services for children and adults in foster care, adoption services, services related to the management and maintenance of the home, day care services for adults, and services to meet the special needs of children, older individuals, and individuals with disabilities (including physical, mental, or emotional disabilities);

(ii) transportation services;

(iii) job training and related services, and employment services;

(iv) information, referral, and counseling services;

(v) the preparation and delivery of meals and services related to soup kitchens or food banks;

(vi) health support services;

(vii) literacy and mentoring programs;

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(viii) services for the prevention and treatment of juvenile delinquency and substance abuse, services for the prevention of crime and the provision of assistance to the victims and the families of criminal offenders, and services related to intervention in, and prevention of, domestic violence; and

(ix) services related to the provision of assistance for housing under Federal law.

(c) “Policies that have implications for faith-based and other neighborhood organizations” refers to all policies, programs, and regulations, including official guidance and internal agency procedures, that have significant effects on faith-based organizations participating in or seeking to participate in social service programs supported with Federal financial assistance.

(d) “Agency” means a department or agency in the executive branch.

(e) “Specified agency heads” means:

(i) the Attorney General;

(ii) the Secretary of Agriculture;

(iii) the Secretary of Commerce;

(iv) the Secretary of Labor;

(v) the Secretary of Health and Human Services;

(vi) the Secretary of Housing and Urban Development;

(vii) the Secretary of Education;

(viii) the Secretary of Veterans Affairs;

(ix) the Secretary of Homeland Security;

(x) the Administrator of the Environmental Protection Agency;

(xi) the Administrator of the Small Business Administration;

(xii) the Administrator of the United States Agency for International Development; and

(xiii) the Chief Executive Officer of the Corporation for National and Community Service.

Sec. 2. Fundamental Principles. In formulating and implementing policies that have implications for faith-based and other neighborhood organizations, agencies that administer social service programs or that support (including through prime awards or sub-awards) social service programs with Federal financial assistance shall, to the extent permitted by law, be guided by the following fundamental principles:

(a) Federal financial assistance for social service programs should be distributed in the most effective and efficient manner possible.

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(b) The Nation's social service capacity will benefit if all eligible organizations, including faith-based and other neighborhood organizations, are able to compete on an equal footing for Federal financial assistance used to support social service programs.

(c) No organization should be discriminated against on the basis of religion or religious belief in the administration or distribution of Federal financial assistance under social service programs.

(d) All organizations that receive Federal financial assistance under social service programs should be prohibited from discriminating against beneficiaries or prospective beneficiaries of the social service programs on the basis of religion or religious belief. Accordingly, organizations, in providing services supported in whole or in part with Federal financial assistance, and in their outreach activities related to such services, should not be allowed to discriminate against current or prospective program beneficiaries on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.

(e) The Federal Government must implement Federal programs in accordance with the Establishment Clause and the Free Exercise Clause of the First Amendment to the United States Constitution, as well as other applicable law, and must monitor and enforce standards regarding the relationship between religion and government in ways that avoid excessive entanglement between religious bodies and governmental entities.

(f) Organizations that engage in explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction, or proselytization) must perform such activities and offer such services outside of programs that are supported with direct Federal financial assistance (including through prime awards or sub-awards), separately in time or location from any such programs or services supported with direct Federal financial assistance, and participation in any such explicitly religious activities must be voluntary for the beneficiaries of the social service program supported with such Federal financial assistance.

(g) Faith-based organizations should be eligible to compete for Federal financial assistance used to support social service programs and to participate fully in the social service programs supported with Federal financial assistance without impairing their independence, autonomy, expression outside the programs in question, or religious character. Accordingly, a faith-based organization that applies for, or participates in, a social service program supported with Federal financial assistance may retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct Federal financial assistance that it receives (including through a prime award or sub-award) to support or engage in any explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction, or proselytization), or in any other manner prohibited by law. Among other things, faith-based organizations that receive Federal financial assistance may use their facilities to provide social services supported with Federal financial assistance, without removing or altering religious art, icons, scriptures, or other symbols from these facilities. In addition, a faith-based organization that applies for, or participates in, a social service program supported with Federal financial assistance may retain religious terms in its name, select its board members on a religious basis, and include religious references in its organization's mission statements and other chartering or governing documents.

(h) To promote transparency and accountability, agencies that provide Federal financial assistance for social service programs shall post online, in an easily accessible manner, regulations, guidance documents, and policies that reflect or elaborate upon the fundamental principles described in this section. Agencies shall also post online a list of entities that receive Federal financial assistance for provision of social service programs, consistent with law and pursuant to guidance set forth in paragraph (c) of section 3 of this order.

(i) Decisions about awards of Federal financial assistance must be free from political interference or even the appearance of such interference and must be made on the basis of merit, not on the basis of the religious affiliation of a recipient organization or lack thereof.

Sec. 3. Ensuring Uniform Implementation Across the Federal Government.

In order to promote uniformity in agencies' policies that have implications for faith-based and other neighborhood organizations and in related guidance, and to ensure that those policies and guidance are consistent with the fundamental principles set forth in section 2 of this order, there is established an Interagency Working Group on Faith-Based and Other Neighborhood Partnerships (Working Group).

(a) Mission and Function of the Working Group. The Working Group shall meet periodically to review and evaluate existing agency regulations, guidance documents, and policies that have implications for faith-based and other neighborhood organizations. Where appropriate, specified agency heads shall, to the extent permitted by law, amend all such existing policies of their respective agencies to ensure that they are consistent with the fundamental principles set forth in section 2 of this order.

(b) Uniform Agency Implementation. Within 120 days of the date of this order, the Working Group shall submit a report to the President on amendments, changes, or additions that are necessary to ensure that regulations and guidance documents associated with the distribution of Federal financial assistance for social service programs are consistent with the fundamental principles set forth in section 2 of this order. The Working Group's report should include, but not be limited to, a model set of regulations and guidance documents for agencies to adopt in the following areas:

(i) prohibited uses of direct Federal financial assistance and separation requirements; **(ii)** protections for religious identity; **(iii)** the distinction between “direct” and “indirect” Federal financial assistance; **(iv)** protections for beneficiaries of social service programs; **(v)** transparency requirements, consistent with and in furtherance of existing open government initiatives; **(vi)** obligations of nongovernmental and governmental intermediaries; **(vii)** instructions for peer reviewers and those who recruit peer reviewers; and **(viii)** training on these matters for government employees and for Federal, State, and local governmental and nongovernmental organizations that receive Federal financial assistance under social service programs. In developing this report and in reviewing agency regulations and guidance for consistency with section 2 of this order, the Working Group shall consult the March 2010 report and recommendations prepared by the President's Advisory Council on Faith-Based and Neighborhood Partnerships on the topic of reforming the White House Faith and Opportunity Initiative.

(c) Guidance. The Director of the Office of Management and Budget (OMB), following receipt of a copy of the report of the Working Group, and in coordination with the Department of Justice, shall issue guidance to agencies on the implementation of this order, including in particular subsections 2(h)-(j).

(d) Membership of the Working Group. The Director of the White House Faith and Opportunity Initiative and a senior official from the OMB designated by the Director of the OMB shall serve as the Co-Chairs of the Working Group. The Co-Chairs shall convene regular meetings of the Working Group, determine its agenda, and direct its work. In addition to the Co-Chairs, the Working Group shall consist of a senior official with knowledge of policies that have implications for faith-based and other neighborhood organizations from the following agencies and offices:

(i) the Department of State;

(ii) the Department of Justice;

(iii) the Department of the Interior;

(iv) the Department of Agriculture;

(v) the Department of Commerce;

(vi) the Department of Labor;

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(vii) the Department of Health and Human Services;

(viii) the Department of Housing and Urban Development;

(ix) the Department of Education;

(x) the Department of Veterans Affairs;

(xi) the Department of Homeland Security;

(xii) the Environmental Protection Agency;

(xiii) the Small Business Administration;

(xiv) the United States Agency for International Development;

(xv) the Corporation for National and Community Service; and

(xvi) other agencies and offices as the President, from time to time, may designate.

(e) Administration of the Initiative. The Department of Health and Human Services shall provide funding and administrative support for the Working Group to the extent permitted by law and within existing appropriations.

Sec. 4. Amendment of Executive Order 11246.

Pursuant to [section 121\(a\) of title 40, United States Code](#), and [section 301 of title 3, United States Code](#), and in order to further the strong Federal interest in ensuring that the cost and progress of Federal procurement contracts are not adversely affected by an artificial restriction of the labor pool caused by the unwarranted exclusion of faith-based organizations from such contracts, section 204 of [Executive Order 11246](#) of September 24, 1965, as amended [set out under [42 U.S.C.A. § 2000e](#)], is hereby further amended to read as follows:

“**Sec. 204(a)** The Secretary of Labor may, when the Secretary deems that special circumstances in the national interest so require, exempt a contracting agency from the requirement of including any or all of the provisions of Section 202 of this Order in any specific contract, subcontract, or purchase order.

(b) The Secretary of Labor may, by rule or regulation, exempt certain classes of contracts, subcontracts, or purchase orders (1) whenever work is to be or has been performed outside the United States and no recruitment of workers within the limits of the United States is involved; (2) for standard commercial supplies or raw materials; (3) involving less than specified amounts of money or specified numbers of workers; or (4) to the extent that they involve subcontracts below a specified tier.

(c) Section 202 of this Order shall not apply to a Government contractor or subcontractor that is a religious corporation, association, educational institution, or society, with respect to the employment of individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities. Such contractors and subcontractors are not exempted or excused from complying with the other requirements contained in this Order.

(d) The Secretary of Labor may also provide, by rule, regulation, or order, for the exemption of facilities of a contractor that are in all respects separate and distinct from activities of the contractor related to the performance of the contract: provided, that

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such an exemption will not interfere with or impede the effectuation of the purposes of this Order: and provided further, that in the absence of such an exemption all facilities shall be covered by the provisions of this Order.”

Sec. 5. General Provisions.

(a) This order supplements but does not supersede the requirements contained in [Executive Orders 13198](#) [set out under this section] and 13199 [set out preceding [3 U.S.C.A. § 101](#)] of January 29, 2001.

(b) The agencies shall coordinate with the White House Faith and Opportunity Initiative concerning the implementation of this order.

(c) Nothing in this order shall be construed to require an agency to take any action that would impair the conduct of foreign affairs or the national security.

Sec. 6. Responsibilities of Executive Departments and Agencies. All executive departments and agencies (agencies) shall:

(a) designate an agency employee to serve as the liaison and point of contact with the White House Faith and Opportunity Initiative; and

(b) cooperate with the White House Faith and Opportunity Initiative and provide such information, support, and assistance to the White House Faith and Opportunity Initiative as it may request, to the extent permitted by law.

Sec. 7. Judicial Review.

This order is intended only to improve the internal management of the executive branch, and it is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, or entities, its officers, employees or agents, or any person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13280

<Dec. 12, 2002, [67 F.R. 77145](#), as amended [Ex. Ord. No. 13831](#), § 2, May 3, 2018, [83 F.R. 20715](#)>

Responsibilities of the Department of Agriculture and the Agency for International Development With Respect to Faith-Based and Community Initiatives

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to help the Federal Government coordinate a national effort to expand opportunities for faith-based and other community organizations and to strengthen their capacity to better meet social needs in America's communities, it is hereby ordered as follows:

Section 1. Establishment of Centers for Faith and Opportunity Initiatives at the Department of Agriculture and the Agency for International Development. (a) The Secretary of Agriculture and the Administrator of the Agency for International Development shall each establish within their respective agencies a Centers for Faith and Opportunity Initiatives (Center).

(b) Each of these Centers shall be supervised by a Director, appointed by the agency head in consultation with the White House Faith and Opportunity Initiative (White House Faith and Opportunity Initiative).

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(c) Each agency shall provide its Center with appropriate staff, administrative support, and other resources to meet its responsibilities under this order.

(d) Each Center shall begin operations no later than 45 days from the date of this order.

Sec. 2. Purpose of Executive Branch Centers for Faith and Opportunity Initiatives. The purpose of the agency Centers will be to coordinate agency efforts to eliminate regulatory, contracting, and other programmatic obstacles to the participation of faith-based and other community organizations in the provision of social services.

Sec. 3. Responsibilities of the Centers for Faith and Opportunity Initiatives. Each Center shall, to the extent permitted by law:

(a) conduct, in coordination with the White House Faith and Opportunity Initiative, an agency-wide audit to identify all existing barriers to the participation of faith-based and other community organizations in the delivery of social services by the agency, including but not limited to regulations, rules, orders, procurement, and other internal policies and practices, and outreach activities that either facially discriminate against or otherwise discourage or disadvantage the participation of faith-based and other community organizations in Federal programs;

(b) coordinate a comprehensive agency effort to incorporate faith-based and other community organizations in agency programs and initiatives to the greatest extent possible;

(c) propose initiatives to remove barriers identified pursuant to section 3(a) of this order, including but not limited to reform of regulations, procurement, and other internal policies and practices, and outreach activities;

(d) propose the development of innovative pilot and demonstration programs to increase the participation of faith-based and other community organizations in Federal as well as State and local initiatives; and

(e) develop and coordinate agency outreach efforts to disseminate information more effectively to faith-based and other community organizations with respect to programming changes, contracting opportunities, and other agency initiatives, including but not limited to Web and Internet resources.

Sec. 4. Reporting Requirements.

(a) **Report.** Not later than 180 days from the date of this order and annually thereafter, each of the two Centers described in section 1 of this order shall prepare and submit a report to the White House Faith and Opportunity Initiative.

(b) **Contents.** The report shall include a description of the agency's efforts in carrying out its responsibilities under this order, including but not limited to:

(i) a comprehensive analysis of the barriers to the full participation of faith-based and other community organizations in the delivery of social services identified pursuant to section 3(a) of this order and the proposed strategies to eliminate those barriers; and

(ii) a summary of the technical assistance and other information that will be available to faith-based and other community organizations regarding the program activities of the agency and the preparation of applications or proposals for grants, cooperative agreements, contracts, and procurement.

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(c) Performance Indicators. The first report, filed 180 days after the date of this order, shall include annual performance indicators and measurable objectives for agency action. Each report filed thereafter shall measure the agency's performance against the objectives set forth in the initial report.

Sec. 5. Responsibilities of the Secretary of Agriculture and the Administrator of the Agency for International Development. The Secretary and the Administrator shall:

(a) designate an employee within their respective agencies to serve as the liaison and point of contact with the White House Faith and Opportunity Initiative; and

(b) cooperate with the White House Faith and Opportunity Initiative and provide such information, support, and assistance to the White House Faith and Opportunity Initiative as it may request, to the extent permitted by law.

Sec. 6. Administration and Judicial Review. (a) The agency actions directed by this executive order shall be carried out subject to the availability of appropriations and to the extent permitted by law.

(b) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, or entities, its officers, employees or agents, or any other person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13342

<June 1, 2004, 69 F.R. 31509, as amended Ex. Ord. No. 13831, § 2, May 3, 2018, 83 F.R. 20715>

Responsibilities of the Departments of Commerce and Veterans Affairs and the Small Business Administration with Respect to Faith-Based and Community Initiatives

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to help the Federal Government coordinate a national effort to expand opportunities for faith-based and other community organizations and to strengthen their capacity to better meet America's social and community needs, it is hereby ordered as follows:

Section 1. Establishment of Centers for Faith, Based and Community Initiatives at the Departments of Commerce and Veterans Affairs and the Small Business Administration

(a) The Secretaries of Commerce and Veterans Affairs and the Administrator of the Small Business Administration shall each establish within their respective agencies a Centers for Faith and Opportunity Initiatives (Center).

(b) Each of these Centers shall be supervised by a Director, appointed by the agency head in consultation with the White House Faith and Opportunity Initiative (White House Faith and Opportunity Initiative).

(c) Each agency shall provide its Center with appropriate staff, administrative support, and other resources to meet its responsibilities under this order.

(d) Each Center shall begin operations no later than 45 days from the date of this order [June 1, 2004].

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Sec. 2. Purpose of Executive Branch Centers for Faith and Opportunity Initiatives. The purpose of the agency Centers will be to coordinate agency efforts to eliminate regulatory, contracting, and other programmatic obstacles to the participation of faith-based and other community organizations in the provision of social and community services.

Sec. 3. Responsibilities of the Centers for Faith and Opportunity Initiatives. Each Center shall, to the extent permitted by law:

(a) conduct, in coordination with the White House Faith and Opportunity Initiative, an agency-wide audit to identify all existing barriers to the participation of faith-based and other community organizations in the delivery of social and community services by the agency, including but not limited to regulations, rules, orders, procurement, and other internal policies and practices, and outreach activities that either facially discriminate against or otherwise discourage or disadvantage the participation of faith-based and other community organizations in Federal programs;

(b) coordinate a comprehensive agency effort to incorporate faith-based and other community organizations in agency programs and initiatives to the greatest extent possible;

(c) propose initiatives to remove barriers identified pursuant to section 3(a) of this order [of this note], including but not limited to reform of regulations, procurement, and other internal policies and practices, and outreach activities;

(d) propose the development of innovative pilot and demonstration programs to increase the participation of faith-based and other community organizations in Federal as well as State and local initiatives; and

(e) develop and coordinate agency outreach efforts to disseminate information more effectively to faith-based and other community organizations with respect to programming changes, contracting opportunities, and other agency initiatives, including but not limited to Web and Internet resources.

Sec. 4. Reporting Requirements. (a) Report. Not later than 180 days from the date of this order [June 1, 2004] and annually thereafter, each of the three Centers described in section 1 of this order [of this note] shall prepare and submit a report to the President through the White House Faith and Opportunity Initiative.

(b) **Contents.** The report shall include a description of the agency's efforts in carrying out its responsibilities under this order, including but not limited to:

(i) a comprehensive analysis of the barriers to the full participation of faith-based and other community organizations in the delivery of social and community services identified pursuant to section 3(a) of this order [of this note] and the proposed strategies to eliminate those barriers; and

(ii) a summary of the technical assistance and other information that will be available to faith-based and other community organizations regarding the program activities of the agency and the preparation of applications or proposals for grants, cooperative agreements, contracts, and procurement.

(c) **Performance Indicators.** The first report, filed pursuant to section 4(a) of this order [of this note], shall include annual performance indicators and measurable objectives for agency action. Each report filed thereafter shall measure the agency's performance against the objectives set forth in the initial report.

Sec. 5. Responsibilities of the Secretaries of Commerce and Veterans Affairs and the Administrator of the Small Business Administration. The Secretaries and the Administrator shall:

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(a) designate an employee within their respective agencies to serve as the liaison and point of contact with the White House Faith and Opportunity Initiative; and

(b) cooperate with the White House Faith and Opportunity Initiative and provide such information, support, and assistance to the White House Faith and Opportunity Initiative as it may request, to the extent permitted by law.

Sec. 6. Administration and Judicial Review. (a) The agency actions directed by this executive order shall be carried out subject to the availability of appropriations and to the extent permitted by law.

(b) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its departments, agencies, instrumentalities or entities, its officers, employees or agents, or any other person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13353

Ex. Ord. No. 13353, Aug. 27, 2004, 69 F.R. 53585, which established the President's Board on Safeguarding Americans' Civil Liberties, is set out as a note under [42 U.S.C.A. § 2000ee](#) note.

EXECUTIVE ORDER NO. 13397

<Mar. 7, 2006, [71 F.R. 12275](#), as amended Ex. Ord. No. 13831, § 2, May 3, 2018, [83 F.R. 20715](#)>

Responsibilities of the Department of Homeland Security with Respect to Faith-Based and Community Initiatives

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to help the Federal Government coordinate a national effort to expand opportunities for faith-based and other community organizations and to strengthen their capacity to better meet America's social and community needs, it is hereby ordered as follows:

Section 1. Establishment of a Centers for Faith and Opportunity Initiatives at the Department of Homeland Security.

(a) The Secretary of Homeland Security (Secretary) shall establish within the Department of Homeland Security (Department) a Centers for Faith and Opportunity Initiatives (Center).

(b) The Center shall be supervised by a Director appointed by Secretary. The Secretary shall consult with the Director of the White House Faith and Opportunity Initiative (White House Faith and Opportunity Initiative Director) prior to making such appointment.

(c) The Department shall provide the Center with appropriate staff, administrative support, and other resources to meet its responsibilities under this order.

(d) The Center shall begin operations no later than 45 days from the date of this order [March 7, 2006].

Sec. 2. Purpose of Center. The purpose of the Center shall be to coordinate agency efforts to eliminate regulatory, contracting, and other programmatic obstacles to the participation of faith-based and other community organizations in the provision of social and community services.

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Sec. 3. Responsibilities of the Centers for Faith and Opportunity Initiatives. In carrying out the purpose set forth in section 2 of this order, the Center shall:

- (a) conduct, in coordination with the WHOFBCI Director, a department-wide audit to identify all existing barriers to the participation of faith-based and other community organizations in the delivery of social and community services by the Department, including but not limited to regulations, rules, orders, procurement, and other internal policies and practices, and outreach activities that unlawfully discriminate against, or otherwise discourage or disadvantage the participation of faith-based and other community organizations in Federal programs;
- (b) coordinate a comprehensive departmental effort to incorporate faith-based and other community organizations in Department programs and initiatives to the greatest extent possible;
- (c) propose initiatives to remove barriers identified pursuant to section 3(a) of this order, including but not limited to reform of regulations, procurement, and other internal policies and practices, and outreach activities;
- (d) propose the development of innovative pilot and demonstration programs to increase the participation of faith-based and other community organizations in Federal as well as State and local initiatives; and
- (e) develop and coordinate Departmental outreach efforts to disseminate information more effectively to faith-based and other community organizations with respect to programming changes, contracting opportunities, and other agency initiatives, including but not limited to Web and Internet resources.

Sec. 4. Reporting Requirements.

- (a) **Report.** Not later than 180 days from the date of this order [March 7, 2006] and annually thereafter, the Center shall prepare and submit a report to the WHOFBCI Director.
- (b) **Contents.** The report shall include a description of the Department's efforts in carrying out its responsibilities under this order, including but not limited to:
 - (i) a comprehensive analysis of the barriers to the full participation of faith-based and other community organizations in the delivery of social and community services identified pursuant to section 3(a) of this order and the proposed strategies to eliminate those barriers; and
 - (ii) a summary of the technical assistance and other information that will be available to faith-based and other community organizations regarding the program activities of the agency and the preparation of applications or proposals for grants, cooperative agreements, contracts, and procurement.
- (c) **Performance Indicators.** The first report shall include annual performance indicators and measurable objectives for Departmental action. Each report filed thereafter shall measure the Department's performance against the objectives set forth in the initial report.

Sec. 5. Responsibilities of the Secretary. The Secretary shall:

- (a) designate an employee within the department to serve as the liaison and point of contact with the WHOFBCI Director; and
- (b) cooperate with the WHOFBCI Director and provide such information, support, and assistance to the WHOFBCI Director as requested to implement this order.

Sec. 6. General Provisions. (a) This order shall be implemented subject to the availability of appropriations and to the extent permitted by law.

(b) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13406

<June 23, 2006, 71 F.R. 36973>

Protecting the Property Rights of the American People

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to strengthen the rights of the American people against the taking of their private property, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the United States to protect the rights of Americans to their private property, including by limiting the taking of private property by the Federal Government to situations in which the taking is for public use, with just compensation, and for the purpose of benefiting the general public and not merely for the purpose of advancing the economic interest of private parties to be given ownership or use of the property taken.

Sec. 2. Implementation. (a) The Attorney General shall:

- (i)** issue instructions to the heads of departments and agencies to implement the policy set forth in section 1 of this order; and
- (ii)** monitor takings by departments and agencies for compliance with the policy set forth in section 1 of this order.

(b) Heads of departments and agencies shall, to the extent permitted by law:

- (i)** comply with instructions issued under subsection (a)(i); and
- (ii)** provide to the Attorney General such information as the Attorney General determines necessary to carry out subsection (a)(ii).

Sec. 3. Specific Exclusions. Nothing in this order shall be construed to prohibit a taking of private property by the Federal Government, that otherwise complies with applicable law, for the purpose of:

- (a)** public ownership or exclusive use of the property by the public, such as for a public medical facility, roadway, park, forest, governmental office building, or military reservation;
- (b)** projects designated for public, common carrier, public transportation, or public utility use, including those for which a fee is assessed, that serve the general public and are subject to regulation by a governmental entity;
- (c)** conveying the property to a nongovernmental entity, such as a telecommunications or transportation common carrier, that makes the property available for use by the general public as of right;
- (d)** preventing or mitigating a harmful use of land that constitutes a threat to public health, safety, or the environment;

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- (e) acquiring abandoned property;
- (f) quieting title to real property;
- (g) acquiring ownership or use by a public utility;
- (h) facilitating the disposal or exchange of Federal property; or
- (i) meeting military, law enforcement, public safety, public transportation, or public health emergencies.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

- (i) authority granted by law to a department or agency or the head thereof; or
- (ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(c) This order shall be implemented in a manner consistent with [Executive Order 12630](#) of March 15, 1988 [Ex. Ord. No. 12630, Mar. 15, 1988, 53 F.R. 8859, set out under this section].

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity against the United States, its departments, agencies, entities, officers, employees, or agents, or any other person.

GEORGE W. BUSH

EXECUTIVE ORDER NO. 13443

For [Executive Order No. 13443](#), “Facilitation of Hunting Heritage and Wildlife Conservation”, see Ex. Ord. No. 13443, August 16, 2007, 72 F.R. 46537, set out as a note under 16 U.S.C.A. § 661.

EXECUTIVE ORDER NO. 13497

For [Executive Order No. 13497](#), “Revocation of Certain Executive Orders Concerning Regulatory Planning and Review”, see Ex. Ord. No. 13497, Jan. 30, 2009, 74 F.R. 6113, which is set out as a note following [Ex. Ord. No. 12866](#), Sept. 30, 1993, 58 F.R. 51735, set out as a note under this section.

EXECUTIVE ORDER NO. 13559

<Nov. 17, 2010, 75 FR 71319>

**Fundamental Principles and Policymaking Criteria for Partnerships
with Faith-Based and Other Neighborhood Organizations**

§ 601. Definitions, 5 USCA § 601

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to guide Federal agencies in formulating and developing policies with implications for faith-based and other neighborhood organizations, to promote compliance with constitutional and other applicable legal principles, and to strengthen the capacity of faith-based and other neighborhood organizations to deliver services effectively to those in need, it is hereby ordered:

Section 1. [Omitted; Amended [Ex. Ord. No. 13279](#), Dec. 12, 2002, 67 F.R. 77141, set out as a note under this section.]

Sec. 2. General Provisions.

(a) This order amends the requirements contained in [Executive Order 13279](#). This order supplements, but does not supersede, the requirements contained in [Executive Orders 13198](#) and [13199](#) of January 29, 2001, and [Executive Order 13498](#) of February 5, 2009.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the OMB relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13563

<Jan. 18, 2011, 76 F.R. 3821>

Improving Regulation and Regulatory Review

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve regulation and regulatory review, it is hereby ordered as follows:

Section 1. General Principles of Regulation. (a) Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.

(b) This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in [Executive Order 12866](#) of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to

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impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(c) In applying these principles, each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

Sec. 2. Public Participation. (a) Regulations shall be adopted through a process that involves public participation. To that end, regulations shall be based, to the extent feasible and consistent with law, on the open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole.

(b) To promote that open exchange, each agency, consistent with [Executive Order 12866](#) and other applicable legal requirements, shall endeavor to provide the public with an opportunity to participate in the regulatory process. To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days. To the extent feasible and permitted by law, each agency shall also provide, for both proposed and final rules, timely online access to the rulemaking docket on [regulations.gov](#), including relevant scientific and technical findings, in an open format that can be easily searched and downloaded. For proposed rules, such access shall include, to the extent feasible and permitted by law, an opportunity for public comment on all pertinent parts of the rulemaking docket, including relevant scientific and technical findings.

(c) Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.

Sec. 3. Integration and Innovation. Some sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping. Greater coordination across agencies could reduce these requirements, thus reducing costs and simplifying and harmonizing rules. In developing regulatory actions and identifying appropriate approaches, each agency shall attempt to promote such coordination, simplification, and harmonization. Each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation.

Sec. 4. Flexible Approaches. Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.

Sec. 5. Science. Consistent with the President's Memorandum for the Heads of Executive Departments and Agencies, "Scientific Integrity" (March 9, 2009), and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions.

Sec. 6. Retrospective Analyses of Existing Rules. (a) To facilitate the periodic review of existing significant regulations, agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or

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excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.

(b) Within 120 days of the date of this order, each agency shall develop and submit to the Office of Information and Regulatory Affairs a preliminary plan, consistent with law and its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

Sec. 7. General Provisions. (a) For purposes of this order, “agency” shall have the meaning set forth in section 3(b) of [Executive Order 12866](#).

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13579

<July 11, 2011, 76 F.R. 41587>

Regulation and Independent Regulatory Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve regulation and regulatory review, it is hereby ordered as follows:

Section 1. Policy. (a) Wise regulatory decisions depend on public participation and on careful analysis of the likely consequences of regulation. Such decisions are informed and improved by allowing interested members of the public to have a meaningful opportunity to participate in rulemaking. To the extent permitted by law, such decisions should be made only after consideration of their costs and benefits (both quantitative and qualitative).

(b) [Executive Order 13563](#) of January 18, 2011, “Improving Regulation and Regulatory Review,” directed to executive agencies, was meant to produce a regulatory system that protects “public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” Independent regulatory agencies, no less than executive agencies, should promote that goal.

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(c) [Executive Order 13563](#) set out general requirements directed to executive agencies concerning public participation, integration and innovation, flexible approaches, and science. To the extent permitted by law, independent regulatory agencies should comply with these provisions as well.

Sec. 2. Retrospective Analyses of Existing Rules. (a) To facilitate the periodic review of existing significant regulations, independent regulatory agencies should consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data and evaluations, should be released online whenever possible.

(b) Within 120 days of the date of this order, each independent regulatory agency should develop and release to the public a plan, consistent with law and reflecting its resources and regulatory priorities and processes, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

Sec. 3. General Provisions. (a) For purposes of this order, “executive agency” shall have the meaning set forth for the term “agency” in section 3(b) of [Executive Order 12866](#) of September 30, 1993, and “independent regulatory agency” shall have the meaning set forth in [44 U.S.C. 3502\(5\)](#).

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13580

For [Executive Order No. 13580](#), relating to establishment of an interagency working group on coordination of domestic energy development and permitting in Alaska, see [Ex. Ord. No. 13580](#), July 12, 2011, 76 F.R. 41989, set out as a note preceding [16 U.S.C.A. § 3101](#).

EXECUTIVE ORDER NO. 13604

<March 22, 2012, [77 F.R. 18887](#)>

Improving Performance of Federal Permitting and Review of Infrastructure Projects

§ 601. Definitions, 5 USCA § 601

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to significantly reduce the aggregate time required to make decisions in the permitting and review of infrastructure projects by the Federal Government, while improving environmental and community outcomes, it is hereby ordered as follows:

Section 1. Policy. (a) To maintain our Nation's competitive edge and ensure an economy built to last, the United States must have fast, reliable, resilient, and environmentally sound means of moving people, goods, energy, and information. In a global economy, we will compete for the world's investments based in significant part on the quality of our infrastructure. Investing in the Nation's infrastructure provides immediate and long-term economic benefits for local communities and the Nation as a whole.

The quality of our Nation's infrastructure depends in critical part on Federal permitting and review processes, including planning, approval, and consultation processes. These processes inform decision-makers and affected communities about the potential benefits and impacts of proposed infrastructure projects, and ensure that projects are designed, built, and maintained in a manner that is consistent with protecting our public health, welfare, safety, national security, and environment. Reviews and approvals of infrastructure projects can be delayed due to many factors beyond the control of the Federal Government, such as poor project design, incomplete applications, uncertain funding, or multiple reviews and approvals by State, local, tribal, or other jurisdictions. Given these factors, it is critical that executive departments and agencies (agencies) take all steps within their authority, consistent with available resources, to execute Federal permitting and review processes with maximum efficiency and effectiveness, ensuring the health, safety, and security of communities and the environment while supporting vital economic growth.

To achieve that objective, our Federal permitting and review processes must provide a transparent, consistent, and predictable path for both project sponsors and affected communities. They must ensure that agencies set and adhere to timelines and schedules for completion of reviews, set clear permitting performance goals, and track progress against those goals. They must encourage early collaboration among agencies, project sponsors, and affected stakeholders in order to incorporate and address their interests and minimize delays. They must provide for transparency and accountability by utilizing cost-effective information technology to collect and disseminate information about individual projects and agency performance, so that the priorities and concerns of all our citizens are considered. They must rely upon early and active consultation with State, local, and tribal governments to avoid conflicts or duplication of effort, resolve concerns, and allow for concurrent rather than sequential reviews. They must recognize the critical role project sponsors play in assuring the timely and cost-effective review of projects by providing complete information and analysis and by supporting, as appropriate, the costs associated with review. And, they must enable agencies to share priorities, work collaboratively and concurrently to advance reviews and permitting decisions, and facilitate the resolution of disputes at all levels of agency organization.

Each of these elements must be incorporated into routine agency practice to provide demonstrable improvements in the performance of Federal infrastructure permitting and review processes, including lower costs, more timely decisions, and a healthier and cleaner environment. Also, these elements must be integrated into project planning processes so that projects are designed appropriately to avoid, to the extent practicable, adverse impacts on public health, security, historic properties and other cultural resources, and the environment, and to minimize or mitigate impacts that may occur. Permitting and review process improvements that have proven effective must be expanded and institutionalized.

(b) In advancing this policy, this order expands upon efforts undertaken pursuant to [Executive Order 13580](#) of July 12, 2011 (Interagency Working Group on Coordination of Domestic Energy Development and Permitting in Alaska), [Executive Order 13563](#) of January 18, 2011 (Improving Regulation and Regulatory Review), and my memorandum of August 31, 2011 (Speeding Infrastructure Development Through More Efficient and Effective Permitting and Environmental Review), as well as other ongoing efforts.

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Sec. 2. Steering Committee on Federal Infrastructure Permitting and Review Process Improvement. There is established a Steering Committee on Federal Infrastructure Permitting and Review Process Improvement (Steering Committee), to be chaired by the Chief Performance Officer (CPO), in consultation with the Chair of the Council on Environmental Quality (CEQ).

(a) Infrastructure Projects Covered by this Order. The Steering Committee shall facilitate improvements in Federal permitting and review processes for infrastructure projects in sectors including surface transportation, aviation, ports and waterways, water resource projects, renewable energy generation, electricity transmission, broadband, pipelines, and other such sectors as determined by the Steering Committee.

(b) Membership. Each of the following agencies (Member Agencies) shall be represented on the Steering Committee by a Deputy Secretary or equivalent officer of the United States:

- (i)** the Department of Defense;
- (ii)** the Department of the Interior;
- (iii)** the Department of Agriculture;
- (iv)** the Department of Commerce;
- (v)** the Department of Transportation;
- (vi)** the Department of Energy;
- (vii)** the Department of Homeland Security;
- (viii)** the Environmental Protection Agency;
- (ix)** the Advisory Council on Historic Preservation;
- (x)** the Department of the Army; and
- (xi)** such other agencies or offices as the CPO may invite to participate.

(c) Projects of National or Regional Significance. In furtherance of the policies of this order, the Member Agencies shall coordinate and consult with each other to select, submit to the CPO by April 30, 2012, and periodically update thereafter, a list of infrastructure projects of national or regional significance that will have their status tracked on the online Federal Infrastructure Projects Dashboard (Dashboard) created pursuant to my memorandum of August 31, 2011.

(d) Responsibilities of the Steering Committee. The Steering Committee shall:

- (i)** develop a Federal Permitting and Review Performance Plan (Federal Plan), as described in section 3(a) of this order;
- (ii)** implement the Federal Plan and coordinate resolution of disputes among Member Agencies relating to implementation of the Federal Plan; and
- (iii)** coordinate and consult with other agencies, offices, and interagency working groups as necessary, including the President's Management Council and Performance Improvement Councils, and, with regard to use and expansion of the Dashboard, the Chief Information Officer (CIO) and Chief Technology Officer to implement this order.

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(e) Duties of the CPO. The CPO shall:

- (i) in consultation with the Chair of CEQ and Member Agencies, issue guidance on the implementation of this order;
 - (ii) in consultation with Member Agencies, develop and track performance metrics for evaluating implementation of the Federal Plan and Agency Plans; and
 - (iii) by January 31, 2013, and annually thereafter, after input from interested agencies, evaluate and report to the President on the implementation of the Federal Plan and Agency Plans, and publish the report on the Dashboard.
- (f) No Involvement in Particular Permits or Projects.** Neither the Steering Committee, nor the CPO, may direct or coordinate agency decisions with respect to any particular permit or project.

Sec. 3. Plans for Measurable Performance Improvement. (a) By May 31, 2012, the Steering Committee shall, following coordination with Member Agencies and other interested agencies, develop and publish on the Dashboard a Federal Plan to significantly reduce the aggregate time required to make Federal permitting and review decisions on infrastructure projects while improving outcomes for communities and the environment. The Federal Plan shall include, but not be limited to, the following actions to implement the policies outlined in section 1 of this order, and shall reflect the agreement of any Member Agency with respect to requirements in the Federal Plan affecting such agency:

- (i) institutionalizing best practices for: enhancing Federal, State, local, and tribal government coordination on permitting and review processes (such as conducting reviews concurrently rather than sequentially to the extent practicable); avoiding duplicative reviews; and engaging with stakeholders early in the permitting process;
- (ii) developing mechanisms to better communicate priorities and resolve disputes among agencies at the national and regional levels;
- (iii) institutionalizing use of the Dashboard, working with the CIO to enhance the Dashboard, and utilizing other cost-effective information technology systems to share environmental and project-related information with the public, project sponsors, and permit reviewers; and
- (iv) identifying timeframes and Member Agency responsibilities for the implementation of each proposed action.

(b) Each Member Agency shall:

- (i) by June 30, 2012, submit to the CPO an Agency Plan identifying those permitting and review processes the Member Agency views as most critical to significantly reducing the aggregate time required to make permitting and review decisions on infrastructure projects while improving outcomes for communities and the environment, and describing specific and measurable actions the agency will take to improve these processes, including:
 - (1) performance metrics, including timelines or schedules for review;
 - (2) technological improvements, such as institutionalized use of the Dashboard and other information technology systems;
 - (3) other practices, such as pre-application procedures, early collaboration with other agencies, project sponsors, and affected stakeholders, and coordination with State, local, and tribal governments; and
 - (4) steps the Member Agency will take to implement the Federal Plan.

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(ii) by July 31, 2012, following coordination with other Member Agencies and interested agencies, publish its Agency Plan on the Dashboard; and

(iii) by December 31, 2012, and every 6 months thereafter, report progress to the CPO on implementing its Agency Plan, as well as specific opportunities for additional improvements to its permitting and review procedures.

Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order shall be implemented consistent with [Executive Order 13175](#) of November 6, 2000 (Consultation and Coordination with Indian Tribal Governments) and my memorandum of November 5, 2009 (Tribal Consultation).

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13609

<May 1, 2012, [77 F.R. 26413](#)>

Promoting International Regulatory Cooperation

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to promote international regulatory cooperation, it is hereby ordered as follows:

Section 1. Policy. [Executive Order 13563](#) of January 18, 2011 (Improving Regulation and Regulatory Review), states that our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. In an increasingly global economy, international regulatory cooperation, consistent with domestic law and prerogatives and U.S. trade policy, can be an important means of promoting the goals of [Executive Order 13563](#).

The regulatory approaches taken by foreign governments may differ from those taken by U.S. regulatory agencies to address similar issues. In some cases, the differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts might not be necessary and might impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

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Sec. 2. Coordination of International Regulatory Cooperation. (a) The Regulatory Working Group (Working Group) established by [Executive Order 12866](#) of September 30, 1993 (Regulatory Planning and Review), which was reaffirmed by [Executive Order 13563](#), shall, as appropriate:

(i) serve as a forum to discuss, coordinate, and develop a common understanding among agencies of U.S. Government positions and priorities with respect to:

(A) international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions;

(B) efforts across the Federal Government to support significant, cross-cutting international regulatory cooperation activities, such as the work of regulatory cooperation councils; and

(C) the promotion of good regulatory practices internationally, as well as the promotion of U.S. regulatory approaches, as appropriate; and

(ii) examine, among other things:

(A) appropriate strategies for engaging in the development of regulatory approaches through international regulatory cooperation, particularly in emerging technology areas, when consistent with section 1 of this order;

(B) best practices for international regulatory cooperation with respect to regulatory development, and, where appropriate, information exchange and other regulatory tools; and

(C) factors that agencies should take into account when determining whether and how to consider other regulatory approaches under section 3(d) of this order.

(b) As Chair of the Working Group, the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) shall convene the Working Group as necessary to discuss international regulatory cooperation issues as described above, and the Working Group shall include a representative from the Office of the United States Trade Representative and, as appropriate, representatives from other agencies and offices.

(c) The activities of the Working Group, consistent with law, shall not duplicate the efforts of existing interagency bodies and coordination mechanisms. The Working Group shall consult with existing interagency bodies when appropriate.

(d) To inform its discussions, and pursuant to section 4 of [Executive Order 12866](#), the Working Group may commission analytical reports and studies by OIRA, the Administrative Conference of the United States, or any other relevant agency, and the Administrator of OIRA may solicit input, from time to time, from representatives of business, nongovernmental organizations, and the public.

(e) The Working Group shall develop and issue guidelines on the applicability and implementation of sections 2 through 4 of this order.

(f) For purposes of this order, the Working Group shall operate by consensus.

Sec. 3. Responsibilities of Federal Agencies. To the extent permitted by law, and consistent with the principles and requirements of [Executive Order 13563](#) and [Executive Order 12866](#), each agency shall:

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- (a) if required to submit a [Regulatory Plan pursuant to Executive Order 12866](#), include in that plan a summary of its international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations, with an explanation of how these activities advance the purposes of [Executive Order 13563](#) and this order;
- (b) ensure that significant regulations that the agency identifies as having significant international impacts are designated as such in the Unified Agenda of Federal Regulatory and Deregulatory Actions, on RegInfo.gov, and on Regulations.gov;
- (c) in selecting which regulations to include in its retrospective review plan, as required by [Executive Order 13563](#), consider:
 - (i) reforms to existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners, consistent with section 1 of this order, when stakeholders provide adequate information to the agency establishing that the differences are unnecessary; and
 - (ii) such reforms in other circumstances as the agency deems appropriate; and
- (d) for significant regulations that the agency identifies as having significant international impacts, consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan.

Sec. 4. Definitions. For purposes of this order:

- (a) “Agency” means any authority of the United States that is an “agency” under [44 U.S.C. 3502\(1\)](#), other than those considered to be independent regulatory agencies, as defined in [44 U.S.C. 3502\(5\)](#).
- (b) “International impact” is a direct effect that a proposed or final regulation is expected to have on international trade and investment, or that otherwise may be of significant interest to the trading partners of the United States.
- (c) “International regulatory cooperation” refers to a bilateral, regional, or multilateral process, other than processes that are covered by section 6(a)(ii), (iii), and (v) of this order, in which national governments engage in various forms of collaboration and communication with respect to regulations, in particular a process that is reasonably anticipated to lead to the development of significant regulations.
- (d) “Regulation” shall have the same meaning as “regulation” or “rule” in section 3(d) of [Executive Order 12866](#).
- (e) “Significant regulation” is a proposed or final regulation that constitutes a significant regulatory action.
- (f) “Significant regulatory action” shall have the same meaning as in section 3(f) of [Executive Order 12866](#).

Sec. 5. Independent Agencies. Independent regulatory agencies are encouraged to comply with the provisions of this order.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to a department or agency, or the head thereof;
- (ii) the coordination and development of international trade policy and negotiations pursuant to section 411 of the Trade Agreements Act of 1979 ([19 U.S.C. 2451](#)) and section 141 of the Trade Act of 1974 ([19 U.S.C. 2171](#));

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(iii) international trade activities undertaken pursuant to section 3 of the Act of February 14, 1903 (15 U.S.C. 1512), subtitle C of the Export Enhancement Act of 1988, as amended (15 U.S.C. 4721 et seq.), and Reorganization Plan No. 3 of 1979 (19 U.S.C. 2171 note);

(iv) the authorization process for the negotiation and conclusion of international agreements pursuant to 1 U.S.C. 112b(c) and its implementing regulations (22 C.F.R. 181.4) and implementing procedures (11 FAM 720);

(v) activities in connection with subchapter II of chapter 53 of title 31 of the United States Code, title 26 of the United States Code, or Public Law 111-203 and other laws relating to financial regulation; or (vi) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13610

<May 10, 2012, 77 F.R. 28469>

Identifying and Reducing Regulatory Burdens

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to modernize our regulatory system and to reduce unjustified regulatory burdens and costs, it is hereby ordered as follows:

Section 1. Policy. Regulations play an indispensable role in protecting public health, welfare, safety, and our environment, but they can also impose significant burdens and costs. During challenging economic times, we should be especially careful not to impose unjustified regulatory requirements. For this reason, it is particularly important for agencies to conduct retrospective analyses of existing rules to examine whether they remain justified and whether they should be modified or streamlined in light of changed circumstances, including the rise of new technologies.

[Executive Order 13563](#) of January 18, 2011 (Improving Regulation and Regulatory Review), states that our regulatory system “must measure, and seek to improve, the actual results of regulatory requirements.” To promote this goal, that Executive Order requires agencies not merely to conduct a single exercise, but to engage in “periodic review of existing significant regulations.” Pursuant to section 6(b) of that Executive Order, agencies are required to develop retrospective review plans to review existing significant regulations in order to “determine whether any such regulations should be modified, streamlined, expanded, or repealed.” The purpose of this requirement is to “make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.”

In response to [Executive Order 13563](#), agencies have developed and made available for public comment retrospective review plans that identify over five hundred initiatives. A small fraction of those initiatives, already finalized or formally proposed to the public, are anticipated to eliminate billions of dollars in regulatory costs and tens of millions of hours in annual paperwork burdens. Significantly larger savings are anticipated as the plans are implemented and as action is taken on additional initiatives.

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As a matter of longstanding practice and to satisfy statutory obligations, many agencies engaged in periodic review of existing regulations prior to the issuance of [Executive Order 13563](#). But further steps should be taken, consistent with law, agency resources, and regulatory priorities, to promote public participation in retrospective review, to modernize our regulatory system, and to institutionalize regular assessment of significant regulations.

Sec. 2. Public Participation in Retrospective Review. Members of the public, including those directly and indirectly affected by regulations, as well as State, local, and tribal governments, have important information about the actual effects of existing regulations. For this reason, and consistent with [Executive Order 13563](#), agencies shall invite, on a regular basis (to be determined by the agency head in consultation with the Office of Information and Regulatory Affairs (OIRA)), public suggestions about regulations in need of retrospective review and about appropriate modifications to such regulations. To promote an open exchange of information, retrospective analyses of regulations, including supporting data, shall be released to the public online wherever practicable.

Sec. 3. Setting Priorities. In implementing and improving their retrospective review plans, and in considering retrospective review suggestions from the public, agencies shall give priority, consistent with law, to those initiatives that will produce significant quantifiable monetary savings or significant quantifiable reductions in paperwork burdens while protecting public health, welfare, safety, and our environment. To the extent practicable and permitted by law, agencies shall also give special consideration to initiatives that would reduce unjustified regulatory burdens or simplify or harmonize regulatory requirements imposed on small businesses. Consistent with [Executive Order 13563](#) and [Executive Order 12866](#) of September 30, 1993 (Regulatory Planning and Review), agencies shall give consideration to the cumulative effects of their own regulations, including cumulative burdens, and shall to the extent practicable and consistent with law give priority to reforms that would make significant progress in reducing those burdens while protecting public health, welfare, safety, and our environment.

Sec. 4. Accountability. Agencies shall regularly report on the status of their retrospective review efforts to OIRA. Agency reports should describe progress, anticipated accomplishments, and proposed timelines for relevant actions, with an emphasis on the priorities described in section 3 of this order. Agencies shall submit draft reports to OIRA on September 10, 2012, and on the second Monday of January and July for each year thereafter, unless directed otherwise through subsequent guidance from OIRA. Agencies shall make final reports available to the public within a reasonable period (not to exceed three weeks from the date of submission of draft reports to OIRA).

Sec. 5. General Provisions. (a) For purposes of this order, “agency” means any authority of the United States that is an “agency” under [44 U.S.C. 3502\(1\)](#), other than those considered to be independent regulatory agencies, as defined in [44 U.S.C. 3502\(5\)](#).

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to a department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13707

<Sept. 15, 2015, 80 F.R. 56365>

Using Behavioral Science Insights To Better Serve the American People

A growing body of evidence demonstrates that behavioral science insights_research findings from fields such as behavioral economics and psychology about how people make decisions and act on them_can be used to design government policies to better serve the American people.

Where Federal policies have been designed to reflect behavioral science insights, they have substantially improved outcomes for the individuals, families, communities, and businesses those policies serve. For example, automatic enrollment and automatic escalation in retirement savings plans have made it easier to save for the future, and have helped Americans accumulate billions of dollars in additional retirement savings. Similarly, streamlining the application process for Federal financial aid has made college more financially accessible for millions of students.

To more fully realize the benefits of behavioral insights and deliver better results at a lower cost for the American people, the Federal Government should design its policies and programs to reflect our best understanding of how people engage with, participate in, use, and respond to those policies and programs. By improving the effectiveness and efficiency of Government, behavioral science insights can support a range of national priorities, including helping workers to find better jobs; enabling Americans to lead longer, healthier lives; improving access to educational opportunities and support for success in school; and accelerating the transition to a low-carbon economy.

NOW, THEREFORE, by the authority vested in me as President by the Constitution and the laws of the United States, I hereby direct the following:

Section 1. Behavioral Science Insights Policy Directive.

(a) Executive departments and agencies (agencies) are encouraged to:

(i) identify policies, programs, and operations where applying behavioral science insights may yield substantial improvements in public welfare, program outcomes, and program cost effectiveness;

(ii) develop strategies for applying behavioral science insights to programs and, where possible, rigorously test and evaluate the impact of these insights;

(iii) recruit behavioral science experts to join the Federal Government as necessary to achieve the goals of this directive; and

(iv) strengthen agency relationships with the research community to better use empirical findings from the behavioral sciences.

(b) In implementing the policy directives in section (a), agencies shall:

(i) identify opportunities to help qualifying individuals, families, communities, and businesses access public programs and benefits by, as appropriate, streamlining processes that may otherwise limit or delay participation_for example, removing administrative hurdles, shortening wait times, and simplifying forms;

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(ii) improve how information is presented to consumers, borrowers, program beneficiaries, and other individuals, whether as directly conveyed by the agency, or in setting standards for the presentation of information, by considering how the content, format, timing, and medium by which information is conveyed affects comprehension and action by individuals, as appropriate;

(iii) identify programs that offer choices and carefully consider how the presentation and structure of those choices, including the order, number, and arrangement of options, can most effectively promote public welfare, as appropriate, giving particular consideration to the selection and setting of default options; and

(iv) review elements of their policies and programs that are designed to encourage or make it easier for Americans to take specific actions, such as saving for retirement or completing education programs. In doing so, agencies shall consider how the timing, frequency, presentation, and labeling of benefits, taxes, subsidies, and other incentives can more effectively and efficiently promote those actions, as appropriate. Particular attention should be paid to opportunities to use nonfinancial incentives.

(e) For policies with a regulatory component, agencies are encouraged to combine this behavioral science insights policy directive with their ongoing review of existing significant regulations to identify and reduce regulatory burdens, as appropriate and consistent with [Executive Order 13563](#) of January 18, 2011 (Improving Regulation and Regulatory Review), and [Executive Order 13610](#) of May 10, 2012 (Identifying and Reducing Regulatory Burdens).

Sec. 2. Implementation of the Behavioral Science Insights Policy Directive. (a) The Social and Behavioral Sciences Team (SBST), under the National Science and Technology Council (NSTC) and chaired by the Assistant to the President for Science and Technology, shall provide agencies with advice and policy guidance to help them execute the policy objectives outlined in section 1 of this order, as appropriate.

(b) The NSTC shall release a yearly report summarizing agency implementation of section 1 of this order each year until 2019. Member agencies of the SBST are expected to contribute to this report.

(c) To help execute the policy directive set forth in section 1 of this order, the Chair of the SBST shall, within 45 days of the date of this order and thereafter as necessary, issue guidance to assist agencies in implementing this order.

Sec. 3. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to a department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) Independent agencies are strongly encouraged to comply with the requirements of this order.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13725

<April 15, 2016, 81 F.R. 23417>

**Steps to Increase Competition and Better Inform Consumers and
Workers to Support Continued Growth of the American Economy**

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to protect American consumers and workers and encourage competition in the U.S. economy, it is hereby ordered as follows:

Section 1. Policy. Maintaining, encouraging, and supporting a fair, efficient, and competitive marketplace is a cornerstone of the American economy. Consumers and workers need both competitive markets and information to make informed choices.

Certain business practices such as unlawful collusion, illegal bid rigging, price fixing, and wage setting, as well as anticompetitive exclusionary conduct and mergers stifle competition and erode the foundation of America's economic vitality. The immediate results of such conduct—higher prices and poorer service for customers, less innovation, fewer new businesses being launched, and reduced opportunities for workers—can impact Americans in every walk of life.

Competitive markets also help advance national priorities, such as the delivery of affordable health care, energy independence, and improved access to fast and affordable broadband. Competitive markets also promote economic growth, which creates opportunity for American workers and encourages entrepreneurs to start innovative companies that create jobs.

The Department of Justice (DOJ) and the Federal Trade Commission (FTC) have a proven record of detecting and stopping anticompetitive conduct and challenging mergers and acquisitions that threaten to consolidate markets and reduce competition.

Promoting competitive markets and ensuring that consumers and workers have access to the information needed to make informed choices must be a shared priority across the Federal Government. Executive departments and agencies can contribute to these goals through, among other things, pro-competitive rulemaking and regulations, and by eliminating regulations that create barriers to or limit competition. Such Government-wide action is essential to ensuring that consumers, workers, startups, small businesses, and farms reap the full benefits of competitive markets.

Sec. 2. Agency Responsibilities. (a) Executive departments and agencies with authorities that could be used to enhance competition (agencies) shall, where consistent with other laws, use those authorities to promote competition, arm consumers and workers with the information they need to make informed choices, and eliminate regulations that restrict competition without corresponding benefits to the American public.

(b) Agencies shall identify specific actions that they can take in their areas of responsibility to build upon efforts to detect abuses such as price fixing, anticompetitive behavior in labor and other input markets, exclusionary conduct, and blocking access to critical resources that are needed for competitive entry. Behaviors that appear to violate our antitrust laws should be referred to antitrust enforcers at DOJ and the FTC. Such a referral shall not preclude further action by the referring agency against that behavior under that agency's relevant statutory authority.

(c) Agencies shall also identify specific actions that they can take in their areas of responsibility to address undue burdens on competition. As permitted by law, agencies shall consult with other interested parties to identify ways that the agency can promote competition through pro-competitive rulemaking and regulations, by providing consumers and workers with information they need to make informed choices, and by eliminating regulations that restrict competition without corresponding benefits to the American public.

(d) Not later than 30 days from the date of this order, agencies shall submit to the Director of the National Economic Council an initial list of (1) actions each agency can potentially take to promote more competitive markets; (2) any specific practices, such as blocking access to critical resources, that potentially restrict meaningful consumer or worker choice or unduly stifle new market

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entrants, along with any actions the agency can potentially take to address those practices; and (3) any relevant authorities and tools potentially available to enhance competition or make information more widely available for consumers and workers.

(e) Not later than 60 days from the date of this order, agencies shall report to the President, through the Director of the National Economic Council, recommendations on agency-specific actions that eliminate barriers to competition, promote greater competition, and improve consumer access to information needed to make informed purchasing decisions. Such recommendations shall include a list of priority actions, including rulemakings, as well as timelines for completing those actions.

(f) Subsequently, agencies shall report semi-annually to the President, through the Director of the National Economic Council, on additional actions that they plan to undertake to promote greater competition.

(g) Sections 2(d), 2(e), and 2(f) of this order do not require reporting of information related to law enforcement policy and activities.

Sec. 3. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Independent agencies are strongly encouraged to comply with the requirements of this order.

(c) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to a department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13748

<November 16, 2016, 81 F.R. 83619>

Establishing a Community Solutions Council

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Place is a strong determinant of opportunity and well-being. Research shows that the neighborhood in which a child grows up impacts his or her odds of going to college, enjoying good health, and obtaining a lifetime of economic opportunities. Even after 73 consecutive months of total job growth since 2009, communities of persistent poverty remain and for far too many, the odds are stacked against opportunity and achieving the American dream. In addition, between now and 2050, growing our economy, expected population growth, climate change, and demographic shifts will require major new investments in physical, social, and technological infrastructure.

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Specific challenges in communities—including crime, access to care, opportunities to pursue quality education, lack of housing options, unemployment, and deteriorating infrastructure—can be met by leveraging Federal assistance and resources. While the Federal Government provides rural, suburban, urban, and tribal communities with significant investments in aid annually, coordinating these investments, as appropriate, across agencies based on locally led visions can more effectively reach communities of greatest need to maximize impact. In recent years, the Federal Government has deepened its engagement with communities, recognizing the critical role of these partnerships in enabling Americans to live healthier and more prosperous lives. Since 2015, the Community Solutions Task Force, comprising executive departments, offices, and agencies (agencies) across the Federal Government, has served as the primary interagency coordinator of agency work to engage with communities to deliver improved outcomes. This order builds on recent work to facilitate inter-agency and community-level collaboration to meet the unique needs of communities in a way that reflects these communities' local assets, economies, geography, size, history, strengths, talent networks, and visions for the future.

Sec. 2. Principles. Our effort to modernize the Federal Government's work with communities is rooted in the following principles:

- (a) A community-driven, locally led vision and long-term plan for clear outcomes should guide individual projects.
- (b) The Federal Government should coordinate its efforts at the Federal, regional, State, local, tribal, and community level, and with cross-sector partners, to offer a more seamless process for communities to access needed support and ensure equitable investments.
- (c) The Federal Government should help communities identify, develop, and share local solutions, rely on data to determine what does and does not work, and harness technology and modern collaboration and engagement methods to help share these solutions and help communities meet their local goals.

Sec. 3. Community Solutions Council.

(a) **Establishment.** There is hereby established a Council for Community Solutions (Council), led by two Co-Chairs. One Co-Chair will be an Assistant to the President or the Director of the Office of Management and Budget, as designated by the President. The second Co-Chair will be rotated every 4 years and designated by the President from among the heads of the Departments of Justice, Agriculture, Commerce, Labor, Health and Human Services, Housing and Urban Development, Transportation, and Education, and the Environmental Protection Agency (Agency Co-Chair).

(b) **Membership.** The Council shall consist of the following members:

- (i) the Secretary of State;
- (ii) the Secretary of the Treasury;
- (iii) the Secretary of Defense;
- (iv) the Attorney General;
- (v) the Secretary of the Interior;
- (vi) the Secretary of Agriculture;
- (vii) the Secretary of Commerce;

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- (viii) the Secretary of Labor;
- (ix) the Secretary of Health and Human Services;
- (x) the Secretary of Housing and Urban Development;
- (xi) the Secretary of Transportation;
- (xii) the Secretary of Energy;
- (xiii) the Secretary of Education;
- (xiv) the Secretary of Veterans Affairs;
- (xv) the Secretary of Homeland Security;
- (xvi) the Administrator of the Environmental Protection Agency;
- (xvii) the Administrator of General Services;
- (xviii) the Administrator of the Small Business Administration;
- (xix) the Chief Executive Officer of the Corporation for National and Community Service;
- (xx) the Chairperson of the National Endowment for the Arts;
- (xxi) the Director of the Institute for Museum and Library Services;
- (xxii) the Federal Co-Chair of the Delta Regional Authority;
- (xxiii) the Federal Co-Chair of the Appalachian Regional Commission;
- (xxiv) the Director of the Office of Personnel Management;
- (xxv) the Director of the Office of Management and Budget;
- (xxvi) the Chair of the Council of Economic Advisers;
- (xxvii) the Assistant to the President for Intergovernmental Affairs and Public Engagement;
- (xxviii) the Assistant to the President and Cabinet Secretary;
- (xxix) the Assistant to the President for Economic Policy and Director of the National Economic Council;
- (xxx) the Chair of the Council on Environmental Quality;
- (xxxi) the Director of the Office of Science and Technology Policy;
- (xxxii) the Assistant to the President and Chief Technology Officer;

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(xxxiii) the Administrator of the United States Digital Service; and

(xxxiv) other officials, as the Co-Chairs may designate or invite to participate.

(c) Administration.

(i) The President will designate one of the Co-Chairs to appoint or designate, as appropriate, an Executive Director, who shall coordinate the Council's activities. The department, agency, or component within the Executive Office of the President in which the Executive Director is appointed or designated, as appropriate, (funding entity) shall provide funding and administrative support for the Council to the extent permitted by law and within existing appropriations as may be necessary for the performance of its functions.

(ii) To the extent permitted by law, including the Economy Act, and within existing appropriations, participating agencies may detail staff to the funding entity to support the Council's coordination and implementation efforts.

(iii) The Co-Chairs shall convene regular meetings of the Council, determine its agenda, and direct its work. At the direction of the Co-Chairs, the Council may establish subgroups consisting exclusively of Council members or their designees, as appropriate.

(iv) A member of the Council may designate a senior-level official who is part of the member's department, agency, or office to perform the Council functions of the member.

Sec. 4. Mission and Priorities of the Council. (a) The Council shall foster collaboration across agencies, policy councils, and offices to coordinate actions, identify working solutions to share broadly, and develop and implement policy recommendations that put the community-driven, locally led vision at the center of policymaking. The Council shall:

(i) Work across agencies to coordinate investments in initiatives and practices that align the work of the Federal Government to have the greatest impact on the lives of individuals and communities.

(ii) Use evidence-based practices in policymaking, including identifying existing solutions, scaling up practices that are working, and designing solutions with regular input of the individuals and communities to be served.

(iii) Invest in recruiting, training, and retaining talent to further the effective delivery of services to individuals and communities and empower them with best-practice community engagement options, open government transparency methods, equitable policy approaches, technical assistance and capacity building tools, and data-driven practice.

(b) Consistent with the principles set forth in this order and in accordance with applicable law, including the Federal Advisory Committee Act, the Council should conduct outreach to representatives of nonprofit organizations, civil rights organizations, businesses, labor and professional organizations, start-up and entrepreneurial communities, State, local, and tribal government agencies, school districts, youth, elected officials, seniors, faith and other community-based organizations, philanthropies, technologists, other institutions of local importance, and other interested or affected persons with relevant expertise in the expansion and improvement of efforts to build local capacity, ensure equity, and address economic, social, environmental, and other issues in communities or regions.

Sec. 5. Executive Orders 13560 and 13602, and Building Upon Other Efforts. This order supersedes Executive Order 13560 of December 14, 2010 (White House Council for Community Solutions), and Executive Order 13602 of March 15, 2012 (Establishing a White House Council on Strong Cities, Strong Communities), which are hereby revoked.

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This Council builds on existing efforts involving Federal working groups, task forces, memoranda of agreement, and initiatives, including the Community Solutions Task Force, the Federal Working Groups dedicated to supporting the needs and priorities of local leadership in Detroit, Baltimore, and Pine Ridge; the Interagency Working Group on Environmental Justice; the Partnership for Sustainable Communities; Local Foods, Local Places; Performance Partnership Pilots for Disconnected Youth; Empowerment Zones; StrikeForce; Partnerships for Opportunity and Workforce and Economic Revitalization; the Neighborhood Revitalization Initiative; Climate Action Champions; Better Communities Alliance; Investing in Manufacturing Communities Partnership; Promise Zones; and the 2016 Memorandum of Agreement on Interagency Technical Assistance. The Council shall also coordinate with existing Chief Officer Councils across the government with oversight responsibility for human capital, performance improvement, and financial assistance.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof, or the status of that department or agency within the Federal Government; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

EXECUTIVE ORDER NO. 13771

<January 30, 2017, 82 F.R. 9339>

Reducing Regulation and Controlling Regulatory Costs

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Budget and Accounting Act of 1921, as amended (31 U.S.C. 1101 *et seq.*), [section 1105 of title 31, United States Code](#), and [section 301 of title 3, United States Code](#), it is hereby ordered as follows:

Section 1. Purpose. It is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources. In addition to the management of the direct expenditure of taxpayer dollars through the budgeting process, it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations. Toward that end, it is important that for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.

Sec. 2. Regulatory Cap for Fiscal Year 2017. (a) Unless prohibited by law, whenever an executive department or agency (agency) publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed.

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(b) For fiscal year 2017, which is in progress, the heads of all agencies are directed that the total incremental cost of all new regulations, including repealed regulations, to be finalized this year shall be no greater than zero, unless otherwise required by law or consistent with advice provided in writing by the Director of the Office of Management and Budget (Director).

(c) In furtherance of the requirement of subsection (a) of this section, any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Any agency eliminating existing costs associated with prior regulations under this subsection shall do so in accordance with the Administrative Procedure Act and other applicable law.

(d) The Director shall provide the heads of agencies with guidance on the implementation of this section. Such guidance shall address, among other things, processes for standardizing the measurement and estimation of regulatory costs; standards for determining what qualifies as new and offsetting regulations; standards for determining the costs of existing regulations that are considered for elimination; processes for accounting for costs in different fiscal years; methods to oversee the issuance of rules with costs offset by savings at different times or different agencies; and emergencies and other circumstances that might justify individual waivers of the requirements of this section. The Director shall consider phasing in and updating these requirements.

Sec. 3. Annual Regulatory Cost Submissions to the Office of Management and Budget. (a) Beginning with the [Regulatory Plans \(required under Executive Order 12866](#) of September 30, 1993, as amended, or any successor order) for fiscal year 2018, and for each fiscal year thereafter, the head of each agency shall identify, for each regulation that increases incremental cost, the offsetting regulations described in section 2(c) of this order, and provide the agency's best approximation of the total costs or savings associated with each new regulation or repealed regulation.

(b) Each regulation approved by the Director during the Presidential budget process shall be included in the Unified [Regulatory Agenda required under Executive Order 12866](#), as amended, or any successor order.

(c) Unless otherwise required by law, no regulation shall be issued by an agency if it was not included on the most recent version or update of the published Unified Regulatory Agenda as required under [Executive Order 12866](#), as amended, or any successor order, unless the issuance of such regulation was approved in advance in writing by the Director.

(d) During the Presidential budget process, the Director shall identify to agencies a total amount of incremental costs that will be allowed for each agency in issuing new regulations and repealing regulations for the next fiscal year. No regulations exceeding the agency's total incremental cost allowance will be permitted in that fiscal year, unless required by law or approved in writing by the Director. The total incremental cost allowance may allow an increase or require a reduction in total regulatory cost.

(e) The Director shall provide the heads of agencies with guidance on the implementation of the requirements in this section.

Sec. 4. Definition. For purposes of this order the term “regulation” or “rule” means an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency, but does not include:

(a) regulations issued with respect to a military, national security, or foreign affairs function of the United States;

(b) regulations related to agency organization, management, or personnel; or

(c) any other category of regulations exempted by the Director.

Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

- (ii) the functions of the Director relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

EXECUTIVE ORDER NO. 13777

<February 24, 2017, 82 F.R. 12285>

Enforcing the Regulatory Reform Agenda

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to lower regulatory burdens on the American people by implementing and enforcing regulatory reform, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people.

Sec. 2. Regulatory Reform Officers. (a) Within 60 days of the date of this order, the head of each agency, except the heads of agencies receiving waivers under section 5 of this order, shall designate an agency official as its Regulatory Reform Officer (RRO). Each RRO shall oversee the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. These initiatives and policies include:

- (i) [Executive Order 13771](#) of January 30, 2017 (Reducing Regulation and Controlling Regulatory Costs), regarding offsetting the number and cost of new regulations;
- (ii) [Executive Order 12866](#) of September 30, 1993 (Regulatory Planning and Review), as amended, regarding regulatory planning and review;
- (iii) section 6 of [Executive Order 13563](#) of January 18, 2011 (Improving Regulation and Regulatory Review), regarding retrospective review; and
- (iv) the termination, consistent with applicable law, of programs and activities that derive from or implement Executive Orders, guidance documents, policy memoranda, rule interpretations, and similar documents, or relevant portions thereof, that have been rescinded.

(b) Each agency RRO shall periodically report to the agency head and regularly consult with agency leadership.

Sec. 3. Regulatory Reform Task Forces. (a) Each agency shall establish a Regulatory Reform Task Force composed of:

- (i) the agency RRO;
- (ii) the agency Regulatory Policy Officer designated under section 6(a)(2) of [Executive Order 12866](#);

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- (iii) a representative from the agency's central policy office or equivalent central office; and
- (iv) for agencies listed in [section 901\(b\)\(1\) of title 31, United States Code](#), at least three additional senior agency officials as determined by the agency head.
- (b) Unless otherwise designated by the agency head, the agency RRO shall chair the agency's Regulatory Reform Task Force.
- (c) Each entity staffed by officials of multiple agencies, such as the Chief Acquisition Officers Council, shall form a joint Regulatory Reform Task Force composed of at least one official described in subsection (a) of this section from each constituent agency's Regulatory Reform Task Force. Joint Regulatory Reform Task Forces shall implement this order in coordination with the Regulatory Reform Task Forces of their members' respective agencies.
- (d) Each Regulatory Reform Task Force shall evaluate existing regulations (as defined in section 4 of [Executive Order 13771](#)) and make recommendations to the agency head regarding their repeal, replacement, or modification, consistent with applicable law. At a minimum, each Regulatory Reform Task Force shall attempt to identify regulations that:
- (i) eliminate jobs, or inhibit job creation;
 - (ii) are outdated, unnecessary, or ineffective;
 - (iii) impose costs that exceed benefits;
 - (iv) create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
 - (v) are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 ([44 U.S.C. 3516](#) note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or
 - (vi) derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.
- (e) In performing the evaluation described in subsection (d) of this section, each Regulatory Reform Task Force shall seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal governments, small businesses, consumers, non-governmental organizations, and trade associations.
- (f) When implementing the regulatory offsets required by [Executive Order 13771](#), each agency head should prioritize, to the extent permitted by law, those regulations that the agency's Regulatory Reform Task Force has identified as being outdated, unnecessary, or ineffective pursuant to subsection (d)(ii) of this section.
- (g) Within 90 days of the date of this order, and on a schedule determined by the agency head thereafter, each Regulatory Reform Task Force shall provide a report to the agency head detailing the agency's progress toward the following goals:
- (i) improving implementation of regulatory reform initiatives and policies pursuant to section 2 of this order; and
 - (ii) identifying regulations for repeal, replacement, or modification.

Sec. 4. Accountability. Consistent with the policy set forth in section 1 of this order, each agency should measure its progress in performing the tasks outlined in section 3 of this order.

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(a) Agencies listed in [section 901\(b\)\(1\) of title 31, United States Code](#), shall incorporate in their annual performance plans (required under the Government Performance and Results Act, as amended (see [31 U.S.C. 1115\(b\)](#))), performance indicators that measure progress toward the two goals listed in section 3(g) of this order. Within 60 days of the date of this order, the Director of the Office of Management and Budget (Director) shall issue guidance regarding the implementation of this subsection. Such guidance may also address how agencies not otherwise covered under this subsection should be held accountable for compliance with this order.

(b) The head of each agency shall consider the progress toward the two goals listed in section 3(g) of this order in assessing the performance of the Regulatory Reform Task Force and, to the extent permitted by law, those individuals responsible for developing and issuing agency regulations.

Sec. 5. Waiver. Upon the request of an agency head, the Director may waive compliance with this order if the Director determines that the agency generally issues very few or no regulations (as defined in section 4 of [Executive Order 13771](#)). The Director may revoke a waiver at any time. The Director shall publish, at least once every 3 months, a list of agencies with current waivers.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

EXECUTIVE ORDER NO. 13828

<April 10, 2018, [83 F.R. 15941](#)>

Reducing Poverty in America by Promoting Opportunity and Economic Mobility

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to promote economic mobility, strong social networks, and accountability to American taxpayers, it is hereby ordered as follows:

Section 1. Purpose. The United States and its Constitution were founded on the principles of freedom and equal opportunity for all. To ensure that all Americans would be able to realize the benefits of those principles, especially during hard times, the Government established programs to help families with basic unmet needs. Unfortunately, many of the programs designed to help families have instead delayed economic independence, perpetuated poverty, and weakened family bonds. While bipartisan welfare reform enacted in 1996 was a step toward eliminating the economic stagnation and social harm that can result from long-term Government dependence, the welfare system still traps many recipients, especially children, in poverty and is in need of further reform and modernization in order to increase self-sufficiency, well-being, and economic mobility.

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Sec. 2. Policy. (a) In 2017, the Federal Government spent more than \$700 billion on low-income assistance. Since its inception, the welfare system has grown into a large bureaucracy that might be susceptible to measuring success by how many people are enrolled in a program rather than by how many have moved from poverty into financial independence. This is not the type of system that was envisioned when welfare programs were instituted in this country. The Federal Government's role is to clear paths to self-sufficiency, reserving public assistance programs for those who are truly in need. The Federal Government should do everything within its authority to empower individuals by providing opportunities for work, including by investing in Federal programs that are effective at moving people into the workforce and out of poverty. It must examine Federal policies and programs to ensure that they are consistent with principles that are central to the American spirit—work, free enterprise, and safeguarding human and economic resources. For those policies or programs that are not succeeding in those respects, it is our duty to either improve or eliminate them.

(b) It shall be the policy of the Federal Government to reform the welfare system of the United States so that it empowers people in a manner that is consistent with applicable law and the following principles, which shall be known as the Principles of Economic Mobility:

(i) Improve employment outcomes and economic independence (including by strengthening existing work requirements for work-capable people and introducing new work requirements when legally permissible);

(ii) Promote strong social networks as a way of sustainably escaping poverty (including through work and marriage);

(iii) Address the challenges of populations that may particularly struggle to find and maintain employment (including single parents, formerly incarcerated individuals, the homeless, substance abusers, individuals with disabilities, and disconnected youth);

(iv) Balance flexibility and accountability both to ensure that State, local, and tribal governments, and other institutions, may tailor their public assistance programs to the unique needs of their communities and to ensure that welfare services and administering agencies can be held accountable for achieving outcomes (including by designing and tracking measures that assess whether programs help people escape poverty);

(v) Reduce the size of bureaucracy and streamline services to promote the effective use of resources;

(vi) Reserve benefits for people with low incomes and limited assets;

(vii) Reduce wasteful spending by consolidating or eliminating Federal programs that are duplicative or ineffective;

(viii) Create a system by which the Federal Government remains updated on State, local, and tribal successes and failures, and facilitates access to that information so that other States and localities can benefit from it; and

(ix) Empower the private sector, as well as local communities, to develop and apply locally based solutions to poverty.

(c) As part of our pledge to increase opportunities for those in need, the Federal Government must first enforce work requirements that are required by law. It must also strengthen requirements that promote obtaining and maintaining employment in order to move people to independence. To support this focus on employment, the Federal Government should:

(i) review current federally funded workforce development programs. If more than one executive department or agency (agency) administers programs that are similar in scope or population served, they should be consolidated, to the extent permitted by law, into the agency that is best equipped to fulfill the expectations of the programs, while ineffective programs should be eliminated; and

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(ii) invest in effective workforce development programs and encourage, to the greatest extent possible, entities that have demonstrated success in equipping participants with skills necessary to obtain employment that enables them to financially support themselves and their families in today's economy.

(d) It is imperative to empower State, local, and tribal governments and private-sector entities to effectively administer and manage public assistance programs. Federal policies should allow local entities to develop and implement programs and strategies that are best for their respective communities. Specifically, policies should allow the private sector, including community and faith-based organizations, to create solutions that alleviate the need for welfare assistance, promote personal responsibility, and reduce reliance on government intervention and resources.

(i) To promote the proper scope and functioning of government, the Federal Government must afford State, local, and tribal governments the freedom to design and implement programs that better allocate limited resources to meet different community needs.

(ii) States and localities can use such flexibility to devise and evaluate innovative programs that serve diverse populations and families. States and localities can also model their own initiatives on the successful programs of others. To achieve the right balance, Federal leaders must continue to discuss opportunities to improve public assistance programs with State and local leaders, including our Nation's governors.

(e) The Federal Government owes it to Americans to use taxpayer dollars for their intended purposes. Relevant agencies should establish clear metrics that measure outcomes so that agencies administering public assistance programs can be held accountable. These metrics should include assessments of whether programs help individuals and families find employment, increase earnings, escape poverty, and avoid long-term dependence. Whenever possible, agencies should harmonize their metrics to facilitate easier cross-year programmatic comparisons and to encourage further integration of service delivery at the local level. Agencies should also adopt policies to ensure that only eligible persons receive benefits and enforce all relevant laws providing that aliens who are not otherwise qualified and eligible may not receive benefits.

(i) All entities that receive funds should be required to guarantee the integrity of the programs they administer. Technology and innovation should drive initiatives that increase program integrity and reduce fraud, waste, and abuse in the current system.

(ii) The Federal Government must support State, local, and tribal partners by investing in tools to combat payment errors and verify eligibility for program participants. It must also work alongside public and private partners to assist recipients of welfare assistance to maximize access to services and benefits that support paths to self-sufficiency.

Sec. 3. Review of Regulations and Guidance Documents. (a) The Secretaries of the Treasury, Agriculture, Commerce, Labor, Health and Human Services, Housing and Urban Development, Transportation, and Education (Secretaries) shall:

(i) review all regulations and guidance documents of their respective agencies relating to waivers, exemptions, or exceptions for public assistance program eligibility requirements to determine whether such documents are, to the extent permitted by law, consistent with the principles outlined in this order;

(ii) review any public assistance programs of their respective agencies that do not currently require work for receipt of benefits or services, and determine whether enforcement of a work requirement would be consistent with Federal law and the principles outlined in this order;

(iii) review any public assistance programs of their respective agencies that do currently require work for receipt of benefits or services, and determine whether the enforcement of such work requirements is consistent with Federal law and the principles outlined in this order;

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(iv) within 90 days of the date of this order, and based on the reviews required by this section, submit to the Director of the Office of Management and Budget and the Assistant to the President for Domestic Policy a list of recommended regulatory and policy changes and other actions to accomplish the principles outlined in this order; and

(v) not later than 90 days after submission of the recommendations required by section 3(a)(iv) of this order, and in consultation with the Director of the Office of Management and Budget and the Assistant to the President for Domestic Policy, take steps to implement the recommended administrative actions.

(b) Within 90 days of the date of this order, the Secretaries shall each submit a report to the President, through the Director of the Office of Management and Budget and the Assistant to the President for Domestic Policy, that:

(i) states how their respective agencies are complying with 8 U.S.C. 1611(a), which provides that an alien who is not a “qualified alien” as defined by 8 U.S.C. 1641 is, subject to certain statutorily defined exceptions, not eligible for any Federal public benefit as defined by 8 U.S.C. 1611(c);

(ii) provides a list of Federal benefit programs that their respective agencies administer that are restricted pursuant to 8 U.S.C. 1611; and

(iii) provides a list of Federal benefit programs that their respective agencies administer that are not restricted pursuant to 8 U.S.C. 1611.

Sec. 4. Definitions. For the purposes of this order:

(a) the terms “individuals,” “families,” and “persons” mean any United States citizen, lawful permanent resident, or other lawfully present alien who is qualified to or otherwise may receive public benefits;

(b) the terms “work” and “workforce” include unsubsidized employment, subsidized employment, job training, apprenticeships, career and technical education training, job searches, basic education, education directly related to current or future employment, and workfare; and

(c) the terms “welfare” and “public assistance” include any program that provides means-tested assistance, or other assistance that provides benefits to people, households, or families that have low incomes (i.e., those making less than twice the Federal poverty level), the unemployed, or those out of the labor force.

Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

EXECUTIVE ORDER NO. 13891

<October 9, 2019, 84 FR 55235>

Promoting the Rule of Law Through Improved Agency Guidance Documents

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations, it is hereby ordered as follows:

Section 1. Policy. Departments and agencies (agencies) in the executive branch adopt regulations that impose legally binding requirements on the public even though, in our constitutional democracy, only Congress is vested with the legislative power. The Administrative Procedure Act (APA) generally requires agencies, in exercising that solemn responsibility, to engage in notice-and-comment rulemaking to provide public notice of proposed regulations under [section 553 of title 5, United States Code](#), allow interested parties an opportunity to comment, consider and respond to significant comments, and publish final regulations in the Federal Register.

Agencies may clarify existing obligations through non-binding guidance documents, which the APA exempts from notice-and-comment requirements. Yet agencies have sometimes used this authority inappropriately in attempts to regulate the public without following the rulemaking procedures of the APA. Even when accompanied by a disclaimer that it is non-binding, a guidance document issued by an agency may carry the implicit threat of enforcement action if the regulated public does not comply. Moreover, the public frequently has insufficient notice of guidance documents, which are not always published in the Federal Register or distributed to all regulated parties.

Americans deserve an open and fair regulatory process that imposes new obligations on the public only when consistent with applicable law and after an agency follows appropriate procedures. Therefore, it is the policy of the executive branch, to the extent consistent with applicable law, to require that agencies treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract, take public input into account when appropriate in formulating guidance documents, and make guidance documents readily available to the public. Agencies may impose legally binding requirements on the public only through regulations and on parties on a case-by-case basis through adjudications, and only after appropriate process, except as authorized by law or as incorporated into a contract.

Sec. 2. Definitions. For the purposes of this order:

- (a) “Agency” has the meaning given in section 3(b) of [Executive Order 12866](#) (Regulatory Planning and Review), as amended.
- (b) “Guidance document” means an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation, but does not include the following:
 - (i) rules promulgated pursuant to notice and comment under [section 553 of title 5, United States Code](#), or similar statutory provisions;
 - (ii) rules exempt from rulemaking requirements under [section 553\(a\) of title 5, United States Code](#);
 - (iii) rules of agency organization, procedure, or practice;
 - (iv) decisions of agency adjudications under [section 554 of title 5, United States Code](#), or similar statutory provisions;

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(v) internal guidance directed to the issuing agency or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; or

(vi) internal executive branch legal advice or legal opinions addressed to executive branch officials.

(c) “Significant guidance document” means a guidance document that may reasonably be anticipated to:

(i) lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(ii) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(iii) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(iv) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of [Executive Order 12866](#).

(d) “Pre-enforcement ruling” means a formal written communication by an agency in response to an inquiry from a person concerning compliance with legal requirements that interprets the law or applies the law to a specific set of facts supplied by the person. The term includes informal guidance under section 213 of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121 (Title II), as amended, letter rulings, advisory opinions, and no-action letters.

Sec. 3. Ensuring Transparent Use of Guidance Documents. (a) Within 120 days of the date on which the Office of Management and Budget (OMB) issues an implementing memorandum under section 6 of this order, each agency or agency component, as appropriate, shall establish or maintain on its website a single, searchable, indexed database that contains or links to all guidance documents in effect from such agency or component. The website shall note that guidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.

(b) Within 120 days of the date on which OMB issues an implementing memorandum under section 6 of this order, each agency shall review its guidance documents and, consistent with applicable law, rescind those guidance documents that it determines should no longer be in effect. No agency shall retain in effect any guidance document without including it in the relevant database referred to in subsection (a) of this section, nor shall any agency, in the future, issue a guidance document without including it in the relevant database. No agency may cite, use, or rely on guidance documents that are rescinded, except to establish historical facts. Within 240 days of the date on which OMB issues an implementing memorandum, an agency may reinstate a guidance document rescinded under this subsection without complying with any procedures adopted or imposed pursuant to section 4 of this order, to the extent consistent with applicable law, and shall include the guidance document in the relevant database.

(c) The Director of OMB (Director), or the Director's designee, may waive compliance with subsections (a) and (b) of this section for particular guidance documents or categories of guidance documents, or extend the deadlines set forth in those subsections.

(d) As requested by the Director, within 240 days of the date on which OMB issues an implementing memorandum under section 6 of this order, an agency head shall submit a report to the Director with the reasons for maintaining in effect any guidance documents identified by the Director. The Director shall provide such reports to the President. This subsection shall apply only to guidance documents existing as of the date of this order.

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Sec. 4. Promulgation of Procedures for Issuing Guidance Documents. (a) Within 300 days of the date on which OMB issues an implementing memorandum under section 6 of this order, each agency shall, consistent with applicable law, finalize regulations, or amend existing regulations as necessary, to set forth processes and procedures for issuing guidance documents. The process set forth in each regulation shall be consistent with this order and shall include:

(i) a requirement that each guidance document clearly state that it does not bind the public, except as authorized by law or as incorporated into a contract;

(ii) procedures for the public to petition for withdrawal or modification of a particular guidance document, including a designation of the officials to which petitions should be directed; and

(iii) for a significant guidance document, as determined by the Administrator of OMB's Office of Information and Regulatory Affairs (Administrator), unless the agency and the Administrator agree that exigency, safety, health, or other compelling cause warrants an exemption from some or all requirements, provisions requiring:

(A) a period of public notice and comment of at least 30 days before issuance of a final guidance document, and a public response from the agency to major concerns raised in comments, except when the agency for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest;

(B) approval on a non-delegable basis by the agency head or by an agency component head appointed by the President, before issuance;

(C) review by the Office of Information and Regulatory Affairs (OIRA) under [Executive Order 12866](#), before issuance; and

(D) compliance with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in [Executive Orders 12866](#), [13563](#) (Improving Regulation and Regulatory Review), [13609](#) (Promoting International Regulatory Cooperation), [13771](#) (Reducing Regulation and Controlling Regulatory Costs), and [13777](#) (Enforcing the Regulatory Reform Agenda).

(b) The Administrator shall issue memoranda establishing exceptions from this order for categories of guidance documents, and categorical presumptions regarding whether guidance documents are significant, as appropriate, and may require submission of significant guidance documents to OIRA for review before the finalization of agency regulations under subsection (a) of this section. In light of the Memorandum of Agreement of April 11, 2018, this section and section 5 of this order shall not apply to the review relationship (including significance determinations) between OIRA and any component of the Department of the Treasury, or to compliance by the latter with [Executive Orders 12866](#), [13563](#), [13609](#), [13771](#), and [13777](#). Section 4(a)(iii) and section 5 of this order shall not apply to pre-enforcement rulings.

Sec. 5. Executive Orders 12866, 13563, and 13609. The requirements and procedures of [Executive Orders 12866](#), [13563](#), and [13609](#) shall apply to guidance documents, consistent with section 4 of this order.

Sec. 6. Implementation. The Director shall issue memoranda and, as appropriate, regulations pursuant to [sections 3504\(d\)\(1\)](#) and [3516 of title 44, United States Code](#), and other appropriate authority, to provide guidance regarding or otherwise implement this order.

Sec. 7. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

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(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) Notwithstanding any other provision in this order, nothing in this order shall apply:

(i) to any action that pertains to foreign or military affairs, or to a national security or homeland security function of the United States (other than guidance documents involving procurement or the import or export of non-defense articles and services);

(ii) to any action related to a criminal investigation or prosecution, including undercover operations, or any civil enforcement action or related investigation by the Department of Justice, including any action related to a civil investigative demand under [18 U.S.C. 1968](#);

(iii) to any investigation of misconduct by an agency employee or any disciplinary, corrective, or employment action taken against an agency employee;

(iv) to any document or information that is exempt from disclosure under [section 552\(b\) of title 5, United States Code](#) (commonly known as the Freedom of Information Act); or

(v) in any other circumstance or proceeding to which application of this order, or any part of this order, would, in the judgment of the head of the agency, undermine the national security.

DONALD J. TRUMP

EXECUTIVE ORDER NO. 13893

<October 10, 2019, [84 FR 55487](#)>

Increasing Government Accountability for Administrative Actions by Reinvigorating Administrative PAYGO

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. In May 2005, the Office of Management and Budget (OMB) implemented a budget-neutrality requirement on executive branch administrative actions affecting mandatory spending. This mechanism, commonly referred to as “Administrative pay-as-you-go” (Administrative PAYGO), requires each executive department and agency (agency) to include one or more proposals for reducing mandatory spending whenever an agency proposes to undertake a discretionary administrative action that would increase mandatory spending.

In practice, however, agencies have applied this requirement with varying degrees of stringency, sometimes resulting in higher mandatory spending. Accordingly, institutionalizing and reinvigorating Administrative PAYGO through this order is a prudent approach to keeping mandatory spending under control.

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Sec. 2. Policy. It is the policy of the executive branch to control Federal spending and restore the Nation's fiscal security. This policy includes ensuring that agencies consider the costs of their administrative actions, take steps to offset those costs, and curtail costly administrative actions.

Sec. 3. Definitions. For the purposes of this order:

(a) the term “discretionary administrative action” means any administrative action that is not required by statute and that would impact mandatory spending, including, but not limited to, the issuance of any agency rule, demonstration, program notice, or guidance; and

(b) the term “increase” in the context of mandatory spending means an increase relative to the projection in the most recent President's Budget, as described in [31 U.S.C. 1105](#), or Mid-Session Review, as described in [31 U.S.C. 1106](#), of what is required, under current law, to fund the mandatory-spending program.

Sec. 4. Scope. This order applies to discretionary administrative actions undertaken by agencies. If an agency determines that a proposed administrative action that would increase mandatory spending is required by statute and therefore is not a discretionary administrative action, the agency's general counsel shall provide a written opinion to the Director of OMB (Director) explaining that legal conclusion, and the agency shall consult with OMB prior to taking further action.

Sec. 5. Agency Proposal Requirements. (a) Before an agency may undertake any discretionary administrative action, the head of the agency shall submit the proposed discretionary administrative action to the Director for review. Such submission shall include an estimate of the budgetary effects of such action.

(b) If an agency's proposed discretionary administrative action would increase mandatory spending, the agency head's submission under subsection (a) of this section shall include a proposal to undertake other administrative action(s) that would comparably reduce mandatory spending. Submissions to increase mandatory spending that do not include a proposal to offset such increased spending shall be returned to the agency for reconsideration. The Director shall have the discretion to determine whether a proposed offset in mandatory spending is comparable to the relevant increase in mandatory spending, taking into account the magnitude of the offset and the increase and any other factors the Director deems appropriate.

Sec. 6. Issuance of Administrative PAYGO Guidance and Revocation of OMB PAYGO Memorandum. Within 90 days of the date of this order, the Director shall issue instructions regarding the implementation of this order, including how agency administrative action proposals that increase mandatory spending and non-tax receipts will be evaluated. In addition, within 90 days of the date of this order, the Director shall revoke OMB Memorandum M-05-13.

Sec. 7. Waiver. The Director may waive the requirements of section 5 of this order when the Director concludes that such a waiver is necessary for the delivery of essential services, for effective program delivery, or because a waiver is otherwise warranted by the public interest.

Sec. 8. Flexibility for the Director of OMB to Pursue Additional Deficit Reduction. The Director may pursue additional deficit reduction through agency administrative actions.

Sec. 9. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

**MEMORANDA OF PRESIDENT
PRESIDENTIAL MEMORANDUM**

<Apr. 21, 1995, [60 F.R. 20621](#)>

Regulatory Reform--Waiver of Penalties and Reduction of Reports

Memorandum for

The Secretary of State

The Secretary of the Treasury

The Secretary of Defense

The Attorney General

The Secretary of the Interior

The Secretary of Agriculture

The Secretary of Commerce

The Secretary of Labor

The Secretary of Health and Human Services

The Secretary of Housing and Urban Development

The Secretary of Transportation

The Secretary of Energy

The Secretary of Education

The Secretary of Veterans Affairs

The Administrator, Environmental Protection Agency

The Administrator, Small Business Administration

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The Secretary of the Army

The Secretary of the Navy

The Secretary of the Air Force

The Director, Federal Emergency Management Agency

The Administrator, National Aeronautics and Space Administration

The Director, National Science Foundation

The Acting Archivist of the United States

The Administrator of General Services

The Chair, Railroad Retirement Board

The Chairperson, Architectural and Transportation Barriers Compliance Board

The Executive Director, Pension Benefit Guaranty Corporation

On March 16, I announced that the Administration would implement new policies to give compliance officials more flexibility in dealing with small business and to cut back on paperwork. These Governmentwide policies, as well as the specific agency actions I announced, are part of this Administration's continuing commitment to sensible regulatory reform. With your help and cooperation, we hope to move the Government toward a more flexible, effective, and user friendly approach to regulation.

A. Actions: This memorandum directs the designated department and agency heads to implement the policies set forth below.

1. Authority to Waive Penalties. (a) To the extent permitted by law, each agency shall use its discretion to modify the penalties for small businesses in the following situations. Agencies shall exercise their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within a time period appropriate to the violation in question. For those violations that may take longer to correct than the period set by the agency, the agency shall use its enforcement discretion to waive up to 100 percent of the financial penalties if the amounts waived are used to bring the entity into compliance. The provisions in paragraph 1(a) of this memorandum shall apply only where there has been a good faith effort to comply with applicable regulations and the violation does not involve criminal wrongdoing or significant threat to health, safety, or the environment.

(b) Each agency shall, by June 15, 1995, submit a plan to the Director of the Office of Management and Budget ("Director") describing the actions it will take to implement the policies in paragraph 1(a) of this memorandum. The plan shall provide that the agency will implement the policies described in paragraph 1(a) of this memorandum on or before July 14, 1995. Plans should include information on how notification will be given to frontline workers and small businesses.

2. Cutting Frequency of Reports. (a) Each agency shall reduce by one-half the frequency of the regularly scheduled reports that the public is required, by rule or by policy, to provide to the Government (from quarterly to semiannually, from semiannually to annually, etc.), unless the department or agency head determines that such action is not legally permissible; would not adequately protect health, safety, or the environment; would be inconsistent with achieving regulatory flexibility or reducing regulatory burdens; or would impede the effective administration of the agency's program. The duty to make such determinations shall be nondelegable.

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(b) Each agency shall, by June 15, 1995, submit a plan to the Director describing the actions it will take to implement the policies in paragraph 2(a), including a copy of any determination that certain reports are excluded.

B. Application and Scope: 1. The Director may issue further guidance as necessary to carry out the purposes of this memorandum.

2. This memorandum does not apply to matters related to law enforcement, national security, or foreign affairs, the importation or exportation of prohibited or restricted items, Government taxes, duties, fees, revenues, or receipts; nor does it apply to agencies (or components thereof) whose principal purpose is the collection, analysis, and dissemination of statistical information.

3. This memorandum is not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees.

4. The Director of the Office of Management and Budget is authorized and directed to publish this memorandum in the Federal Register.

WILLIAM J. CLINTON

[References to the Director of the Federal Emergency Management Agency to be considered to refer and apply to the Administrator of the Federal Emergency Management Agency, see section 612(c) of Pub.L. 109-295, set out as a note under [6 U.S.C.A. § 313](#).]

PRESIDENTIAL MEMORANDUM

<June 1, 1998, [63 F.R. 31885](#)>

Plain Language in Government Writing

Memorandum for the Heads of Executive Departments and Agencies

The Vice President and I have made reinventing the Federal Government a top priority of my Administration. We are determined to make the Government more responsive, accessible, and understandable in its communications with the public.

The Federal Government's writing must be in plain language. By using plain language, we send a clear message about what the Government is doing, what it requires, and what services it offers. Plain language saves the Government and the private sector time, effort, and money.

Plain language requirements vary from one document to another, depending on the intended audience. Plain language documents have logical organization, easy-to-read design features, and use:

- common, everyday words, except for necessary technical terms;
- “you” and other pronouns;
- the active voice; and
- short sentences.

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To ensure the use of plain language, I direct you to do the following:

- By October 1, 1998, use plain language in all new documents, other than regulations, that explain how to obtain a benefit or service or how to comply with a requirement you administer or enforce. For example, these documents may include letters, forms, notices, and instructions. By January 1, 2002, all such documents created prior to October 1, 1998, must also be in plain language.
- By January 1, 1999, use plain language in all proposed and final rulemaking documents published in the Federal Register, unless you proposed the rule before that date. You should consider rewriting existing regulations in plain language when you have the opportunity and resources to do so.

The National Partnership for Reinventing Government will issue guidance to help you comply with these directives and to explain more fully the elements of plain language. You should also use customer feedback and common sense to guide your plain language efforts.

I ask the independent agencies to comply with these directives.

This memorandum does not confer any right or benefit enforceable by law against the United States or its representatives. The Director of the Office of Management and Budget will publish this memorandum in the Federal Register.

WILLIAM J. CLINTON

PRESIDENTIAL MEMORANDUM

<May 20, 2009, [74 F.R. 24693](#)>

Preemption

Memorandum for the Heads of Executive Departments and Agencies

From our Nation's founding, the American constitutional order has been a Federal system, ensuring a strong role for both the national Government and the States. The Federal Government's role in promoting the general welfare and guarding individual liberties is critical, but State law and national law often operate concurrently to provide independent safeguards for the public. Throughout our history, State and local governments have frequently protected health, safety, and the environment more aggressively than has the national Government.

An understanding of the important role of State governments in our Federal system is reflected in longstanding practices by executive departments and agencies, which have shown respect for the traditional prerogatives of the States. In recent years, however, notwithstanding [Executive Order 13132](#) of August 4, 1999 (Federalism), executive departments and agencies have sometimes announced that their regulations preempt State law, including State common law, without explicit preemption by the Congress or an otherwise sufficient basis under applicable legal principles.

The purpose of this memorandum is to state the general policy of my Administration that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption. Executive departments and agencies should be mindful that in our Federal system, the citizens of the several States have distinctive circumstances and values, and that in many instances it is appropriate for them to apply to themselves rules and principles that reflect these circumstances and values. As Justice Brandeis explained more than

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70 years ago, “[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”

To ensure that executive departments and agencies include statements of preemption in regulations only when such statements have a sufficient legal basis:

1. Heads of departments and agencies should not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation.
2. Heads of departments and agencies should not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in [Executive Order 13132](#).
3. Heads of departments and agencies should review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption. Where the head of a department or agency determines that a regulatory statement of preemption or codified regulatory provision cannot be so justified, the head of that department or agency should initiate appropriate action, which may include amendment of the relevant regulation.

Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory authorities. Heads of departments and agencies should consult as necessary with the Attorney General and the Office of Management and Budget's Office of Information and Regulatory Affairs to determine how the requirements of this memorandum apply to particular situations.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

The Director of the Office of Management and Budget is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

PRESIDENTIAL MEMORANDUM

<Jan. 18, 2011, [76 F.R. 3825](#)>

Regulatory Compliance

Memorandum for the Heads of Executive Departments and Agencies

My Administration is committed to enhancing effectiveness and efficiency in Government. Pursuant to the Memorandum on Transparency and Open Government, issued on January 21, 2009, executive departments and agencies (agencies) have been working steadily to promote accountability, encourage collaboration, and provide information to Americans about their Government's activities.

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To that end, much progress has been made toward strengthening our democracy and improving how Government operates. In the regulatory area, several agencies, such as the Department of Labor and the Environmental Protection Agency, have begun to post online (at ogesdw.dol.gov and www.epa-echo.gov), and to make readily accessible to the public, information concerning their regulatory compliance and enforcement activities, such as information with respect to administrative inspections, examinations, reviews, warnings, citations, and revocations (but excluding law enforcement or otherwise sensitive information about ongoing enforcement actions).

Greater disclosure of regulatory compliance information fosters fair and consistent enforcement of important regulatory obligations. Such disclosure is a critical step in encouraging the public to hold the Government and regulated entities accountable. Sound regulatory enforcement promotes the welfare of Americans in many ways, by increasing public safety, improving working conditions, and protecting the air we breathe and the water we drink. Consistent regulatory enforcement also levels the playing field among regulated entities, ensuring that those that fail to comply with the law do not have an unfair advantage over their law-abiding competitors. Greater agency disclosure of compliance and enforcement data will provide Americans with information they need to make informed decisions. Such disclosure can lead the Government to hold itself more accountable, encouraging agencies to identify and address enforcement gaps.

Accordingly, I direct the following:

First, agencies with broad regulatory compliance and administrative enforcement responsibilities, within 120 days of this memorandum, to the extent feasible and permitted by law, shall develop plans to make public information concerning their regulatory compliance and enforcement activities accessible, downloadable, and searchable online. In so doing, agencies should prioritize making accessible information that is most useful to the general public and should consider the use of new technologies to allow the public to have access to real-time data. The independent agencies are encouraged to comply with this directive.

Second, the Federal Chief Information Officer and the Chief Technology Officer shall work with appropriate counterparts in each agency to make such data available online in searchable form, including on centralized platforms such as data.gov, in a manner that facilitates easy access, encourages cross-agency comparisons, and engages the public in new and creative ways of using the information.

Third, the Federal Chief Information Officer and the Chief Technology Officer, in coordination with the Director of the Office of Management and Budget (OMB) and their counterparts in each agency, shall work to explore how best to generate and share enforcement and compliance information across the Government, consistent with law. Such data sharing can assist with agencies' risk-based approaches to enforcement: A lack of compliance in one area by a regulated entity may indicate a need for examination and closer attention by another agency. Efforts to share data across agencies, where appropriate and permitted by law, may help to promote flexible and coordinated enforcement regimes.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Nothing in this memorandum shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

The Director of OMB is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

PRESIDENTIAL MEMORANDUM

<Jan. 21, 2011, [76 F.R. 3827](#)>

Regulatory Flexibility, Small Business, and Job Creation

Memorandum for the Heads of Executive Departments and Agencies

Small businesses play an essential role in the American economy; they help to fuel productivity, economic growth, and job creation. More than half of all Americans working in the private sector either are employed by a small business or own one. During a recent 15-year period, small businesses created more than 60 percent of all new jobs in the Nation.

Although small businesses and new companies provide the foundations for economic growth and job creation, they have faced severe challenges as a result of the recession. One consequence has been the loss of significant numbers of jobs.

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, establishes a deep national commitment to achieving statutory goals without imposing unnecessary burdens on the public. The RFA emphasizes the importance of recognizing “differences in the scale and resources of regulated entities” and of considering “alternative regulatory approaches . . . which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions.” 5 U.S.C. 601 note.

To promote its central goals, the RFA imposes a series of requirements designed to ensure that agencies produce regulatory flexibility analyses that give careful consideration to the effects of their regulations on small businesses and explore significant alternatives in order to minimize any significant economic impact on small businesses. Among other things, the RFA requires that when an agency proposing a rule with such impact is required to provide notice of the proposed rule, it must also produce an initial regulatory flexibility analysis that includes discussion of significant alternatives. Significant alternatives include the use of performance rather than design standards; simplification of compliance and reporting requirements for small businesses; establishment of different timetables that take into account the resources of small businesses; and exemption from coverage for small businesses.

Consistent with the goal of open government, the RFA also encourages public participation in and transparency about the rulemaking process. Among other things, the statute requires agencies proposing rules with a significant economic impact on small businesses to provide an opportunity for public comment on any required initial regulatory flexibility analysis, and generally requires agencies promulgating final rules with such significant economic impact to respond, in a final regulatory flexibility analysis, to comments filed by the Chief Counsel for Advocacy of the Small Business Administration.

In the current economic environment, it is especially important for agencies to design regulations in a cost-effective manner consistent with the goals of promoting economic growth, innovation, competitiveness, and job creation.

Accordingly, I hereby direct executive departments and agencies and request independent agencies, when initiating rulemaking that will have a significant economic impact on a substantial number of small entities, to give serious consideration to whether and how it is appropriate, consistent with law and regulatory objectives, to reduce regulatory burdens on small businesses, through increased flexibility. As the RFA recognizes, such flexibility may take many forms, including:

- extended compliance dates that take into account the resources available to small entities;
- performance standards rather than design standards;
- simplification of reporting and compliance requirements (as, for example, through streamlined forms and electronic filing options);
- different requirements for large and small firms; and

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- partial or total exemptions.

I further direct that whenever an executive agency chooses, for reasons other than legal limitations, not to provide such flexibility in a proposed or final rule that is likely to have a significant economic impact on a substantial number of small entities, it should explicitly justify its decision not to do so in the explanation that accompanies that proposed or final rule.

Adherence to these requirements is designed to ensure that regulatory actions do not place unjustified economic burdens on small business owners and other small entities. If regulations are preceded by careful analysis, and subjected to public comment, they are less likely to be based on intuition and guesswork and more likely to be justified in light of a clear understanding of the likely consequences of alternative courses of action. With that understanding, agencies will be in a better position to protect the public while avoiding excessive costs and paperwork.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Nothing in this memorandum shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

The Director of the Office of Management and Budget is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

PRESIDENTIAL MEMORANDUM

<May 17, 2013, [78 F.R. 30733](#)>

Modernizing Federal Infrastructure Review and Permitting Regulations, Policies, and Procedures

Memorandum for the Heads of Executive Departments and Agencies

Reliable, safe, and resilient infrastructure is the backbone of an economy built to last. Investing in our Nation's infrastructure serves as an engine for job creation and economic growth, while bringing immediate and long-term economic benefits to communities across the country. The quality of our infrastructure is critical to maintaining our Nation's competitive edge in a global economy and to securing our path to energy independence. In taking steps to improve our infrastructure, we must remember that the protection and continued enjoyment of our Nation's environmental, historical, and cultural resources remain an equally important driver of economic opportunity, resiliency, and quality of life.

Through the implementation of [Executive Order 13604](#) of March 22, 2012 (Improving Performance of Federal Permitting and Review of Infrastructure Projects), executive departments and agencies (agencies) have achieved better outcomes for communities and the environment and realized substantial time savings in review and permitting by prioritizing the deployment of resources to specific sectors and projects, and by implementing best-management practices.

These best-management practices include: integrating project reviews among agencies with permitting responsibilities; ensuring early coordination with other Federal agencies, as well as with State, local, and tribal governments; strategically engaging with, and conducting outreach to, stakeholders; employing project-planning processes and individual project designs that consider local and regional ecological planning goals; utilizing landscape-and watershed-level mitigation practices; promoting the sharing of scientific and environmental data in open-data formats to minimize redundancy, facilitate informed project planning, and identify data gaps early in the review and permitting process; promoting performance-based permitting and

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regulatory approaches; expanding the use of general permits where appropriate; improving transparency and accountability through the electronic tracking of review and permitting schedules; and applying best environmental and cultural practices as set forth in existing statutes and policies.

Based on the process and policy improvements that are already being implemented across the Federal Government, we can continue to modernize the Federal Government's review and permitting of infrastructure projects and reduce aggregate timelines for major infrastructure projects by half, while also improving outcomes for communities and the environment by institutionalizing these best-management practices, and by making additional improvements to enhance efficiencies in the application of regulations and processes involving multiple agencies--including expanding the use of web-based techniques for sharing project-related information, facilitating targeted and relevant environmental reviews, and providing meaningful opportunities for public input through stakeholder engagement.

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to advance the goal of cutting aggregate timelines for major infrastructure projects in half, while also improving outcomes for communities and the environment, I hereby direct the following:

Section 1. Modernization of Review and Permitting Regulations, Policies, and Procedures. (a) The Steering Committee on [Federal Infrastructure Permitting and Review Process Improvement \(Steering Committee\)](#), established by [Executive Order 13604](#), shall work with the Chief Performance Officer (CPO), in coordination with the Office of Information and Regulatory Affairs (OIRA) and the Council on Environmental Quality (CEQ), to modernize Federal infrastructure review and permitting regulations, policies, and procedures to significantly reduce the aggregate time required by the Federal Government to make decisions in the review and permitting of infrastructure projects, while improving environmental and community outcomes.

This modernization shall build upon and incorporate reforms identified by agencies pursuant to [Executive Order 13604](#) and [Executive Order 13563](#) of January 18, 2011 (Improving Regulation and Regulatory Review).

(b) Through an interagency process, coordinated by the CPO and working closely with CEQ and OIRA, the Steering Committee shall conduct the following modernization efforts:

(i) Within 60 days of the date of this memorandum, the Steering Committee shall identify and prioritize opportunities to modernize key regulations, policies, and procedures--both agency-specific and those involving multiple agencies--to reduce the aggregate project review and permitting time, while improving environmental and community outcomes.

(ii) Within 120 days of the date of this memorandum, the Steering Committee shall prepare a plan for a comprehensive modernization of Federal review and permitting for infrastructure projects based on the analysis required by subsection (b)(i) of this section that outlines specific steps for re-engineering both the intra-and inter-agency review and approval processes based on experience implementing [Executive Order 13604](#). The plan shall identify proposed actions and associated timelines to:

(1) institutionalize or expand best practices or process improvements that agencies are already implementing to improve the efficiency of reviews, while improving outcomes for communities and the environment;

(2) revise key review and permitting regulations, policies, and procedures (both agency-specific and Government-wide);

(3) identify high-performance attributes of infrastructure projects that demonstrate how the projects seek to advance existing statutory and policy objectives and how they lead to improved outcomes for communities and the environment, thereby facilitating a faster and more efficient review and permitting process;

(4) create process efficiencies, including additional use of concurrent and integrated reviews;

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- (5) identify opportunities to use existing share-in-cost authorities and other non-appropriated funding sources to support early coordination and project review;
- (6) effectively engage the public and interested stakeholders;
- (7) expand coordination with State, local, and tribal governments;
- (8) strategically expand the use of information technology (IT) tools and identify priority areas for IT investment to replace paperwork processes, enhance effective project siting decisions, enhance interagency collaboration, and improve the monitoring of project impacts and mitigation commitments; and
- (9) identify improvements to mitigation policies to provide project developers with added predictability, facilitate landscape-scale mitigation based on conservation plans and regional environmental assessments, facilitate interagency mitigation plans where appropriate, ensure accountability and the long-term effectiveness of mitigation activities, and utilize innovative mechanisms where appropriate.

The modernization plan prepared pursuant to this section shall take into account funding and resource constraints and shall prioritize implementation accordingly.

(c) Infrastructure sectors covered by the modernization effort include: surface transportation, such as roadways, bridges, railroads, and transit; aviation; ports and related infrastructure, including navigational channels; water resources projects; renewable energy generation; conventional energy production in high-demand areas; electricity transmission; broadband; pipelines; storm water infrastructure; and other sectors as determined by the Steering Committee.

(d) The following agencies or offices and their relevant sub-divisions shall engage in the modernization effort:

- (i) the Department of Defense;
- (ii) the Department of the Interior;
- (iii) the Department of Agriculture;
- (iv) the Department of Commerce;
- (v) the Department of Transportation;
- (vi) the Department of Energy;
- (vii) the Department of Homeland Security;
- (viii) the Environmental Protection Agency;
- (ix) the Advisory Council on Historic Preservation;
- (x) the Department of the Army;
- (xi) the Council on Environmental Quality; and
- (xii) such other agencies or offices as the CPO may invite to participate.

Sec. 2. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department, agency, or the head thereof; or
 - (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals, or the regulatory review process.
- (b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This memorandum shall be implemented consistent with [Executive Order 12898](#) of February 11, 1994 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations), [Executive Order 13175](#) of November 6, 2000 (Consultation and Coordination with Indian Tribal Governments), and my memorandum of November 5, 2009 (Tribal Consultation).
- (d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.
- (e) The Director of the Office of Management and Budget is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

PRESIDENTIAL MEMORANDUM

<January 16, 2015, [80 F.R. 3455](#)>

Expanding Federal Support for Predevelopment Activities for Nonfederal Domestic Infrastructure Assets

Memorandum for the Heads of Executive Departments and Agencies

The United States is significantly underinvesting in both the maintenance of existing public infrastructure and the development of new infrastructure projects. While there is no replacement for adequate public funding, innovative financing options and increased collaboration between the private and public sectors can help to increase overall investment in infrastructure.

However, a major challenge for innovative infrastructure projects, whether using emerging technologies or alternative financing, is the lack of funding for the phases of infrastructure project development that precede actual construction. Infrastructure projects require upfront costs, commonly known as “predevelopment” costs, for activities such as project and system planning, economic impact analyses, preliminary engineering assessments, and environmental review. Although only accounting for a small percentage of total costs, predevelopment activities have considerable influence on which projects will move forward, where and how they will be built, who will fund them, and who will benefit from them. Yet, in light of factors like fiscal constraints, the extent of overall needs, and risk aversion, State, local, and tribal governments tend to focus scarce resources on constructing and developing conventional projects and addressing their most critical infrastructure needs, thereby underinvesting in predevelopment.

Greater attention to the predevelopment phase could yield a range of benefits-- for example, providing the opportunity to develop longer-term, more innovative, and more complex infrastructure projects and facilitating assessment of a range of financing

§ 601. Definitions, 5 USCA § 601

approaches, including public-private partnerships. Additional investment in predevelopment costs also may enable State, local, and tribal governments to utilize innovations in infrastructure design and emerging technologies, reduce long-term costs to infrastructure project users, and provide other benefits, such as improved environmental performance and enhanced resilience to climate change.

The Federal Government can meaningfully expand opportunities for public-private collaboration, encourage more transformational projects, and improve project outcomes by encouraging Federal investment in robust predevelopment activities and providing other forms of support, such as technical assistance, to communities during the predevelopment phase.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

Section 1. Policy. It shall be the policy of the Federal Government for all executive departments and agencies (agencies) that provide grants, technical assistance, and other forms of support for nonfederal domestic infrastructure assets, or regulate the development of these infrastructure assets, to actively support nonfederal predevelopment activities with all available tools, including grants, technical assistance, and regulatory changes, to the extent permitted by law and consistent with agency mission. Agencies shall seek to make predevelopment funding and support available, as permitted by law and consistent with agency mission and where it is in the public interest and does not supplant existing public investment, to encourage opportunities for private sector investment. Agencies shall pay particular attention to predevelopment activities in sectors where State, local, and tribal governments have traditionally played a significant role, such as surface transportation, drinking water, sewage and storm water management systems, landside ports, and social infrastructure like schools and community facilities.

Sec. 2. Definitions. For the purposes of this memorandum:

(a) “Predevelopment activities” means activities that provide decisionmakers with the opportunity to identify and assess potential infrastructure projects and modifications to existing infrastructure projects, and to advance those projects from the conceptual phase to actual construction. Predevelopment activities include:

(i) project planning, feasibility studies, economic assessments and cost-benefit analyses, and public benefit studies and value-for-money analyses;

(ii) design and engineering;

(iii) financial planning (including the identification of funding and financing options);

(iv) permitting, environmental review, and regulatory processes;

(v) assessment of the impacts of potential projects on the area, including the effect on communities, the environment, the workforce, and wages and benefits, as well as assessment of infrastructure vulnerability and resilience to climate change and other risks; and

(vi) public outreach and community engagement.

(b) “Predevelopment funding” means funding for predevelopment activities and associated costs, such as flexible staff, external advisors, convening potential investment partners, and associated legal costs directly related to predevelopment activities.

Sec. 3. Federal Action to Support Predevelopment Activities. Agencies shall take the following actions to support predevelopment activities:

§ 601. Definitions, 5 USCA § 601

(a) the Department of Commerce, through the Economic Development Administration's Public Works grants and Economic Adjustment Assistance grants, and consistent with the programs' mission and goals, shall take steps to increase assistance for the predevelopment phase of infrastructure projects;

(b) the Department of Transportation shall develop guidance to clarify where predevelopment activities are eligible for funding through its programs. To further encourage early collaboration in the project development process, the Department of Transportation shall also clarify options for providing early feedback into environmental review processes;

(c) the Department of Homeland Security shall clarify for grantees where predevelopment funding is available through the Hazard Mitigation Grant Program;

(d) the Department of Housing and Urban Development shall clarify for grantees how the Community Development Block Grant program and other Federal funding sources can be used for predevelopment activities;

(e) the Department of Agriculture shall develop guidance to clarify where predevelopment activities are eligible for funding through its programs, including grants for water and waste projects pursuant to 7 CFR 1780.1 et seq., the Special Evaluation Assistance for Rural Communities and Households Program, the Community Facilities Grant program, and the Watershed and Flood Prevention Operations Program. To encourage innovative predevelopment work, the Department of Agriculture shall also train Water and Environmental Programs field staff on predevelopment best practices and prioritize predevelopment in the Department of Agriculture's project development process; and

(f) the other members of the Working Group established in section 3 of my memorandum of July 17, 2014 (Expanding Public-Private Collaboration on Infrastructure Development and Financing), shall take such steps as appropriate to clarify program eligibilities related to predevelopment activities for nonfederal domestic infrastructure assets.

Sec. 4. Implementation, Public Education, and Best Practices. The Departments of Agriculture, Commerce, Labor, Housing and Urban Development, Transportation, Energy, and Homeland Security, and the Environmental Protection Agency shall develop plans for implementing the requirements of this memorandum, providing technical assistance to nonfederal actors engaged in predevelopment activities, and educating grantees and the public on the benefits of predevelopment and the Federal resources available for these activities. These agencies shall also work together to develop a guide for nonfederal actors undertaking nonfederal predevelopment activities that includes best practices on how to evaluate and compare traditional and alternative financing strategies. No later than 60 days after the date of this memorandum, these agencies shall provide these plans and the best practice guide to the Director of the National Economic Council. Subsequently, these agencies shall provide regular updates to the Director of the National Economic Council on their progress in increasing support for predevelopment activities.

Sec. 5. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(c) The Secretary of Transportation is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

§ 601. Definitions, 5 USCA § 601


Notes of Decisions (5)

5 U.S.C.A. § 601, 5 USCA § 601
Current through P.L. 116-145.

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§ 602. Regulatory agenda, 5 USCA § 602

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Proposed Legislation

United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 602

§ 602. Regulatory agenda

Currentness

(a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain--

(1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;

(2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking,¹ and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda.

CREDIT(S)

(Added Pub.L. 96-354, § 3(a), Sept. 19, 1980, 94 Stat. 1166.)

[Notes of Decisions \(1\)](#)

§ 602. Regulatory agenda, 5 USCA § 602


Footnotes

¹ So in original. The comma probably should be a semicolon.
5 U.S.C.A. § 602, 5 USCA § 602
Current through P.L. 116-145.

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§ 603. Initial regulatory flexibility analysis, 5 USCA § 603

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United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 603

§ 603. Initial regulatory flexibility analysis

Currentness

(a) Whenever an agency is required by [section 553](#) of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretative rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule. The agency shall transmit a copy of the initial regulatory flexibility analysis to the Chief Counsel for Advocacy of the Small Business Administration. In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement.

(b) Each initial regulatory flexibility analysis required under this section shall contain--

- (1) a description of the reasons why action by the agency is being considered;
- (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

(c) Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as--

§ 603. Initial regulatory flexibility analysis, 5 USCA § 603

- (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
 - (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
 - (3) the use of performance rather than design standards; and
 - (4) an exemption from coverage of the rule, or any part thereof, for such small entities.
- (d)(1) For a covered agency, as defined in [section 609\(d\)\(2\)](#), each initial regulatory flexibility analysis shall include a description of--
- (A) any projected increase in the cost of credit for small entities;
 - (B) any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities; and
 - (C) advice and recommendations of representatives of small entities relating to issues described in subparagraphs (A) and (B) and subsection (b).
- (2) A covered agency, as defined in [section 609\(d\)\(2\)](#), shall, for purposes of complying with paragraph (1)(C)--
- (A) identify representatives of small entities in consultation with the Chief Counsel for Advocacy of the Small Business Administration; and
 - (B) collect advice and recommendations from the representatives identified under subparagraph (A) relating to issues described in subparagraphs (A) and (B) of paragraph (1) and subsection (b).

CREDIT(S)

(Added [Pub.L. 96-354](#), § 3(a), Sept. 19, 1980, 94 Stat. 1166; amended [Pub.L. 104-121, Title II, § 241\(a\)\(1\)](#), Mar. 29, 1996, 110 Stat. 864; [Pub.L. 111-203, Title X, § 1100G\(b\)](#), July 21, 2010, 124 Stat. 2112.)

[Notes of Decisions \(22\)](#)


5 U.S.C.A. § 603, 5 USCA § 603
Current through P.L. 116-145.

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§ 604. Final regulatory flexibility analysis, 5 USCA § 604

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Part I. The Agencies Generally
Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 604

§ 604. Final regulatory flexibility analysis

Effective: July 21, 2011

[Currentness](#)

(a) When an agency promulgates a final rule under [section 553](#) of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in [section 603\(a\)](#), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain--

- (1) a statement of the need for, and objectives of, the rule;
- (2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- (3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- (4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- (5) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- (6) ¹ a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected; and

§ 604. Final regulatory flexibility analysis, 5 USCA § 604

(6)¹ for a covered agency, as defined in [section 609\(d\)\(2\)](#), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

CREDIT(S)


(Added [Pub.L. 96-354](#), § 3(a), Sept. 19, 1980, 94 Stat. 1167; amended [Pub.L. 104-121, Title II, § 241\(b\)](#), Mar. 29, 1996, 110 Stat. 864; [Pub.L. 111-203, Title X, § 1100G\(c\)](#), July 21, 2010, 124 Stat. 2113; [Pub.L. 111-240, Title I, § 1601](#), Sept. 27, 2010, 124 Stat. 2551.)

[Notes of Decisions \(37\)](#)

Footnotes

¹ So in original. Two pars. (6) were enacted.
5 U.S.C.A. § 604, 5 USCA § 604
Current through P.L. 116-145.

§ 605. Avoidance of duplicative or unnecessary analyses, 5 USCA § 605

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Proposed Legislation

United States Code Annotated
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Part I. The Agencies Generally
Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 605**§ 605. Avoidance of duplicative or unnecessary analyses****Currentness**

- (a) Any Federal agency may perform the analyses required by [sections 602, 603, and 604](#) of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.
- (b) [Sections 603 and 604](#) of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.
- (c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of [sections 602, 603, 604 and 610](#) of this title.

CREDIT(S)

(Added [Pub.L. 96-354](#), § 3(a), Sept. 19, 1980, 94 Stat. 1167; amended [Pub.L. 104-121, Title II, § 243\(a\)](#), Mar. 29, 1996, 110 Stat. 866.)

Notes of Decisions (18)

5 U.S.C.A. § 605, 5 USCA § 605
Current through P.L. 116-145.

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§ 608. Procedure for waiver or delay of completion, 5 USCA § 608



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Title 5. Government Organization and Employees (Refs & Annos)

Part I. The Agencies Generally

Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 608

§ 608. Procedure for waiver or delay of completion

Currentness

(a) An agency head may waive or delay the completion of some or all of the requirements of [section 603](#) of this title by publishing in the Federal Register, not later than the date of publication of the final rule, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of [section 603](#) of this title impracticable.

(b) Except as provided in [section 605\(b\)](#), an agency head may not waive the requirements of [section 604](#) of this title. An agency head may delay the completion of the requirements of [section 604](#) of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of [section 604](#) of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to [section 604](#) of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency.

CREDIT(S)

(Added [Pub.L. 96-354](#), § 3(a), Sept. 19, 1980, 94 Stat. 1168.)


5 U.S.C.A. § 608, 5 USCA § 608

Current through P.L. 116-145.

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§ 611. Judicial review, 5 USCA § 611

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Part I. The Agencies Generally
Chapter 6. The Analysis of Regulatory Functions (Refs & Annos)

5 U.S.C.A. § 611

§ 611. Judicial review

Currentness

(a)(1) For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of [sections 601, 604, 605\(b\), 608\(b\), and 610](#) in accordance with chapter 7. Agency compliance with [sections 607 and 609\(a\)](#) shall be judicially reviewable in connection with judicial review of [section 604](#).

(2) Each court having jurisdiction to review such rule for compliance with [section 553](#), or under any other provision of law, shall have jurisdiction to review any claims of noncompliance with [sections 601, 604, 605\(b\), 608\(b\), and 610](#) in accordance with chapter 7. Agency compliance with [sections 607 and 609\(a\)](#) shall be judicially reviewable in connection with judicial review of [section 604](#).

(3)(A) A small entity may seek such review during the period beginning on the date of final agency action and ending one year later, except that where a provision of law requires that an action challenging a final agency action be commenced before the expiration of one year, such lesser period shall apply to an action for judicial review under this section.

(B) In the case where an agency delays the issuance of a final regulatory flexibility analysis pursuant to [section 608\(b\)](#) of this chapter, an action for judicial review under this section shall be filed not later than--

(i) one year after the date the analysis is made available to the public, or

(ii) where a provision of law requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period, the number of days specified in such provision of law that is after the date the analysis is made available to the public.

(4) In granting any relief in an action under this section, the court shall order the agency to take corrective action consistent with this chapter and chapter 7, including, but not limited to--

(A) remanding the rule to the agency, and

§ 611. Judicial review, 5 USCA § 611

(B) deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

(5) Nothing in this subsection shall be construed to limit the authority of any court to stay the effective date of any rule or provision thereof under any other provision of law or to grant any other relief in addition to the requirements of this section.

(b) In an action for the judicial review of a rule, the regulatory flexibility analysis for such rule, including an analysis prepared or corrected pursuant to paragraph (a)(4), shall constitute part of the entire record of agency action in connection with such review.

(c) Compliance or noncompliance by an agency with the provisions of this chapter shall be subject to judicial review only in accordance with this section.

(d) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise permitted by law.

CREDIT(S)

(Added [Pub.L. 96-354](#), § 3(a), Sept. 19, 1980, 94 Stat. 1169; amended [Pub.L. 104-121, Title II, § 242](#), Mar. 29, 1996, 110 Stat. 865.)

[Notes of Decisions \(18\)](#)

5 U.S.C.A. § 611, 5 USCA § 611
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552 F.Supp.2d 999
United States District Court,
N.D. California.

AMERICAN FEDERATION
OF LABOR, et al., Plaintiffs,
v.
Michael CHERTOFF, et al., Defendants.

No. C 07-04472 CRB.

|
Oct. 10, 2007.

Synopsis

Background: Consortium of unions and business groups brought action challenging Department of Homeland Security's (DHS) final rule regarding safe-harbor procedures for employers receiving no-match letters from Social Security Administration (SSA). Plaintiffs moved for preliminary injunction.

Holdings: The District Court, [Charles R. Breyer, J.](#), held that:

[1] implementation of final rule would irreparably harm employers and employees;

[2] plaintiffs had standing to challenge final rule; and

[3] action was ripe for adjudication.

Motion granted.

Procedural Posture(s): Motion for Preliminary Injunction.

West Headnotes (12)

[1] **Injunction** 🔑 Grounds in general; multiple factors

Preliminary injunction is appropriate when plaintiff demonstrates either: (1) likelihood of success on merits and possibility of irreparable injury; or (2) that serious questions going to merits were raised and balance of hardships tips sharply in plaintiff's favor.

[2] **Injunction** 🔑 Aliens, immigration, and citizenship

Implementation of final rule promulgated by Department of Homeland Security (DHS) regarding safe-harbor procedures for employers receiving no-match letters from Social Security Administration (SSA) would irreparably harm employers and employees, and thus preliminary injunction was warranted suspending rule's implementation, where employers would bear significant expense in complying with rule's new 90-day timeframe resolving no-match letters, there was strong likelihood that employers would fire employees who were unable to resolve discrepancy within 90 days, even if employees were actually authorized to work, and there were serious questions as to whether DHS supplied reasoned analysis for its new position that no-match letter was sufficient, by itself, to put employer on notice of employee's unauthorized status, whether DHS exceeded its authority by interpreting Immigration Reform and Control Act's (IRCA) anti-discrimination provision, and whether DHS violated Regulatory Flexibility Act by not conducting final flexibility analysis.

📄 5 U.S.C.A. § 604(a); Immigration Reform and Control Act of 1986, § 101(a)(1), 📄 8 U.S.C.A. § 1324a; 📄 8 C.F.R. § 274a.1(D).

[3] **Administrative Law and Procedure** 🔑 Explanation or reasons for change

When agency adopts rule that changes agency's prior position, agency is obligated to supply reasoned analysis for change.

[4] **Administrative Law and Procedure** 🔑 Explanation or reasons for change

Agency action is arbitrary and capricious if it departs from agency precedent without explanation. 📄 5 U.S.C.A. § 706(2)(A).

1 Cases that cite this headnote

- [5] **Administrative Law and Procedure** ➔ Change of policy; reason or explanation

Agencies are free to change course as their expertise and experience may suggest or require, but when they do so they must provide reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.

1 Cases that cite this headnote

- [6] **Administrative Law and Procedure** ➔ Review for arbitrary, capricious, unreasonable, or illegal actions in general

Agency action is arbitrary and capricious if agency fails to examine relevant data and articulate satisfactory explanation for its action, including rational connection between facts found and choice made. 📄 5 U.S.C.A. § 706(2) (A).

1 Cases that cite this headnote

- [7] **Administrative Law and Procedure** ➔ Statutory limitation

Administrative agency's power to promulgate legislative regulations is limited to authority delegated by Congress.

- [8] **Associations** ➔ Suits on Behalf of Members; Associational or Representational Standing

Organization may bring action on behalf of its members if: (1) individual members would have standing to sue; (2) organization's purpose relates to interests being vindicated; and (3) claims asserted do not require participation of individual members.

- [9] **Corporations and Business Organizations** ➔ Persons entitled to sue; standing

Associations representing employers had standing to challenge Department of Homeland Security's (DHS's) final rule regarding safe-harbor procedures for employers receiving no-match letters from Social Security Administration (SSA), even though final rule had not yet been implemented and no-match letters containing challenged language had been issued, where many employers would be forced to develop systems for resolving no-match letters within new 90-day timeframe.

1 Cases that cite this headnote

- [10] **Aliens, Immigration, and Citizenship** ➔ Eligibility verification; document abuse

Aliens, Immigration, and Citizenship ➔ Proceedings for adoption and review

Unions had standing to challenge Department of Homeland Security's (DHS's) final rule regarding safe-harbor procedures for employers receiving no-match letters from Social Security Administration (SSA), even though final rule had not yet been implemented, and no-match letters containing challenged language had been issued, where DHS's planned no-match mailing would likely identify approximately 600,000 union members as employees with mismatched names and social security numbers, and some of them would be fired pursuant to safe harbor provision because they would not be able resolve discrepancy within 90 days.

1 Cases that cite this headnote

- [11] **Administrative Law and Procedure** ➔ Ripeness; prematurity

Challenge to administrative action is ripe when issues do not require further factual development, and there is direct and immediate risk of hardship to plaintiff.

[12] Federal Courts  Labor and Employment

Action brought by consortium of unions and business groups challenging Department of Homeland Security's (DHS) final rule regarding safe-harbor procedures for employers receiving no-match letters from Social Security Administration (SSA) was ripe for adjudication, where central questions were primarily legal, and regulation, if enforced, and new rule would require immediate and significant change in plaintiffs' conduct.

[2 Cases that cite this headnote](#)

West Codenotes**Validity Called into Doubt**

 [8 C.F.R. § 274a.1\(f\)](#)

Attorneys and Law Firms

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Daniel Bensing, [Thomas H. Dupree, Jr.](#), U.S. Dept. of Justice, Washington, DC, [Jonathan Unruh Lee](#), United States Attorneys Office, [Cynthia Louise Rice](#), California Rural Legal Assistance, San Francisco, CA, [Linda Claxton](#), Lewis Fisher Henderson Claxton & Mulroy, Los Angeles, CA, for Defendants.


**ORDER GRANTING MOTION
FOR PRELIMINARY INJUNCTION**

[CHARLES R. BREYER](#), District Judge.

On August 15, 2007, the Department of Homeland Security (DHS) promulgated a final rule entitled “[Safe-Harbor Procedures for Employers Who Receive a No-Match Letter.](#)” *See* [72 Fed.Reg. 45611 \(Aug. 15, 2007\)](#). Plaintiffs, a consortium of unions and business groups, filed a motion for preliminary injunction, arguing that injunctive relief is appropriate because they have demonstrated a high probability of success on four theories: that the rule (1) contravenes the governing statute; (2) is arbitrary and capricious under the Administrative Procedure Act; (3) is an exercise of *ultra vires* authority by DHS and the Social Security Administration (SSA); and (4) was promulgated in violation of the Regulatory Flexibility Act. The balance of hardships tips sharply in plaintiffs' favor and plaintiffs have raised serious questions ***1002** going to the merits. Accordingly, the motion for a preliminary injunction is GRANTED.

BACKGROUND*A. The SSA No-Match Program*

The SSA maintains earnings information on workers for the purpose of determining eligibility for Social Security benefits for which the worker and his dependents may be entitled.

See  [42 U.S.C. § 405\(c\)\(2\)\(A\)](#). Each year, employers submit employee wages to the SSA on Forms W-2—Wage and Tax Statements—and SSA posts those earnings to its Master Earnings File so that workers receive credit for Social Security benefits. When SSA is unable to match a worker's name and Social Security Number (SSN) from the Form W-2 with its own records, that worker's earnings are posted to SSA's Earnings Suspense File until they can be matched with SSA records. *See* [20 C.F.R. § 422.120\(a\)](#).

The Earnings Suspense File contains more than 255 million mismatched earnings records and is growing at the rate of 8 million to 11 million records per year. Request for Judicial Notice in Support of Motion for Temporary Restraining Order and Preliminary Injunction (RJN) Exh. Q at 8. Although the portion of these earnings that represent unauthorized work is unknown, the United States Government Accountability

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Office has concluded that the Earnings Suspense File “[c]ontains information about many U.S. citizens as well as noncitizens.” *See id.*

Since 1994, SSA has attempted to correct mismatched records by sending so-called “no-match” letters to employers requesting corrected information. *See* 20 C.F.R. § 422.120(a). In previous years, these no-match letters have downplayed the immigration implications of a mismatched SSN. For example, SSA’s model 2006 no-match letter for Tax Year 2005 emphasized that receipt of the letter “does not imply that you or your employee intentionally gave the government wrong information about the employee’s name or Social Security number. Nor does it make any statement about an employee’s immigration status.” RJN Exh. D.¹

B. The Immigration Reform and Control Act of 1986

In 1986, Congress passed the Immigration Reform and Control Act (IRCA), Pub.L. No. 99–603, 100 Stat. 3359 (1986), which subjects employers to criminal and civil liability for knowingly hiring unauthorized aliens, *see* 8 U.S.C. § 1324a(a)(1)(A), and for “continu[ing] to employ the alien in the United States knowing the alien is (or has become) an unauthorized alien with respect to such employment,” *id.* § 1324a(a)(2). IRCA also made it unlawful for employers to hire new employees without complying with an eligibility verification process established by Congress. *See id.* § 1324a(a)(1)(B). That process requires the employer to fill out a Form I–9 (Employment Eligibility Verification), based on documents presented by the employee that prove identity and work authorization. *Id.* § 1324a(b).

In passing IRCA, Congress also sought to prevent employers from responding to their new obligations by terminating employees solely on the basis of national origin. “Concern with protecting [lawful workers whose work authorization has been questioned or who lack adequate documentation] from discrimination based *1003 on national origin engendered by IRCA’s employer sanctions was repeatedly expressed by members of Congress.” *Incalza v. Fendi N. Am., Inc.*, 479 F.3d 1005, 1011 (9th Cir.2007). Accordingly, Congress made it an unfair immigration-related employment practice for an employer “to discriminate against any individual (other than an unauthorized alien, as defined in section 1324a(h)(3) of this title) with respect to the hiring, or recruitment or referral for a fee, of the individual

for employment or the discharging of the individual from employment ... because of such individual’s national origin.”

8 U.S.C. § 1324b(a)(1)(A).

To enforce IRCA’s anti-discrimination provision, Congress created a Special Counsel for Immigration–Related Unfair Employment Practices, based within the Department of Justice. *See id.* § 1324b(c)(1). Congress delegated to the Special Counsel the power to investigate charges of discrimination based on national origin, and to issue complaints. *See id.* § 1324b(c)(2).

C. DHS’s “Safe Harbor” Rule

On June 14, 2006, DHS proposed to amend 8 C.F.R. § 274a.1, a regulation that sets forth DHS interpretations of terms including “knowing.” In short, DHS proposed to add receipt of a no-match letter to a list of examples “that may lead to a finding that an employer had ... constructive knowledge” of an employee’s unauthorized status. *Safe-Harbor Procedures for Employers Who Receive a No-Match Letter*, 71 Fed.Reg. 34281–01, 34281 (June 14, 2006). In addition, DHS proposed to create “‘safe-harbor’ procedures that the employer can follow in response to [a no-match] letter and thereby be certain that DHS will not find that the employer had constructive knowledge that the employee referred to in the letter was an alien not authorized to work in the United States.” *Id.*

Before the sixty day comment period ended on August 14, 2006, a variety of sources—including labor unions, industry trade groups and businesses—submitted approximately 5,000 comments. 72 Fed.Reg. at 45611. The rule then lay dormant for over a year while Congress debated immigration reform legislation. On August 15, 2007, the agency issued a final rule, with an effective date of September 14, 2007. *See id.*

The new rule redefines DHS’s definition of “knowing”, to provide that:

The term *knowing* includes having actual or constructive knowledge. Constructive knowledge is knowledge that may fairly be inferred through notice of certain facts and circumstances that would lead a person, through the exercise of

reasonable care, to know about a certain condition. Examples of situations where the employer may, depending on the totality of relevant circumstances, have constructive knowledge that an employee is an unauthorized alien include, but are not limited to, situations where the employer ... [f]ails to take reasonable steps after receiving information indicating that the employee may be an alien who is not employment authorized, such as ... [w]ritten notice to the employer from the Social Security Administration reporting earnings on a Form W-2 that employees' names and corresponding social security account numbers fail to match Social Security Administration records.

Id. at 45623–24; *see also*, 8 C.F.R. § 274a.1(l)(1)(iii)(B) (emphasis added).

The rule's "safe harbor" provision precludes DHS from using receipt of a no-match letter as evidence of constructive knowledge if the employer takes certain actions set forth in the rule. *See id.* at 45624. Specifically, an employer must check its records for the source of the *1004 mismatch within 30 days. *See* 8 C.F.R. § 274a.1(l)(2)(i)(A). If the discrepancy is not due to error in the employer's records, then the employer must request that the employee confirm his information, and advise the employee to resolve the discrepancy with the SSA within 90 days of the date the employer received the no-match letter. *See id.* § 274a.1(l)(2)(i)(B). If the employer cannot resolve the discrepancy within 90 days, it must complete a new Form I-9 for the employee. *See id.* § 274a.1(l)(2)(iii). The employer may not accept any document that contains a disputed social security number; thus, an employee cannot maintain his eligibility and attempt to retain his employment based on a SSN found to not match SSA records, even if the SSN is accurate and the discrepancy is due to SSA error. *See id.* § 274a.1(l)(2)(iii)(2).

D. The New SSA "No-Match" Letter & DHS Insert

In an apparent effort to coordinate efforts with DHS, SSA has revised its no-match letter in three ways to bring it into accord with the new safe harbor rule. First, SSA's model 2007 no-match letter for Tax Year 2006 includes a new "common reason" why information reported to SSA does not match the agency's records: "[t]he name or Social Security number reported is false, or the number was assigned to someone else." RJN Exh. E. Second, the no-match letter's assurance of immigration implications is now less reassuring for employers. The new letter informs employers that a no-match letter "does not, *by itself*, make any statement about an employee's immigration status." (Amendment in emphasis). Third, the letter instructs employers to follow the instructions contained in a DHS letter inserted into the no-match mailing.

In turn, DHS's insert purports to "provide you with additional guidance on how to respond to the [no-match] letter from the Social Security Administration in a manner that is consistent with your obligations under United States immigration laws." RJN Exh. C. Organized in a question-and-answer format, the insert asks: "*Can I simply disregard the letter from SSA?*" (Emphasis in original). DHS answers:

No. You have received official notification of a problem that may have significant legal consequences for you and your employees. If you elect to disregard the notice you have received and if it is determined that some employees listed in the enclosed letter were not authorized to work, the Department of Homeland Security could determine that you have violated the law by knowingly continuing to employ unauthorized persons. This could lead to civil and criminal sanctions.

Id. (Emphasis in original).

In response to the question, "*What should I do?*," DHS answers that employers should follow the steps set forth in the safe harbor provision of the new rule. *See id.* Finally, DHS provides employers with advice on the nexus between the new rule and IRCA's anti-discrimination provision. The insert asks, "*Will I be liable for discrimination charges brought by the United States if I terminate the employee after following the steps outlined above?*" The answer:

No.... [I]f an employer that follows all of the procedures outlined by DHS in this letter cannot determine that an employee is authorized to work in the United States and therefore terminates that employee, and if that employer

applied the same procedures to all employees referenced in the mismatch letter, then that employer will not be subject to suit by the United States under the Immigration *1005 and Nationality Act's anti-discrimination provision.

Id.

The government acknowledged at oral argument that if a preliminary injunction is not granted, SSA plans to mail approximately 140,000 no-match letters to employers, pertaining to approximately 8 million employees.

E. Procedural History

On August 29, 2007, plaintiffs moved for a temporary restraining order, seeking to prevent DHS from taking any action to implement the new rule. Two days later, another judge of the court granted the motion, concluding that the plaintiffs had “raised serious questions as to whether the new Department of Homeland Security rule is inconsistent with statute and beyond the statutory authority of the Department of Homeland Security and the Social Security Administration.” The Court also found that the plaintiffs had “demonstrated that the balance of harms tips sharply in favor of a stay based on Plaintiffs’ showing that they and their members would suffer irreparable harm if the rule is implemented while Defendants would suffer significantly less harm from a delay in implementation of the rule pending consideration of Plaintiffs’ claims.”

Since the imposition of a TRO, the parties have submitted substantial briefing and this Court conducted a two-hour hearing to consider the propriety of a preliminary injunction.

SUMMARY

At the outset, it should be noted that in the context of a request for preliminary injunction, it is not the court's role to provide a final adjudication of the merits of the claims. Rather, at this stage the court must only determine whether the plaintiffs' claims raise serious issues and if so, whether preliminary relief is warranted to prevent irreparable harm. As demonstrated by plaintiffs, the government's proposal to disseminate no-match letters affecting more than eight million workers will, under the mandated time line, result in the termination of employment to lawfully employed workers. This is so because, as the government recognizes, the no-match letters are based on SSA records that include numerous errors. Moreover, the threat of criminal prosecution (under the

guise of a safe-harbor provision), reinforced by a directive that the employer who receives a no-match letter *must* follow the safe harbor procedures or expose themselves to criminal and civil liability, reflects a major change in DHS policy. In fact, previous DHS (and INS) guidance recognized that receipt of a no-match letter could not impart criminal liability by itself. No such comfort is afforded in the newly proposed letter. Indeed, the opposite is suggested. While a change in agency policy is not the concern of courts, when there is such a change it must be done in compliance with procedures set forth in the Administrative Procedures Act as well as other Congressional dictates. It is the Court's view, as set forth below, that DHS has failed to comply with these mandated requirements and, if allowed to proceed, the mailing of no-match letters, accompanied by DHS's guidance letter, would result in irreparable harm to innocent workers and employers.

STANDARD OF REVIEW

[1] The standard for evaluating a motion for a preliminary injunction requires this Court to balance the likelihood of success against the hardships to the parties. A preliminary injunction is appropriate when a plaintiff demonstrates either: (1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor. See [Lands *1006 Council v. Martin](#), 479 F.3d 636, 639 (9th Cir.2007). These two formulations are not different tests, but merely extremes on a single continuum: “the less certain the district court is of the likelihood of success on the merits, the more plaintiffs must convince the district court that the public interest and balance of hardships tip in their favor.” [Sw. Voter Registration Educ. Project v. Shelley](#), 344 F.3d 914, 918 (9th Cir.2003) (en banc) (per curiam).

Alternatively, the Ninth Circuit has stated the traditional test as requiring a plaintiff to establish “(1) a strong likelihood of success on the merits, (2) the possibility of irreparable injury to plaintiff if preliminary relief is not granted, (3) a balance of hardships favoring the plaintiff, and (4) advancement of the public interest (in certain cases).” [Taylor v. Westly](#), 488 F.3d 1197, 1200 (9th Cir.2007).

DISCUSSION

[2] Contrary to the government's argument, this case is justiciable because the plaintiffs have standing and the issues are ripe for review. The plaintiffs have demonstrated that they will be irreparably harmed if DHS is permitted to enforce the new rule. On the other side of the scale, the government would suffer significantly less harm as a result of a delay in the rule's implementation. Because the balance of harms tips sharply in favor of the plaintiffs, a preliminary injunction is appropriate if the plaintiffs have raised serious questions going to the merits. In this Court's opinion, granting plaintiffs' motion is appropriate because they have raised serious questions whether: (1) the rule is arbitrary and capricious because DHS failed to supply a reasoned analysis for the agency's new position that a no-match letter is sufficient, by itself, to put an employer on notice of an employee's unauthorized status; (2) DHS exceeded its authority by interpreting IRCA's anti-discrimination provision; and (3) DHS violated the Regulatory Flexibility Act by not conducting a final flexibility analysis.

A. Balance of Hardships

The plaintiffs convincingly argue that the balance of hardships tips sharply in their favor because altering the status quo would subject employers to greater compliance costs and employees to an increased risk of termination, while imposing significantly less burdens on the government.

The magnitude of DHS's safe harbor rule is staggering. If enacted, DHS and SSA will immediately mail no-match packets to 140,000 employers, identifying no-matches for approximately 8 million employees. There can be no doubt that the effects of the rule's implementation will be severe.

Thousands of employers would bear the “significant” expense of complying with the rule's new 90-day timeframe. *See Dickson Decl.* ¶ 4. Because there has not been an official timeframe for resolving no-match letters in the past, employers have generally resolved mismatch problems “at their leisure.” *See id.* ¶ 7. Therefore, many employers who want to take advantage of the safe harbor provision will have to develop costly human resources systems capable of resolving problems within the new time frame. *See id.* (“[H]uman resources departments will have to put systems into place designed to resolve mismatches with the employee's cooperation within the ninety-day window,” which “will take time and money to develop and implement.”).


The union plaintiffs have also identified ways in which employees will be irreparably harmed. Kenneth Apfel, ex-Commissioner of the SSA, believes—based on his prior experience at the agency—that “there will be many legally authorized workers who cannot resolve a mismatched earnings report” by the deadline imposed *1007 by the new rule. *See Apfel Decl.* ¶ 17. Because empirical research suggests that mass layoffs often follow receipt of a no-match letter, *see Theodore Decl.* ¶ 11, there is a strong likelihood that employers may simply fire employees who are unable to resolve the discrepancy within 90 days, even if the employees are actually authorized to work.

On the other side of the scale, a preliminary injunction would cause significantly less harm to the government. The government argues that a preliminary injunction would preclude SSA from sending out no-match letters for the 2006 tax year, “and so frustrate the purpose of providing notice to employers that their employees' social security earnings are not being credited to their accounts.” *See Opposition* at 54. But the plaintiffs have not requested a preliminary injunction precluding SSA from sending out its traditional no-match letters for tax purposes, as the agency has for over a decade.

The government also asserts that a preliminary injunction would be harmful because any delay in sending out no-match letters might push SSA's responsibilities over into the agency's period of peak workload during the months of January–March. *See Rust Decl.* ¶ 14. However, the SSA has acknowledged that it could remove the DHS insert and related language from its mailing in 30 days. *See id.* ¶ 8. Thus, even if a preliminary injunction is granted, SSA should be able to coordinate a mailing well before the peak workload season.

DHS waited for an entire year after the notice and comment period was closed to promulgate a final rule. While this Court does not doubt the importance of this rule to DHS, the agency's delay does undercut the assertion that it will be irreparably harmed if the Court maintains the status quo pending a trial on the merits. Because the balance of hardships tips sharply in favor of plaintiffs, the Court reviews plaintiffs' arguments on the merits with an eye towards whether serious questions are raised.

B. Whether the Safe Harbor Rule Contravenes the Governing Statute

Plaintiffs argue that the new rule must be invalidated because it is inconsistent with its governing statute,  8 U.S.C. §

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1324a. The Administrative Procedure Act authorizes courts to set aside agency actions that are “not in accordance with the law,” or “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2) (A), (C); see also *Oregon v. Ashcroft*, 368 F.3d 1118, 1129 (9th Cir.2004) (holding that agency determinations that squarely conflict with governing statutes are not entitled to deference and must be set aside). Plaintiffs argue that DHS's rule is contrary to § 1324a in three respects: (1) it changes the definition meaning of “knowing” as used in the statute; (2) it is inconsistent with the administrative structure that Congress enacted into law; and (3) it fails to respect the statute's grandfather clause. For the following reasons, plaintiffs have not raised a serious question whether the safe harbor rule is inconsistent with § 1324a.

I. Meaning of “Knowing”

Section 1324a(a)(2) prohibits an employer from continuing “to employ an alien ... *knowing* the alien is (or has become) an unauthorized alien with respect to such employment.” (Emphasis added). In 1989, the Ninth Circuit held that § 1324a(a)(2) is violated when the employer acts either with actual or constructive knowledge. See *Mester Mfg. Co. v. INS*, 879 F.2d 561 (9th Cir.1989). The Ninth Circuit rejected the employer's argument that it did not knowingly continue to employ an illegal alien merely because the *1008 employer did not receive positive notice that his employees used false green cards. *Id.* at 566. The court held that it was sufficient for the INS to notify the employer that three employees were *suspected* of green card fraud and instruct the employer to confirm that suspicion. The court explained that section 1324a's knowledge requirement is satisfied even where the employer has no “actual specific knowledge of the employee's unauthorized status” so long as the employer receives “specific information” that the employee “[is] likely to be unauthorized,” and the employer makes no further inquiry. *Id.* at 567.

In *New El Rey Sausage Co. v. INS*, 925 F.2d 1153 (9th Cir.1991), the Ninth Circuit again held that a constructive knowledge standard is authorized by § 1324a. See *id.* at 1157. In *New El Rey*, the INS had warned an employer that his Forms I-9, or Employer Eligibility Verification forms,

contained paperwork deficiencies. See *id.* at 1154. After identifying particular employees with paperwork problems, the INS sued the employer for continuing to employ the allegedly unauthorized workers. The court held that the employer was on constructive notice because he had been “provided with specific, detailed information” explaining “whom [the INS] considered unauthorized and why,” but failed to acquire some additionally independent corroboration of authorization other than the employees' self-serving representations. *Id.* at 1158.


Plaintiffs argue that the rule impermissibly alters the meaning of “knowing,” because receipt of a no-match letter does not reasonably inform the employer that the identified employee “[is] likely to be unauthorized.” *Mester*, 879 F.2d at 567. Accordingly, the employer cannot be said to have been properly put on notice of illegality.

The flaw in plaintiffs' argument is their assumption that receipt of a no-match letter triggers a finding of constructive knowledge in every instance. In fact, the regulation is written such that whether an employer has constructive knowledge depends “on the totality of relevant circumstances.” See 8 C.F.R. 274a.1(i)(1). Depending on the circumstances, a court may agree with plaintiffs that receipt of a no-match letter has not put an employer on notice that his employee is likely to be unauthorized. But this Court cannot agree with plaintiffs' fundamental premise that a no-match letter can *never* trigger constructive knowledge, regardless of the circumstances. Accordingly, there is no serious question whether DHS's rule improperly alters the meaning of “knowing” as used in § 1324a.



2. Conflict with Structure of Verification Process

Plaintiffs also believe that the rule is contrary to statute because it sets up a work-authorization reverification system. According to plaintiffs, the rule contravenes the innate structure created by Congress, which limits work eligibility verification to the initial hiring process. See *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517, 108 S.Ct. 805, 98 L.Ed.2d 898 (1988) (“[T]he Executive Branch is not permitted to administer [a statute] in a manner that is inconsistent with the administrative structure that Congress enacted into law.”).


The Ninth Circuit has already rejected the notion that after an employee is hired, “the government has the entire burden of proving or disproving that a person is unauthorized to work.”

 *New El Rey*, 925 F.2d at 1158. “IRCA clearly placed part of that burden on employers,” by requiring them to reverify the authorization of their employees when the government provides employers with “specific, detailed information” about the allegedly unauthorized employee. *1009 *Id.* Nothing in DHS's rule would alter the fundamental structure that Congress approved when it enacted IRCA.


3. Grandfather Clause


Plaintiffs maintain that the new rule must be set aside because it does not expressly abide by IRCA's grandfather clause, which precludes application of  § 1324a(a)(2) to employees hired before the statute's enactment. The government concedes that the new rule could not apply to grandfathered employees. *See* Opposition at 29 n. 12. Although DHS would be wise to demarcate the rule's temporal boundaries in its guidance letter, plaintiffs have cited to no case law suggesting that the rule is invalid because it does not *expressly* include a grandfather provision; the rule's consistency with  § 1324a's grandfather clause is assumed and implicit.

C. Whether the Safe Harbor Rule is Arbitrary and Capricious

Although the safe harbor rule represents a change in DHS's historical position that no-match letters cannot, by themselves, put an employer on notice, DHS did not supply a reasoned analysis for the change. Accordingly, plaintiffs have raised a serious question whether the rule is arbitrary and capricious and therefore a violation of the Administrative Procedures Act,  5 U.S.C. § 706(2)(A).


1. Change in Position

[3] [4] [5] When an agency adopts a rule that changes the agency's prior position, the agency “is obligated to supply a reasoned analysis for the change.”  *Motor Vehicle Mfgs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). This Court's “review under the APA is highly deferential, but agency action is arbitrary and capricious if it departs from agency precedent without explanation. Agencies are free to change course as their expertise and experience may suggest or

require, but when they do so they must provide a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.”  *Ramaprakash v. FAA*, 346 F.3d 1121, 1124–25 (D.C.Cir.2003) (internal quotation and citation omitted).

From at least 1997 onward, DHS's predecessor took the position in guidance letters that “notice from the Social Security Administration to an employer notifying it of a discrepancy between wage reporting information and SSA records with respect to an employee does not, by itself, put an employer on notice that the employee is not authorized to work.” RJN Ex. H; *see also id.* Exh. I (“We would not consider notice of this discrepancy from SSA to an employer by itself to put the employer on notice that the employee is unauthorized to work, or to require reverification of documents or further inquiry as to the employee's work authorization.”); *id.* Exh. J (“[T]he receipt of this SSA [no-match] letter by an employer, without more, would not be sufficient to establish constructive knowledge on the part of the employer regarding the employment eligibility of the named employee.”). That position even made its way into the preamble of DHS's safe harbor rule, wherein DHS assured employers that “an SSA no-match letter by itself does not impart knowledge that the identified employees are unauthorized aliens.” 72 Fed.Reg. 45616.


However, at some point in the six pages separating the preamble and the text of the final rule, DHS decided to change course. The final rule provides that constructive knowledge may be inferred if an employer fails to take reasonable steps after receiving nothing more than a no-match letter. *See id.* at 45623. At oral argument, the government confirmed that under the new rule, receipt of a no-match *1010 letter by itself *can* be sufficient to impart knowledge that the identified employees are unauthorized. The change in position is further reinforced in DHS's insert, which tells employers that disregarding the no-match letter can lead to civil and criminal sanctions. Nothing in the insert suggests that any evidence of illegality other than receipt of a no-match letter is necessary for liability to be imposed.

It is clear to this Court that DHS has changed course. Under the prior regime, receipt of a no-match letter was not, by itself, sufficient to trigger IRCA's liability under  § 1324a(a)(2). DHS's new position is that an employer who receives a no-match letter can, without any other evidence of illegality, be held liable under the continuing employment provision.

Needless to say, this change in position will have massive ramifications for how employers treat the receipt of no-match letters. DHS may well have the authority to change its position, but because DHS did so without a reasoned analysis, there is at least a serious question whether the agency has “casually ignored” prior precedent in violation of the APA.


2. Rational Connection

[6] An agency action is also arbitrary and capricious if the agency fails to examine the relevant data and articulate a satisfactory explanation for its action including a “rational connection between the facts found and the choice made.”



 *Motor Vehicle Mfgs. Ass'n*, 463 U.S. at 43, 103 S.Ct. 2856. But this Court must “uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.” *Id.* (citation omitted).

According to plaintiffs, DHS has failed to articulate a rational connection between the use of no-match letters for immigration purposes and any evidence that no-match letters are reliable indicators of illegality. To be sure, plaintiffs are correct that there are numerous reasons unrelated to illegality that a mismatch might exist, including name change or typographical error. Nonetheless, the agency's path is reasonably discernable to this Court. As the rule's preamble explains, “[o]ne potential cause” for an earnings report where the employee name and social security number does not match SSA records “may be the submission of information for an alien who is not authorized to work in the United States and who may be using a false SSN or a SSN assigned to someone else.” See 72 Fed.Reg. at 45612. A discrepancy in the SSA database is not a tell-tale sign of ineligibility, but because ineligibility is one reason why discrepancies occur, it is rational for DHS to use no-match letters as an “indicator[] of a potential problem.” See *id.* at 45622. Accordingly, DHS has sufficiently articulated a rational connection between the facts found and the choice made.




D. Ultra Vires Action

[7] “It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress.”  *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988). Plaintiffs have raised a serious question whether DHS exceeded its authority by interpreting the anti-discrimination provisions of the IRCA.

1. DHS's Interpretation of IRCA's Anti-Discrimination Provision

Concerned that  § 1324a's prohibition on the employment of unauthorized aliens would result in employers discriminating against applicants on the basis of nationality, Congress enacted an anti-discrimination provision that prohibits employers from discriminating against any person “with respect to the hiring, or recruitment *1011 or referral for a fee, of the individual for employment or the discharging of the individual from employment—(A) because of such individual's national origin, or (B) in the case of a protected individual ... because of such individual's citizenship status.”  8 U.S.C. § 1324b(a)(1).

The DHS insert provides employers with the reassurance that if they follow the safe harbor provision as set forth in the new rule before terminating an employee, and apply the same procedure to all employees referenced in the mismatch letter, “then that employer will not be subject to suit by the United States under the [IRCA's] anti-discrimination provision.” Similarly, the final rule states that “employers who follow the safe harbor procedures set forth in this rule uniformly and without regard to perceived national origin or citizenship status as required by the provisions of 274B(a)(6) of the INA will not be found to have engaged in unlawful discrimination.” 72 Fed.Reg. at 45613–14.

But Congress delegated to DOJ—through its Office of Special Counsel for Immigration-Related Unfair Employment Practices (Special Counsel)—the responsibility of enforcing the anti-discrimination provisions of  § 1324b. See 72 Fed.Reg. at 45614; see also  8 U.S.C. § 1324b(c). The government has failed to cite to any authority that enables DHS to make the determination whether to sue an employer for violating IRCA's anti-discrimination provision. There is therefore a serious question whether DHS has impermissibly exceeded its authority—and encroached on the authority of the Special Counsel—by interpreting IRCA's anti-discrimination provisions to preclude enforcement where employers follow the safe-harbor framework. See  *Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 865 (D.C.Cir.2006) (invalidating provision of DHS rule that infringed on another agency's statutory authority).

2. DHS Authority to Prescribe Tax Reporting Obligations

Plaintiffs argue that DHS cannot dictate how employers respond to no-match letters because that authority rests with the IRS. To be certain, the IRS has the exclusive authority to sanction employers for failing to comply with the tax code by submitting inaccurate or incomplete tax forms. *See* 26 U.S.C. § 6721. It does not follow, however, that DHS is precluded from relying on no-match letters as one indicator of possible non-compliance with immigration law. If DHS were attempting to levy sanctions for violations of the tax code, plaintiffs' argument would have merit. But DHS is authorized to and may punish employers for violating immigration law by knowingly continuing to employ unauthorized employees.

3. SSA Authority to Enforce Immigration Law

Plaintiffs' assertion that SSA is exceeding its authority by enforcing immigration laws is also unpersuasive. Although the proposed SSA no-match letter would notify employers that they should follow the instructions contained in DHS's insert, that reference hardly renders SSA an enforcer of immigration law. Put simply, the SSA does not exceed the bounds of its enabling statute by referring employers to a document produced by another agency.

E. Regulatory Flexibility Act




The business plaintiffs argue that the safe harbor rule was promulgated in violation of the Regulatory Flexibility Act (RFA) because DHS failed to conduct a final flexibility analysis even though the rule will have a significant impact on small businesses.

The RFA requires agencies, when promulgating a final rule, to prepare a regulatory flexibility analysis that describes, *1012 among other things, “a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues,” and “the steps the agency has taken to minimize the significant economic impact on small entities.” 5 U.S.C. § 604(a).

The RFA has an exception, however, that relieves an agency from its obligation to conduct a flexibility analysis if the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” *Id.* § 605(b). The certification must include “a statement providing the factual basis for” the agency's determination that the rule will not significantly impact small entities. *See id.*

When DHS promulgated the rule, it explained that a final regulatory flexibility analysis was not necessary because “[t]he rule does not mandate any new burdens on the employer and does not impose any new or additional costs on the employer, but merely adds specific examples and a description of a ‘safe harbor’ procedure to an existing DHS regulation for purposes of enforcing the immigration laws and providing guidance to employers.” 72 Fed.Reg. at 45623.

In its briefing to this Court, DHS offered for the first time a new justification for not conducting an RFA analysis: the safe harbor rule is interpretive and therefore the requirements

of the RFA do not apply. *See*  *Central Texas Telephone Co-op., Inc. v. FCC*, 402 F.3d 205, 214 (D.C.Cir.2005) (holding that RFA does not apply to interpretive rules). But “[a]gency decisions must generally be affirmed on the grounds stated in them.” *Ass'n of Civilian Technicians v. Fed. Labor Relations Auth.*, 269 F.3d 1112, 1117 (D.C.Cir.2001) (citation omitted). “The rule barring consideration of post hoc agency rationalizations operates where an agency has provided a particular justification for a determination at the time the determination is made, but provides a different justification for that same determination when it is later reviewed by another body.”  *Independence Mining Co., Inc. v. Babbitt*, 105 F.3d 502, 511 (9th Cir.1997) (citation omitted). Here, DHS provided one reason for not conducting a RFA analysis in the rule, and now offers another justification for purposes of litigation. Because post hoc rationalizations provide an inadequate basis for review, it is unlikely that this Court will even be able to consider DHS's most recent rationale. *See*  *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971).²



The government must, therefore, defend its decision to not conduct a flexibility analysis on the justification provided in the rule, *i.e.*, because the rule will not have a *1013 significant effect on small businesses. Plaintiffs have raised serious doubts about the veracity of DHS's prediction that the safe harbor rule will “not impose any new or additional costs” on employers. Plaintiffs' declarations establish that small businesses can expect to incur significant costs associated complying with the safe harbor rule. These costs include dedicating human resources staff to track and resolve mismatches within the 90-day timeframe, *see* Dolibois Decl. ¶ 4, hiring “legal and consultancy services” to help employers comply, *see* Silvertooth Decl. ¶ 9, and paying for the training

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of in-house counsel and human resources staff, *see id.*; Dickson Decl. ¶ 7.


DHS's response that the safe harbor rule will impose no costs because compliance is "voluntary" is wholly unavailing. It is true that the safe harbor rule does not mandate compliance. This Court's "concern, however, is with the practical effect ... of the rule, not its formal characteristics."

 *Chamber of Commerce v. Dep't of Labor*, 174 F.3d 206, 209 (D.C.Cir.1999). Because failure to comply subjects employers to the threat of civil and criminal liability, the regulation is "the practical equivalent of a rule that obliges an employer to comply or to suffer the consequences; the voluntary form of the rule is but a veil for the threat it obscures."  *Id.* at 210. The rule as good as mandates costly compliance with a new 90-day timeframe for resolving mismatches. Accordingly, there are serious questions whether DHS violated the RFA by refusing to conduct a final flexibility analysis.


F. Justiciability

The government argues that plaintiffs' motion must be denied because they lack standing to challenge the DHS rule and because plaintiffs' claims are not ripe. Although justiciability is a threshold matter, this Court finds it helpful to address the issue last because the preceding analysis of the merits demonstrates how the change in policy proposed by DHS would cause immediate injury to employers and employees alike if implemented.



1. Standing

[8] "An organization may bring an action on behalf of its members if: (1) the individual members would have standing to sue; (2) the organization's purpose relates to the interests being vindicated; and (3) the claims asserted do not require the participation of individual members."  *Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1119 (9th Cir.2005). Individual members have standing to sue if they can demonstrate that "that an actual or threatened injury exists, which is fairly traceable to the challenged action, and that such injury is likely to be redressed by a favorable decision." *Id.*

In order to have standing to seek injunctive relief, a plaintiff must demonstrate a likelihood of repeated injury or future harm to the plaintiff in the absence of the injunction.

See  *City of Los Angeles v. Lyons*, 461 U.S. 95, 103, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983) (describing the standing requirement for injunctive relief as requiring that the "threat to the plaintiffs" of future injury be "sufficiently real and immediate"). The government's argument that the organizational plaintiffs here have not alleged sufficient facts to demonstrate that any of their members have suffered an actual injury or face an imminent future injury is unpersuasive.

[9] The new rule presents employers with the Hobson's choice of complying with DHS's "safe harbor" procedures or confronting liability for knowingly employing unauthorized workers. Presented with that choice, it is certain that many employers represented by the organizational plaintiffs will be forced to develop systems for resolving no-match letters within the *1014 new 90-day timeframe. Indeed, plaintiffs have submitted declarations demonstrating that some businesses, such as the Chamber of Commerce of the United States of America, already have begun to develop costly programs and systems for ensuring compliance with the safe harbor framework. *See* Dickson Decl. ¶ 7. Thus, the business plaintiffs have established not only imminent, but actual injury.

[10] The union plaintiffs have also demonstrated a likelihood of immediate future harm. Plaintiffs have submitted uncontroverted evidence that DHS's planned no-match mailing will identify approximately 600,000 members of the AFL-CIO as employees with mismatched names and SSNs. *See* Reich Decl. ¶ 4. As the SSA itself concedes, the agency will not be able to resolve *all* mismatches—even if the mismatch is the result of SSA error—within the safe harbor's 90-day window. *See* 72 Fed.Reg. at 45617 (acknowledging that the 90-day timeframe may not be sufficient for "difficult" cases). Accordingly, there can be no doubt that at least some of the 600,000 AFL-CIO members who are identified in no-match letters, though authorized, will be fired pursuant to the safe harbor provision because they cannot resolve the discrepancy within 90 days. Loss of a job is an economic injury that constitutes injury in fact for standing. *See*   *San Diego County Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir.1996).³

The government also argues that the plaintiffs lack standing because they seek a remedy that will not provide them with any effective relief. The government's argument is based on the fundamental misconception that the business

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plaintiffs seek relief from the cost of resolving no-match letters under the *current* regime. To the contrary, the business plaintiffs complain of the costs associated with developing new systems and programs necessary for resolving no-match letters under the safe-harbor rule's 90-day timeframe. The business plaintiffs have demonstrated redressability because the costs of complying with the DHS rule would disappear if the rule were not implemented.

Similarly, the union plaintiffs complain of the economic injury that will result from the new rule's 90-day timeframe and the rule's elevation of a no-match letter to a piece of evidence that can, by itself, impute constructive knowledge. If the rule is not implemented, the injuries of which the union plaintiffs complain will also be redressed. Accordingly, the plaintiffs have standing to challenge the safe-harbor rule.

2. Ripeness

[11] A challenge to an administrative action is ripe when the issues are fit for judicial determination—*i.e.*, because the issues do not require further factual development—and there is a “direct and immediate” risk of hardship to the plaintiff.

See  [Abbott Labs. v. Gardner, 387 U.S. 136, 153, 87 S.Ct. 1507, 18 L.Ed.2d 681 \(1967\)](#). Pursuant to *Abbott*, the test for ripeness is not whether the agency's rule has actually been adopted and is seriously meant to be enforced, but whether the threat of its enforcement reasonably affects conduct. See

 *id.* (“[W]here a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to

the courts ... must be permitted, absent a statutory bar or some other unusual circumstance.”).

[12] Here, the issues are fit for judicial determination because the central questions *1015 are primarily legal: whether the DHS rule conflicts with statute, whether the rule is arbitrary and capricious, whether DHS and SSA exceeded their statutory authority, and whether DHS violated the Regulatory Flexibility Act. Moreover, the regulation, if enforced, would require an immediate and significant change in the plaintiffs' conduct. As noted above, some employers have already begun to change their conduct—by creating new programs to properly implement the safe harbor framework within 90 days—in response to the threat of enforcement. Accordingly, access to the courts must be permitted.

CONCLUSION



Because the balance of harms tips sharply in favor of plaintiffs and plaintiffs have raised serious questions going to the merits, the motion for a preliminary injunction is GRANTED. The parties shall meet and confer on the form of the injunction, and submit a proposed order by October 12, 2007.

IT IS SO ORDERED.

All Citations

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Footnotes

- 1 SSA's model 2006 letter reassured employers that there are three common reasons why reported information might mismatch SSA's own records, all unrelated to immigration fraud: (1) typographical errors made in spelling an employee's name or listing the SSN; (2) failure of the employee to report a name change; and (3) submission of a blank or incomplete Form W-2. See RJN Ex. D.
- 2 If the government's new rationalization can be considered, then this Court will have to determine whether the new rule is interpretive and therefore not subject to the RFA's requirements. It appears at first blush that the government's position has merit because the safe-harbor rule does not bear any of the three hallmarks of a legislative rule. See  [Hemp Industries Ass'n v. Drug Enforcement Admin., 333 F.3d 1082, 1087 \(9th Cir.2003\)](#) (identifying three circumstances in which a rule has the “force of law” and is therefore legislative). First, even absent the safe harbor rule, the Attorney General could bring an enforcement action for violations of IRCA's continuing employment provision, see  [8 U.S.C. § 1324a\(e\)\(9\)](#), on the theory that receipt of a no-

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match letter constitutes constructive knowledge under a totality of the circumstances test, see [8 C.F.R. § 274a.1\(f\)\(1\)](#). Second, DHS did not expressly invoke its legislative authority. Third, although the safe harbor rule contradicts INS guidance letters on the effect of receiving no-match letters, the rule “is not inconsistent with any *legislative* rule.” [Oregon v. Ashcroft, 368 F.3d 1118, 1134 \(9th Cir.2004\)](#) (emphasis in original).

- 3 The government argues that the threat of termination is too speculative to constitute an injury in fact. Because of the magnitude of the planned no-match mailing—affecting 8 million workers—the threat of termination is not speculative, but certain.

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KeyCite Yellow Flag - Negative Treatment

Distinguished by [Center For Food Safety v. Johanns](#), D.Hawai'i, September 1, 2006

346 F.Supp.2d 1075
United States District Court,
E.D. California.

CACTUS CORNER, LLC, a California
Limited Liability Corporation; Venida
Packing Company, a California Corporation;
[California Citrus Mutual](#); and California
Grape and Tree Fruit League, Plaintiffs,

v.

U.S. DEPARTMENT OF AGRICULTURE; Ann
V. Veneman, Secretary of Agriculture; and
Bobby R. Acord, Administrator, Animal and
Plant Health Inspection Service, Defendants,
[InterCitrus](#), a Spanish Trade Association;
Ibertrade Commercial Corporation, a New York
Corporation; LGS Special Sales, Ltd., a New York
“S” Corporation; and Luke G. Sears, President of
Lgs Special Sales, Ltd., Intervenor–Defendants.

No. CIV–F–02–6270 OWW SM.

|
March 11, 2004.

Synopsis

Background: Domestic fruit growers and packers sued Department of Agriculture (USDA), its Secretary, and Administrator of Department's Animal and Plant Health Inspection Service (APHIS), challenging rule allowing, and setting conditions for, resumption of importation of Spanish clementines, which had been suspended following discovery of live Mediterranean fruit fly (Medfly) larvae.

Holdings: On cross-motions for summary judgment, the District Court, [Wanger](#), J., held that:

[1] APHIS acted within scope of its authority in promulgating rule;

[2] APHIS did not act arbitrarily or capriciously;

[3] promulgation of rule comported with Regulatory Flexibility Act (RFA);

[4] Plant Protection Act's “sound science” procedures were comported with; and

[5] environmental assessment (EA) or environmental impact statement (EIS) were not required.

USDA's motion granted.

West Headnotes (15)

[1] Evidence [Proceedings in other courts](#)

Federal court may take judicial notice of proceedings in other courts, both within and without federal judicial system, if those proceedings have direct relation to matters at issue. [Fed.Rules Evid.Rule 201](#), 28 U.S.C.A.

[30 Cases that cite this headnote](#)

[2] Agriculture [Destructive insects, birds, and other animals, and diseases of plants](#)

Department of Agriculture (USDA) rule allowing, and setting conditions for, resumption of importation of certain foreign fruit was reviewable under APA abuse-of-discretion standard, not de novo, on domestic growers' challenge to rule, regardless of growers' contention that their argument that adoption of rule violated Plant Protection Act and other statutes raised purely legal issues; USDA's decision to adopt rule was made partly based on facts concerning mitigation of fruit fly infestation, and thus had to be reviewed for reasonableness, and presented mixed questions of law and fact. [5 U.S.C.A. § 706\(2\)\(A, C\)](#); [7 C.F.R. § 319.56–2jj](#) [7 C.F.R. § 319.56–2jj](#).

[3] Evidence [Nature and scope in general](#)

Matter is not properly subject to judicial notice by federal court if it involves central and disputed issue. [Fed.Rules Evid.Rule 201](#), 28 U.S.C.A.

6 Cases that cite this headnote

[4] **Evidence** ➡ Nature and scope in general

Federal court may take judicial notice of public record which has direct relation to matters at issue, but only of existence of those matters of public record, i.e. existence of public document or of representations in document, not of veracity of arguments or disputed facts in document. [Fed.Rules Evid.Rule 201](#), 28 U.S.C.A.

36 Cases that cite this headnote

[5] **Evidence** ➡ Official proceedings and acts

Federal district court hearing challenge to Department of Agriculture (USDA) rule allowing, and setting conditions for, resumption of importation of certain foreign fruit would take judicial notice of USDA report presenting data on insect infestation for period following rule's adoption, and of self-authenticating published USDA letter that also postdated adoption, over objections including fact that documents were not part of administrative record; documents, which were relevant to show USDA's experience with operation of rule, would be noticed for existence and authenticity, but not for accuracy or validity of their contents. [Fed.Rules Evid.Rules 201, 902, 1005](#), 28 U.S.C.A.; [Fed.Rules Civ.Proc.Rule 44](#), 28 U.S.C.A.

6 Cases that cite this headnote

[6] **Administrative Law and Procedure** ➡ Findings; reason or explanation

Although federal agency should articulate reasoning behind its findings justifying adoption of rule, agency need not prepare formal findings of fact in support of decision to adopt rule.

[7] **Agriculture** ➡ Destructive insects, birds, and other animals, and diseases of plants

Animal and Plant Health Inspection Service (APHIS) of Department of Agriculture (USDA) acted within scope of its authority under Plant Protection Act in adopting rule allowing,

and setting conditions for, resumption of importation of Spanish clementines, which had been suspended following discovery of live Mediterranean fruit fly (Medfly); USDA's responsibilities for plant protection and quarantine had been delegated to APHIS, APHIS had conducted complete investigation into causes of Medfly importation, and methodology and safeguards contained in rule were reasonable method of protecting domestic agriculturists against infestation. Plant Protection Act, § 412(a, c), [7 U.S.C.A. § 7712\(a, c\)](#); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, § 331(a), [7 U.S.C.A. § 8320\(a\)](#); [7 C.F.R. §§ 319.56–2jj](#)[7 C.F.R. §§ 319.56–2jj](#), 371.3.

2 Cases that cite this headnote

[8] **Administrative Law and Procedure** ➡ Effect of agency's authority or lack thereof

Party challenging federal agency's adoption of rule on scope-of-authority grounds bears burden of making clear showing that action exceeded agency's authority.

[9] **Administrative Law and Procedure** ➡ Review for arbitrary, capricious, unreasonable, or illegal actions in general

Federal agency action is arbitrary and capricious within meaning of Administrative Procedure Act (APA) when agency: (1) relies on factors which Congress did not intend agency to consider; (2) entirely fails to consider particularly relevant factors; (3) provides explanation for decision which is contradicted by evidence; or (4) reaches decision so implausible that it cannot be said to be mere difference of interpretation or product of agency's expertise. [5 U.S.C.A. § 706\(2\)\(A\)](#).

1 Cases that cite this headnote

[10] **Administrative Law and Procedure** ➡ Consideration of new or additional evidence

Administrative Law and Procedure → Grounds, factors, and considerations

In reviewing reasonableness of federal agency decision, court may consider evidence outside administrative record: (1) when record needs to be expanded to explain agency action; (2) when agency has relied upon documents or materials not included in record; (3) to explain or clarify technical matter involved in agency action; and (4) where there has been strong showing in support of claim of bad faith or improper behavior on agency's part. 📄 5 U.S.C.A. § 706(2)(A).

4 Cases that cite this headnote

[11] **Courts** → Decisions of United States Courts as Authority in Other United States Courts

Doctrine of stare decisis does not compel one district court judge to follow decision of another.

1 Cases that cite this headnote

[12] **Agriculture** → Destructive insects, birds, and other animals, and diseases of plants

Department of Agriculture (USDA) did not act arbitrarily or capriciously in promulgating rule allowing, and setting conditions for, resumption of importation of Spanish clementines, which had been suspended following discovery of live Mediterranean fruit fly (Medfly) larvae; USDA expressly relied on extensive scientific studies to reach its conclusions, and, contrary to domestic growers' contention that rule failed to set exact numeric threshold of "acceptable" risk and thereby acquiesced in risk of importation, set goal of zero infestation and adopted methods reasonably calculated to reduce risk to level of 32 surviving specimens per million imported. Plant Protection Act, §§ 402(3–4), 411(b), 412(a, c), 7 U.S.C.A. §§ 7701(3–4), 7711(b), 7712(a, c); 7 C.F.R. § 319.56–2jj 7 C.F.R. § 319.56–2jj.

[13] **Agriculture** → Destructive insects, birds, and other animals, and diseases of plants

Department of Agriculture (USDA) comported with Regulatory Flexibility Act (RFA) in promulgating rule allowing, and setting conditions for, resumption of importation of Spanish clementines, which had been suspended following discovery of live Mediterranean fruit fly (Medfly) larvae; USDA reasonably certified that rule would not have significant economic impact on substantial number of small businesses, given factors including relatively low percentage of income derived by small wholesalers from clementine sales, and domestic growers opposed to rule failed to provide support for their prediction of possibility of catastrophic infestation. 📄 5 U.S.C.A. § 605(b); 7 C.F.R. § 319.56–2jj 7 C.F.R. § 319.56–2jj.

[14] **Agriculture** → Destructive insects, birds, and other animals, and diseases of plants

Department of Agriculture (USDA) comported with "sound science" procedures required by Plant Protection Act in promulgating rule allowing, and setting conditions for, resumption of importation of Spanish clementines, which had been suspended following discovery of live Mediterranean fruit fly (Medfly) larvae; USDA conducted numerous scientific studies which were relied upon, analyzed, and discussed in reaching conclusions giving rise to rule, and domestic growers opposed to rule presented no evidence of lack of sound science. Plant Protection Act, §§ 411(a), 412(a–c), 421, 7 U.S.C.A. §§ 7711(a), 7712(a–c), 📄 7731; 7 C.F.R. § 319.56–2jj 7 C.F.R. § 319.56–2jj.

[15] **Environmental Law** → Necessity

Environmental Law → Particular Projects

Department of Agriculture (USDA) was not required under National Environmental Policy Act (NEPA) to file either environmental assessment (EA) or environmental impact statement (EIS) for new rule allowing, and setting conditions for, resumption of importation of Spanish clementines, which had been suspended following discovery of live

Mediterranean fruit fly (Medfly) larvae; nature and purpose of rule was to protect human health and environment, and USDA reasonably judged rule to be within regulations' categorical exclusions from EA/EIS requirement. National Environmental Policy Act of 1969, § 102, [42 U.S.C.A. § 4332](#); 7 C.F.R. §§ 319.56–2jj [7 C.F.R. §§ 319.56–2jj](#), [372.5\(c\)](#).

[2 Cases that cite this headline](#)

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MEMORANDUM DECISION AND ORDER RE:

(1) PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT; (2) FEDERAL DEFENDANTS' MOTION FOR SUMMARY JUDGMENT; (3) FEDERAL DEFENDANTS' REQUEST FOR JUDICIAL NOTICE; and (4) INTERVENOR–DEFENDANTS' REQUEST FOR JUDICIAL NOTICE

(DOCS. 23, 31, 34, and 39)

[WANGER](#), District Judge.

I. INTRODUCTION

Cactus Corner, LLC, Venida Packing Company, California Citrus Mutual, and the California Grape and Tree Fruit League (“Plaintiffs”) sue the United States Department of Agriculture, Secretary of Agriculture Ann M. Veneman, and Bobby R. Acord, the Administrator of the Department of Agriculture's Animal and Plant Health Inspection Service (“Defendants” or “Federal Defendants”) seeking judicial review of a final rule entitled “[Importation of Clementines from Spain](#)” (the “Rule”) promulgated in [67 Fed.Reg. 64702 \(October 21, 2002\)](#), effective October 15, 2002. *See* Doc. 1, Complaint for Declaratory and Injunctive Relief (“Complaint”) at ¶¶ 1, 4–10. Plaintiffs advance four claims, that the Rule is: (1) inconsistent with and in excess of Defendants' statutory authority under the Plant Protection Act, 7 U.S.C. §§ 7701 *et seq.*, as provided in section 10 of the Administrative Procedure Act, [5 U.S.C. § 706\(2\)\(C\)](#); (2) “arbitrary, capricious, an ***1079** abuse of discretion, and otherwise not in accordance with law” as provided in section 10 of the Administrative Procedure Act, [5 U.S.C. § 706\(2\)\(A\)](#); (3) violative of the Regulatory Flexibility Act, [5 U.S.C. §§ 601 et seq.](#), and fails to observe procedure required by law, namely the preparation of an initial or final regulatory flexibility analysis for the Rule required by the Regulatory Flexibility Act (RFA), the decisional standards required under the PPA, and (4) violative of section 102 of the National Environmental Policy Act (“NEPA”), [42 U.S.C. § 4332](#). *See id.* at 10. Plaintiffs seek declaratory and injunctive relief to set aside and hold the Rule unlawful, to enjoin Defendants from implementing it or otherwise allowing the importation of clementines from Spain. *See id.* at 10. Plaintiffs also seek an award of costs, disbursements, and reasonable attorneys' fees. *See id.*

On November 12, 2002, InterCitrus, Ibertrade Commercial Corporation, LGS Specialty Sales, Ltd., and Luke G. Sears (Intervenor Defendants) moved under [Fed.R.Civ.P. 24\(a\)\(2\)](#) to intervene in the case as a matter of right. *See* Doc. 6. On December 20, 2002, the motion to intervene was granted. *See* Doc. 11, filed Jan. 7, 2003.

Plaintiffs move for summary judgment. *See* Doc. 23, filed Mar. 24, 2003, and Doc. 24. Federal Defendants filed a cross-motion and supporting memorandum for summary judgment.¹ *See* Doc. 31, filed Apr. 25, 2003, and Doc. 32. Intervenor–Defendants filed opposition. *See* Doc. 30 filed Apr. 22, 2003. Plaintiffs filed opposition to Federal Defendants' motion and a response to Intervenor–Defendants'

opposition to Plaintiffs' motion. *See* Doc. 38 filed May 27, 2003. Federal Defendants filed a response to Plaintiffs' opposition. *See* Doc. 43 filed Jun. 19, 2003.

Pursuant to [Fed.R.Evid. 201](#), Federal Defendants request the Court take judicial notice of a report entitled “Spanish Clementine Data Report and Analysis,” published on the website of the United States Department of Agriculture, Animal and Plant Health Inspection Service (“APHIS”). *See* Doc. 34, filed Apr. 28, 2003. Intervenor–Defendants request the Court take judicial notice of a letter entitled “Clementine Stakeholder Letter,” authored by the Department of Agriculture and published on its website. *See* Doc. 39, filed Jun. 10, 2003. Plaintiffs objected to both requests. *See* Doc. 35 filed May 1, 2003, and Doc. 40, filed Jun. 16, 2003. Intervenor–Defendants filed a supporting memorandum. *See* Doc. 36, filed May 8, 2003.

A. Jurisdiction.

Jurisdiction over the parties exists under [28 U.S.C. § 1331](#) and authority to grant the declaratory and injunctive relief sought by Plaintiffs is provided under [28 U.S.C. § 2201](#) and [5 U.S.C. §§ 705](#) and [706](#). Oral argument was heard on January 8, 2004.

II. BACKGROUND

A. Undisputed Material Facts

On March 24, 2003, the parties submitted a statement of stipulated facts pursuant to Local Rule 56–260(c).² *See* Doc. 25. *1080 The parties agree that “this action for judicial review of an agency rule can be decided by the Court on the basis of the Motion, Opposition thereto and Cross–Motions for Summary Judgment, the responsive pleadings, the stipulated facts set forth below, and the Administrative Record filed by the Federal Defendants–on the understanding that, to do so, the Court will have to examine the portions of the Administrative Record (AR) cited by the parties.”³ *See id.* at 1–2:28–5. The parties further stipulated that “[b]ecause this case involves judicial review under the Administrative Procedure Act, [5 U.S.C. § 706\(2\)](#), the Court's decision on the cross-motions for summary judgment does not involve an inquiry into whether there are any genuine issues of material fact.” Doc. 25 at 2:5–7 (citing [Northwest Motorcycle Association v. United States Department of Agriculture](#), 18

[F.3d 1468, 1472 \(9th Cir.1994\)](#); [Environment Now! v. Espy](#), 877 F.Supp. 1397, 1421 (E.D.Cal.1994)).

The parties agree the following are undisputed material facts:

1. On December 5, 2001, following reports of live Mediterranean fruit fly (“Medfly”) larvae being found in Spanish clementines purchased at retail outlets in a number of states, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (“APHIS”) suspended imports of clementines from Spain indefinitely and initiated an investigation. (Doc. 25 at 2:10–13).
2. On July 11, 2002, APHIS published a proposed rule that would authorize a resumption of Spanish clementine imports on specific conditions. [67 Fed.Reg. 45922](#). APHIS held two public hearings and accepted comments on the proposal until September 9, 2002. (*See id.* at 2:14–16).
3. On October 15, 2002, APHIS promulgated the final rule (“Rule”) that is the subject of this action. The Rule, which was published in the Federal Register on October 21, 2002, [67 Fed.Reg. 64702](#), allows the importation of clementines grown in regions of Spain where Medfly is found—as long as certain conditions specified in the Rule are met. (*See id.* at 2:17–20).
4. APHIS did not prepare an initial or final regulatory flexibility analysis for the Rule, because it determined that the Rule will not have a significant economic impact on a substantial number of small entities. That determination was based on a Regulatory Impact Analysis dated October 15, 2002.
5. The relevant facts for purposes of judicial review are contained in the Administrative Record that APHIS filed with the Court on February 13, 2003. The parties hold differing views as to the meaning, significance, and implications of these facts and will express those views, with appropriate references *1081 to the Administrative Record, in their respective pleadings. (*See id.* at 2:25–28).

B. Factual Background

i. Events Leading up to the Import Suspension of Spanish Clementines in 2001

Clementines (several varieties of *Citrus reticulata*) from Spain have been imported into the United States for over fifteen years. *See* A.R. 1230. (“The U.S. Department of Agriculture (USDA) has allowed the importation of

clementines from Spain since 1985.” A.R. 1130). Prior to the import ban of 2001, Federal Defendants allowed the importation of Spanish clementines under a regimen of cold treatment that was designed to prevent the risk of the Mediterranean Fruit Fly (“Medfly”) using the imported citrus as a pathway into the United States. *See* A.R. 1130, 1238.

The pre-ban cold treatment regimen was specified in the Plant Protection and Quarantine Manual (7 C.F.R. § 300.1), which required fruit to be held at the following temperatures:

Temperature	Exposure Period (Days)
32°F or below	10
33°F or below	11
34°F or below	12
35°F or below	13
36°F or below	14

lines

Pursuant to 7 C.F.R. § 319.56–2(e), Federal Defendants allowed the import of Spanish clementines under permit, subject to inspection at the port of entry to ensure the implementation of cold treatment measures. *See* A.R. 1130; *see also*, Statement of Dr. Inder P.S. Gadh (“Gadh”), APHIS Officer, A.R. 1054 (Inspection at the port of entry was “to verify the cold treatment documents, to take pulp temperatures, and also to do some spot checking for other pest other than the fruit fly.”) “Prior to November and December 2001, there had never been multiple confirmed finds of Medflies in fruit of any kind that had been legally imported into the mainland United States from any source.” *See* A.R. 1130. According to Dr. Gadh, the cold treatment regimen “worked very well since its inception in 1985 other than sporadic incidents of some shipments not making cold treatment or some suspicious looking fruit flies being reported as live but turned out to be dead, when checked.” *See* Gadh, A.R. 1054. Throughout the history of importation of clementines from Spain, “there was no [sic] major incidents to thwart or to raise alarms,” until late 2001. *See* A.R. at 1054.

Between late November and December 2001, APHIS began receiving reports of live Medfly larvae in clementines from Spain. *See* Doc. 19, Notice of Filing, A.R. 1282, 67 Fed.Reg. 64702, filed Feb. 25, 2003.⁴ A list of live Medfly larvae finds discovered in clementines imported from Spain includes:

(1) On November 20, 2001, live Medfly larvae were found in Avon, North Carolina by a consumer, who was also a North Carolina Department of Agriculture official.⁵ *See* A.R. 87, Richard L. Dunkle Letter to the Honorable Luis M.

Esteruelas, *1082 dated Jan. 4, 2002. A North Carolina State Agriculture Inspector was able to collect 4–5 live pupae⁶ from the infested clementine. *See id.* at 121, Letter to Noboru Saito, dated Dec. 19, 2001. The fruit in which larvae were detected were traced back to a shipment aboard the “M/V Green Maloy” which arrived in Philadelphia on November 10, 2001. *See id.* at 87.

(2) On November 27, 2001, live larvae were found by an APHIS employee in Bowie, Maryland, and were confirmed to be alive by a Plant Protection & Quarantine (“PPQ”) Identification staff specialist. *See id.* The infested fruit was traced back to the “M/V Green Maloy” and was also found in “Nadel” brand Spanish clementines. *See id.* at 88.

(3) On December 3, 2001, in Santa Clara County, California, live larvae were found in Spanish clementines by county agriculture officials. *See id.* Fourteen “third instar” larvae were detected, four or five of which were alive. *See* A.R. at 121. The infested fruits were identified as “Bagu” brand, *see id.* at 88, were not in their original boxes, and were re-labeled as “LOT 4450 CUTIES,” a California brand. *See* A.R. at 121. The clementines were from Nob Hill Foods in San Jose, California, an urban supermarket not within close proximity to any citrus-producing areas. *See id.*

(4) On December 4, 2001, eight live larvae were found by APHIS and PPQ officers in Shreveport, Louisiana. *See id.* at 88; A.R. at 166, Clementine Oranges from Spain: Talking Points (“Talking Points”), dated Dec. 5, 2001. “The larvae were identified as Tephritidae, and the only Tephritid in Spain is Medfly.” *See* Talking Points at 166. The infested fruit was

traced back to a shipment which arrived on November 7, 2001 on the “M/V Japan Senator” in Newark, New Jersey. *See* A.R. at 88. The clementines were identified as “Evyan” brand and the “Japan Senator” contained four (4) containers of “Evyan” brand Spanish clementines: HJCU 6986080, HJCU 6010734, HJCU 6984683, and HJCU 6051271. *See id.*

(5) On December 6, 2001, live larvae were found in Riverside and San Diego Counties, in the State of California, by county agriculture officials. *See id.* The infested fruit was found in “Elite” and “Llusar” brand Spanish clementines. *See id.*

(6) On December 7, 2001, county agriculture officials in Riverside County, California, found live larvae in “Bagu” and “Llusar” brand Spanish clementines. *See id.*

In addition to live Medfly larvae found in Spanish clementines, APHIS inspectors “found hundreds of dead larvae [during] the 2001 shipping season.” *See id.* at 115, APHIS Letter to Congressman Robert A. Borski, dated Apr. 22, 2002. The “unusually high number of dead Medfly [larvae] reported” is “indicative of an unusually high Medfly infestation in fruit coming from Spain this shipping season.” *See id.* at 163, Richard L. Dunkle Letter to Dr. Raphael Milan (“Letter Suspending Spanish Clementine Imports”), dated Dec. 5, 2001. Following these finds, APHIS initiated fruit cutting measures at United States’ ports of entry to ensure that appropriate cold treatment measures were in place. *See id.* at 126. On November 30, 2001, APHIS notified the Spanish Government that clementine imports were suspended pending completion of an investigation. *See id.* On December 4, 2001, APHIS notified the Government of Spain that clementine imports would resume on *1083 December 5th, after preliminary investigations indicated that the anomaly was limited to the “M/V Green Maloy.”⁷ *See id.* at 126; *see also*, A.R. 95–109, Cold Treatment Records for the M/V Green Maloy. The following day, APHIS notified the Spanish Government that “it was suspending the importation of clementines [,]” that “all shipments of clementines from Spain were refused entry into the United States,” and “restrictions on the marketing of Spanish clementines that had already been released into domestic commerce” would take effect immediately. *See* A.R. 1282, Final Rule, 67 Fed.Reg. 64702.

ii. *The December 5, 2001 Import Suspension, the Dangers Associated with the Mediterranean Fruit Fly, and the Secretary of Agriculture’s Authority under Section 7712(a) of the Plant Protection Act*

On December 5, 2001, based on the findings of live Medfly larvae in clementines imported from Spain, APHIS took the “emergency action of suspending the entry of Clementine citrus from Spain.” *See* Letter Suspending Spanish Clementine Imports. The same day, APHIS wrote clementine Stakeholders, stating the danger of the possibility of Medfly introduction in the United States and the remedial measures taken:

The Medfly (*Ceratitis capitata*) is one of the world’s most destructive agricultural pests, threatening more than 20 kinds of fruits, nuts, and vegetables. The female Medfly attacks ripening fruit, piercing the soft skin and laying eggs in the puncture. The eggs hatch into larvae, which feed inside the fruit pulp. The United States has no established Medfly populations, and USDA has taken the following steps to guard against further introduction:

- All imports of clementines from Spain are suspended until further notice.
- Clementines cannot be moved into the following States due to climatic conditions and host materials that are favorable to Medflies: Alabama, Arizona, Arkansas, California, Florida, Georgia, Louisiana, Mississippi, North Carolina, Nevada, New Mexico, Oklahoma, Oregon, South Carolina, Tennessee, Texas, and Washington. This prohibition includes Puerto Rico.
- Wholesalers and retailers may not sell or distribute clementines from Spain in the States listed above. The fruit must be removed from retail shelves and held for destruction in the States listed above or shipped to approved States.
- Destruction or movement of fruit should be with advance approval from State agriculture or local USDA Plant Protection and Quarantine (PPQ) officials. State and PPQ contacts may be found on the APHIS website at www.aphis.usda.gov/ppq.
- States that can receive Spanish clementines from prohibited States are as follows: Idaho, Iowa, Utah, Montana, Wyoming, West Virginia, Colorado, Kansas, Nebraska, South Dakota, North Dakota, Minnesota, Wisconsin, Illinois, Missouri, Indiana, Michigan, Ohio, Kentucky, Virginia, Pennsylvania, Maryland, Delaware, Hawaii, New Jersey, the District of Columbia, Rhode Island, Massachusetts, New York, New Hampshire, Vermont, *1084 Montana, Maine, Alaska, and Connecticut.

- Spanish clementines already in the United States will be authorized movement to Canada by USDA, PPQ officials on a case-by-case basis.”

See A.R. at 164–65. At the same time, the Spanish Government dismissed the reports that live Medfly larvae were found in clementines imported from Spain, stating that “cold treatment eliminates any possibility whatsoever of the larvae... surviving[.]” and that, as a result, “the presence of live larvae in the Spanish clementines defies explanation.” See A.R. at 173, Letter from Miguel Arias Cañete, Minister of Agriculture, Fisheries & Food of Spain to Ann M. Veneman, dated Dec. 5, 2001. On December 12, 2001, Mr. Luis M. Esteruelas, on behalf of the Spanish Ministry of Agriculture, requested that APHIS provide: (1) “evidence to date of all of the instances of larvae that has motivated USDA’s decision to suspend the importation of Spanish clementines into the United States...”; and (2) the entomological analyses of the larvae discovered. See Esteruelas Letter to Bill Hawks, Under Secretary for Marketing and Regulatory Programs, USDA, dated Dec. 12, 2001, at A.R. 133. The Spanish Ministry of Agriculture offered their full cooperation, stressing that “finding a solution to this matter is of the utmost urgency for the Spanish government and especially for the Ministry of Agriculture.” See *id.*

According to Dr. Gadh, APHIS’ decision to suspend imports of clementines “was not taken well by Spain and...some importers here in the USA who decided to take the matter to the court.” See Gadh, A.R. 1055. Dr. Gadh opined: “APHIS had to take that action. There was no choice. And we did what we had to do to safeguard our resources and also to protect markets at the time.” See *id.* Intervenor–Defendants filed suit in the United States District Court for the Eastern District of Pennsylvania seeking declaratory and injunctive relief against the USDA/APHIS’ clementine import suspension. See Doc. 6 at 4:18–21. In a subsequent correspondence with APHIS, Intervenor–Defendants disputed the viability of the larvae discovered: “It is our understanding that the larvae were of dubious nature, especially those found in California. Inspectors stated that they were ‘possible [sic] alive’. All were of ‘brownish’ color, not the typical cream color of live larvae, and with the exception of one, all were found in supermarkets, far from the ‘point of entry.’” See A.R. at 205.

The decision to prohibit the importation of Spanish clementines, taken by the Secretary of Agriculture, was made pursuant to her authority under the Plant Protection Act (“PPA”), 7 U.S.C. §§ 7701 *et seq.* See Final Rule at 64702–

03, A.R. 1282–83; see 7 U.S.C. § 7712(a). Under Section 7712(a) of the PPA, the Secretary of Agriculture is authorized to prohibit or restrict the importation or entry of any plant product “if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States...of a plant pest...” like the Medfly, which is not widely distributed within the United States. See 7 U.S.C. § 7712(a). The Secretary should exercise her authority to restrict or prohibit the entry of a plant product into the United States where its entry “could present an unacceptable risk of introducing or spreading plant pests.” See 7 U.S.C. § 7701(7). This exercise of authority was taken after multiple live Medfly larvae finds in the United States because Medfly is “the hoof and mouth, or foot and mouth disease of the fresh food industry, probably of the entire plant industry. This is indeed the worst of the worst. It is an extremely plastic, dynamic, adaptable pest *1085 worldwide, not just in the United States, one of the key pests of fruit production.” See A.R. 1071, Statement of APHIS Official, Dr. Ron Sequeira (“Sequeira”), Public Hearing on Importation of Spanish Clementines, Oxnard, California, Aug. 20, 2002 (“Aug. 20, 2002 Hearing”). Dr. Sequeira opined that the possibility of the introduction of Medfly into citrus-producing areas of the United States “is more than an economic issue. It is a national security issue.” See *id.* at 1072.

iii. *Post–Import Suspension Actions taken by APHIS and the Spanish Government, leading up to the Final Rule*

Immediately after hearing reports that live Medfly larvae discoveries were made in clementines imported from Spain, a team of APHIS specialists visited Spain in mid-December 2001 to investigate the causes of the breakdown. See Spanish Clementine Program Technical Review, A.R. 1788–1800; see Gadh, A.R. 1055–56; see A.R. 1131. The APHIS review team visited clementine orchards, groves and packing houses throughout Spain, in addition to meeting with Spanish and Generalitat Valenciana government representatives.⁸ See Gadh, A.R. at 1055–56. During APHIS’ field visit to groves in the Autonomous Community of Valencia, “it became apparent that trapping and bait spray activities under industry control lacked both consistency and direct Ministry [of Agriculture] oversight.” See Spanish Clementine Program Technical Review, A.R. 1789. APHIS deduced that “these programs are a voluntary ‘best management practice’ and that there are no adverse consequences for noncompliance.” See *id.* The APHIS review team surmised that “[m]any [Spanish] growers may not see the need to participate in established trapping and treatment protocols due to endemic fruit fly

populations and the specific knowledge that fruit will be subject to cold treatment prior to being marketed in the United States.” *See id.*

The review team was unable to determine the exact cause of the failure, but identified several conditions that may have contributed to an overwhelming larval presence: (1) unseasonably warm weather conditions; (2) higher than average fruit fly populations; (3) high host susceptibility of the early season clementine varieties; (4) low trap densities and inadequate bait spray applications; and (5) lack of any fruit cutting activities to adequately monitor larval populations. *See id.* In its final report, the APHIS review team “suggested that a more integrated system approach uncertainty by providing overlapping measures to strengthen several critical points in the certification process.” *See* Doc. 24, Appendix 1, *APHIS Backgrounder*, “Plant Protection and Quarantine—Spanish Clementine”, dated Jan. 9, 2002. APHIS believed that a “systems approach concept would provide additional quarantine security, even if one or more components of the overall protocol fail.” *See id.* “Systems approach” is defined in 7 U.S.C. § 7702(18) as “a...set of phytosanitary procedures, at least two of which have an independent effect in mitigating pest risk associated with the movement of commodities.” *See* 7 U.S.C. § 7702(18). The APHIS review team's visit to Spain led to a study and report required under 7 U.S.C. § 7712(e).⁹

*1086 As a result, APHIS reviewed the evidence and issued a report entitled “Risk mitigation for tephritid fruit flies with special emphasis on risk reduction for commercial imports of clementines (several varieties of *Citrus reticulata*) from Spain using a Phytosanitary Hazard Analysis and Critical Control Point (PHAACP) system,” in March 2002. *See* A.R. 373 (published on April 16, 2002, A.R. 371, 67 Fed.Reg. 18578). The purpose of the Risk Mitigation Analysis (“RMA”) was to describe and evaluate the “systems approach” chosen by APHIS and other risk-mitigating measures associated with the importation of clementines from Spain. *See id.* Public comment was solicited for thirty (30) days after publication of the RMA, *see* A.R. 371, and was extended by notice in the Federal Register until June 14, 2002. *See* A.R. 321, 67 Fed.Reg. 36560–61.

The RMA concluded that two critical control points were essential to prevent the establishment of Medfly in citrus-growing areas of the United States: (1) the application of cold treatment [in transit and storage]; and (2) the limitation of pests in the field [in Spain]. *See* A.R. 1394. The RMA goal

was to achieve “Probit 9” mortality, which is acknowledged to be “a historical, well-recognized benchmark in the area of phytosanitary security.” *See* A.R. 1285. The term “Probit 9” refers to “a level or percentage of mortality of target pests (i.e., 99.9968 percent mortality or 32 survivors out of a million) caused by a control measure.” *See id.* at 1284. Using the available evidence, APHIS determined that “the likelihood of a mated pair in fruit from Spain was less than one in two thousand years, considering the 95th percentile of the distribution (less than one in more than ten thousand years using the mean of the distribution), even assuming multiple containers shipped to suitable areas.” *See* A.R. 1394. According to Ed Miller, an entomologist with APHIS' Risk Analysis Systems, the results of the RMA “show [] a minimization of the probability that a mated pair arrives at an area where it would cause trouble,” when effective cold treatment and other control measures are in place. *See* A.R. 990–91. Miller emphasized that the key to success is “quality control,” stating that “[w]e need documentation and verification and transparency and communication, and research and methods development.” *See id.* at 991.


iv. Adoption of the Rule

The proposed rule, published in the Federal Register on July 11, 2002, harmonized the goals of APHIS in preventing Medflies from using clementines imported from Spain as a pathway for introduction and the goals of the U.S. and Spanish Governments in promoting trade. *See* A.R. 1129–40, 67 Fed.Reg. 45922–33. The rule, which *1087 would require improved field control and quality control guidelines, represented a major improvement from the prior inspection regimen. *See id.* Major features of the proposed rule include:

- Requiring Spanish growers to register and enter into an agreement with the Spanish Government to follow a mandatory pest management program, established by the Spanish Government and approved by APHIS, before exporting to the United States;
- Improved monitoring and field control procedures designed to greatly reduce the number of viable Medfly larvae in clementines upon arrival to packing houses;
- Spanish Government and/or direct APHIS oversight to monitor and record compliance with the program, the number of Medflies caught in the traps and further compliance with FDA pesticide residue regulations;
- APHIS will oversee inspection and fruit cutting before cold treatment in order to detect Medfly larvae. If a

single live Medfly is found in any shipment, the entire shipment will be rejected and no reconditioning or repackaging of fruit will be allowed. If live Medfly larvae are found in any two shipments from a particular grove or grower, that grove/grower will be removed from the U.S. Export Program for the remainder of the clementine season.

In addition, the proposed rule notified stakeholders that APHIS was soliciting comments for sixty (60) days, ending on September 9, 2002. *See* A.R. 1129, [67 Fed.Reg. 45922](#). Two public hearings were also held on August 20, 2002 in Oxnard, California, *see* A.R. 1050–1127, and on August 22, 2002 in Lake Alfred, Florida. *See* A.R. 973–1049. At the Oxnard Public Hearing, Dr. Gadh stated that “[the] conditions under which the Spanish clementines may be imported are that [the] Spanish government will have to institute a Medfly management program which is aimed to reduce the fruit fly infestation to less than 1.5 percent of the fruits.” *See* A.R. 1057. Furthermore, the proposed rule and conditions under which imports may be resumed constitute “a full fledged pre-clearance program set up in Spain.” *See id.*

As required by  [Executive Order 12866, 1993 WL 388305](#), APHIS prepared a Regulatory Impact Analysis (“RIA”) on October 15, 2002, which concluded that regulatory benefits outweigh regulatory costs associated with implementation of the rule, *see* A.R. 1323, and that a regulatory flexibility analysis was not necessary because the proposed rule “will likely not have a significant economic impact on a substantial number of small Medfly host crop producers in the United States.” *See* A.R. 1334; *see also*, A.R. 1318.

v. The Final Rule

On October 22, 2002, APHIS published the Final Rule, *see* 7 C.F.R. § 319.56–2jj [7 C.F.R. § 319.56–2jj](#) (the Rule), effective October 15, 2002, which authorized the resumption of Spanish clementine imports, subject to several new remedial measures which had not existed under [7 C.F.R. § 319.56–2\(e\)](#).¹⁰ Under [*1088](#) the “new Rule” of [7 C.F.R. § 319.56–2jj](#) [7 C.F.R. § 319.56–2jj](#), persons who produce clementines in Spain for export to the United States are required to register with the Government of Spain and enter into an agreement to participate and follow the Medfly management program established by the Spanish Government. The Rule requires the Spanish Government to obtain APHIS approval of Spain’s Medfly management program which, in turn is subject to compliance monitoring by APHIS inspectors, and includes

requirements for fruit fly specifications for trapping and recordkeeping. More specifically, the Rule requires Spanish producers to place traps in Medfly host plants at least 6 weeks prior to harvest and to utilize APHIS-approved pesticide bait treatments in the production areas at the rate specified by Spain’s Medfly management program (also subject to APHIS approval).

The Rule also requires the Spanish Government to keep records documenting the trapping and control activities for all areas that produce clementines for United States export and to make these records available to APHIS upon request. If APHIS determines that an orchard does not operate in compliance with these regulations, it may suspend clementine exports to the U.S. from that orchard. All clementines imported to the U.S. under this rule, must be accompanied by a phytosanitary certificate stating that the fruit meets the conditions of the Government of Spain’s Mediterranean fruit fly management program and applicable APHIS regulations. Under the Rule, boxes in which clementines are packed must be labeled with a lot number which identifies the orchard where the fruit was grown and the packinghouse where the fruit was packed and must display the following statement: “Not for distribution in AZ, CA, FL, LA, TX, Puerto Rico, and any other U.S. Territories.” In addition, the rule provides that for each and every shipment of clementines intended for export to the United States, prior to cold treatment, APHIS inspectors will cut and inspect 200 fruit that are randomly selected from throughout the shipment and, should a single live Medfly in any stage of development be discovered, the entire shipment of clementines will be rejected.¹¹ If a live Mediterranean fruit fly in any stage of development is found in any two lots of fruit from the same orchard during the same shipping season, that orchard will be removed from the export program for the remainder of that shipping season. This random cut inspection is an added level of testing to enhance success of cold treatment efficacy.¹²

One of the most significant protective measures the Rule implements is the change in cold treatment protocol. A *revised* cold treatment schedule has been adopted and is incorporated by reference [*1089](#) at [7 C.F.R. § 300.1](#) in the Plant Protection and Quarantine (PPQ) Treatment Manual. Under this revised cold treatment schedule,¹³ the minimum exposure period for cold treatment is fourteen (14) days, where the temperature applied is 34 degrees or below, ranging up to a requirement of sixteen (16) days if the temperature applied is 35 degrees or below, and up to a maximum requirement of eighteen (18) days, where the temperature

applied is 36 degrees or below. A.R. 1288. These changes add a minimum of two days more of cold treatment for each degree of temperature rise above 32. For cold treatment at temperatures of 32 degrees or below, the Rule's application schedule adds four days; former application time was 10 days for 32 degrees, now, the minimum application period is 14 days. *Id.* The ORACBA analysis increases application periods for cold treatment to ensure even greater prevention than before, based on reliable studies that show that increasing the length of cold treatment applications yields substantially more protection than lowering the temperature. A.R. at 1211, 1220. Scientific study of cold treatment and the extent of its effectiveness in eradication of Medfly continues along with debate among researchers. A.R. at 1220–21. APHIS scientists opine that this revised cold [treatment schedule](#) will achieve a probit 9 level of mortality or even greater. A.R. at 1219, 1288.

Upon arrival of clementines at a United States port of entry, the Rule now requires APHIS inspectors to examine the cold treatment data for *each shipment* to ensure it has been continuous. If APHIS inspectors determine that the cold treatment was not successfully completed, the shipment will be held until appropriate remedial actions have been implemented. The Rule requires an APHIS inspector, at the port of first arrival, to sample and cut clementines from each shipment to detect pest infestation according to sampling rates determined by the Administrator. During this process, if a single live Medfly is found, the shipment will be held and subjected to further investigation and remedial action. The Rule further provides that, if at any time APHIS determines that the safeguards contained in this section are inadequate, it may suspend importation for further investigation as to any deficiency. *See* 7 C.F.R. § 319.56–2jj [7 C.F.R. § 319.56–2jj](#).

The Secretary expressly “determined that it is not necessary to prohibit the importation of clementines from Spain, in order to prevent the introduction into the United States or the dissemination within the United States of a plant pest or noxious weed.” *See* A.R. 1283. The Secretary based her determination on the finding that the protective measures contained in the Final Rule will prevent the introduction of the Medfly into the United States. *See id.* In the rulemaking process, the Secretary was required to: utilize “sound science,” use procedures that were “transparent and accessible,” [7 U.S.C. § 7712\(b\)](#), and to publish procedures and standards that governed consideration of import requests. [7 U.S.C. § 7712\(d\)](#).


Factors that the Secretary considered, include: “(1) A risk management analysis (revised October 4, 2002), (2) a review of the existing cold treatment for clementines from Spain, ‘Evaluation of cold storage treatment against Mediterranean Fruit Fly, *Ceratitidis capitata* (Wiedemann) (Diptera: Tephritidae)’ (May 2, 2002) ..., (3) a quantitative analysis of available data related to cold treatment for Medfly that *1090 was produced by USDA’s Office of Risk Assessment and Cost Benefit Analysis (ORACBA) ..., and (4) the determinations of USDA technical experts.” *See id.*

The Risk Management Analysis (“RMA”) consists of an integrated study and evaluation of five component risks: (1) the number of fruit shipped (number of fruit per container and total amounts per year);¹⁴ (2) fruit infested with larvae in the field;¹⁵ (3) larvae per individual fruit;¹⁶ the effects of cold treatment;¹⁷ *1091 and the likelihood of suitable hosts in the area where clementines are imported and the likelihood of an adult fly emerging from imported fruit finding host material before death.¹⁸ Based upon the integrated application of these five components, the Risk Mitigation Analysis concluded that the probability that a pair of fruit flies *1092 could be enter the United States under the proposed conditions would be less than .001 per year, or one in ten thousand years. A.R. 1408. The probability of a *mated* pair of Medfly being present in a single shipment would be less than one in a million (0.000001). A.R. 1425, Table 4d. The probability that these fruit flies could mate and produce viable larvae in order to repopulate is even more remote. A.R. 1409, 1425.

III. LEGAL STANDARDS

A. SUBJECT MATTER JURISDICTION

The Court “ha[s] an independent obligation to address *sua sponte* whether [it] has subject-matter jurisdiction.”

 [Dittman v. California, 191 F.3d 1020, 1025 \(9th Cir.1999\)](#). United States District Courts have jurisdiction over cases in which the United States is a party. [28 U.S.C. § 1331](#). As the validity of rulemaking by the United States Department of Agriculture, an agency of the United States is at issue, federal subject matter jurisdiction is properly invoked.

B. JUDICIAL NOTICE

“A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known

within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” *FED. R. EVID. 201(b)*. “A court shall take judicial notice if requested by a party and supplied with the necessary information.” *FED. R. EVID. 201(d)*.

Judicially noticed facts often consist of matters of public record, such as prior court proceedings, *see, e.g.*, *Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1198 (9th Cir.1988) (administrative materials), *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir.1994)(city ordinances), *Toney v. Burris*, 829 F.2d 622, 626–27 (7th Cir.1987) (city ordinances and official maps), *Aiello v. Town of Brookhaven*, 136 F.Supp.2d 81, 86 n. 8 (E.D.N.Y.2001) (geological surveys and existing land use maps), and *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir.2000) (taking judicial notice of a filed complaint as a public record).

[1] Federal courts may “take notice of proceedings in other courts, both within and without the federal judicial system, if those proceedings have a direct relation to the matters at issue.” *U.S. ex rel Robinson Rancheria Citizens Council v. Borneo, Inc.*, 971 F.2d 244, 248 (9th Cir.1992).

C. SUMMARY JUDGMENT

Summary judgment is appropriate only “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact.” *FED. R. CIV. P. 56(c)*; *see also* *Maffei v. Northern Ins. Co. of New York*, 12 F.3d 892, 899 (9th Cir.1993). A genuine issue of fact exists when the non-moving party produces evidence on which a reasonable trier of fact could find in its favor viewing the record as a whole in light of the evidentiary burden the law places on that party. *See* *Triton Energy Corp. v. Square D Co.*, 68 F.3d 1216, 1221 (9th Cir.1995); *see also* *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252–56, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The non-moving party cannot simply rest on its allegation without any significant probative evidence tending to support the complaint. *See* *U.A. Local 343 v. Nor-Cal Plumbing, Inc.*, 48 F.3d 1465, 1471 (9th Cir.1994).

[T]he plain language of *Rule 56(c)* mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to *1093 make a showing sufficient to establish the existence of an element essential to the party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be “no genuine issue as to any material fact,” since a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial.


Celotex Corp. v. Catrett, 477 U.S. 317, 322–23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The more implausible the claim or defense asserted by the opposing party, the more persuasive its evidence must be to avoid summary judgment.

See *United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810, 815 (9th Cir.1995). Nevertheless, “[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in its favor.” *Liberty Lobby*, 477 U.S. at 255, 106 S.Ct. 2505. A court's role on summary judgment, however, is generally not to weigh the evidence, *i.e.*, issue resolution, but rather to find genuine factual issues. *See* *Abdul-Jabbar v. General Motors Corp.*, 85 F.3d 407, 410 (9th Cir.1996).

Evidence submitted in support of or in opposition to a motion for summary judgment must be admissible under the standard articulated in *Rule 56(e)*. *See* *Keenan v. Hall*, 83 F.3d 1083, 1090 n. 1 (9th Cir.1996); *Anheuser-Busch, Inc. v. Natural Beverage Distribs.*, 69 F.3d 337, 345 n. 4 (9th Cir.1995). Properly authenticated documents, including discovery documents, although such documents are not admissible in that form at trial, can be used in a motion for summary judgment if appropriately authenticated by affidavit or declaration. *See* *United States v. One Parcel of Real Property*, 904 F.2d 487, 491–492 (9th Cir.1990). Supporting and opposing affidavits must be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. *See* *FED. R. CIV. P. 56(e)*; *Conner v. Sakai*, 15 F.3d 1463, 1470 (9th Cir.1993), *rev'd on other grounds sub nom.* *Sandin v. Conner*, 515 U.S. 472, 115 S.Ct. 2293, 132 L.Ed.2d 418 (1995).

D. SUMMARY ADJUDICATION


The purpose of Rule 56(d) is to salvage some results from the judicial effort involved in evaluating a summary judgment motion and to frame narrow triable issues if the court finds that the order would be helpful with the progress of litigation.


 *National Union Fire Ins. Co. v. L.E. Myers Co. Group*, 937 F.Supp. 276, 285 (S.D.N.Y.1996). An order under Rule 56(d) narrows the issues and enables the parties to more fully recognize their rights, while permitting the court to retain full power to adjudicate all aspects of the case at the proper time. See 10A CHARLES A. WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 2737, at 455–56 (2d ed.1983).

The procedure under Rule 56(d) is designed to be ancillary to a summary judgment motion. Unlike Rule 56(c), which allows for interlocutory judgment on a question of liability, Rule 56(d) does not authorize the entry of a judgment on part of a claim or the granting of partial relief. *Id.* at 457.

The obligation imposed upon the court by Rule 56(d), to specify the uncontroverted material facts, is generally compulsory. See *Woods v. Mertes*, 9 F.R.D. 318, 320 (D.Del.1949). However, if the court determines that identifying indisputable facts through partial summary judgment would not materially expedite the adjudicative process, it may decline to do so. See *1094 WRIGHT, MILLER & KANE, *supra*, § 2737, at 460.

E. JUDICIAL REVIEW UNDER THE ADMINISTRATIVE PROCEDURE ACT

When the court reviews a government agency's final action, the Rule 56(c) standard for summary judgment is amplified by  5 U.S.C. § 706(2) of the Administrative Procedure Act.

 Title 5 U.S.C. § 706 provides the applicable standard of review for agency action:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall-

- (1) compel agency action unlawfully withheld or unreasonably delayed; and

- (2) hold unlawful and set aside agency action, findings, and conclusions found to be—

- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

- (B) contrary to constitutional right, power, privilege, or immunity;



- (C) in excess of statutory jurisdiction, authority, Or limitations, or short of statutory right;



- (D) without observance of procedure required by law;

- (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

- (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

 5 U.S.C. § 706. Summary judgment in a case of judicial review of agency action requires the court to review the administrative record to determine whether the agency's action was “arbitrary and capricious, an abuse of discretion, not in accordance with law, or unsupported by substantial evidence on the record taken as a whole.”  *Environment Now! v. Espy*, 877 F.Supp. 1397, 1421 (E.D.Cal.1994) (citing *Good Samaritan Hospital, Corvallis v. Mathews*, 609 F.2d 949, 951 (9th Cir.1979)).

The parties have stipulated that this dispute can be decided on the administrative record and does not require the taking of evidence. See Doc. 25, Undisputed Statement of Material Facts, filed Mar. 24, 2003 at 2 (citing  *Northwest Motorcycle Association v. United States Department of Agriculture*, 18 F.3d 1468, 1472 (9th Cir.1994) and  *Environment Now! v. Espy*, 877 F.Supp. 1397, 1421 (E.D.Cal.1994)). Plaintiffs challenge the validity of the October 15, 2002, Rule (hereinafter “the Rule”), authorizing Spanish importation of clementines to resume, after imports were suspended due to the presence of Medfly larvae, subject to revised conditions of phytosanitary inspections and

treatment. *See* Doc. 24 at 3. *See also*, 67 Fed.Reg. 64702–64739, A.R. 1282–1319 (and particularly 67 Fed.Reg. 64708–11 and A.R. 1288–91). Plaintiffs seek to invalidate the Rule under 5 U.S.C. § 706 because: (1) the agency acted beyond its statutory authority (5 U.S.C. § 706(2)(C)); (2) the rule is arbitrary, capricious, and unlawful (5 U.S.C. § 706(2)(A)); (3) the agency promulgated the Rule in violation of procedures required by the Plant Protection Act *1095 (PPA) and the Regulatory Flexibility Act (RFA); and/or it was adopted in violation of the National Environmental Protection Act (NEPA) (5 U.S.C. § 706(2)(D)). Doc. 24 at 10, 19, and 38.

Federal Defendants assert that *Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 843, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) deference is owed to the agency's interpretation of the statutory requirements unless Congress's intent unambiguously requires a different interpretation. Doc. 32 at 21. Plaintiffs argue that *Chevron* deference has no application because statutory construction is not at issue. Rather, Plaintiffs contend that USDA failed to meet its legal obligations by promulgating an arbitrary and capricious rule, in excess of its authority, and in violation of various procedures required by law. Doc. 38 at 5.

[2] Plaintiffs maintain that each ground upon which they seek to invalidate the Rule involves only questions of law, making the standard of review *de novo*. Doc. 24 at 10, fn. 38 (citing *Akiak Native Cmty. v. United States Postal Service*, 213 F.3d 1140, 1144 (9th Cir.2000) and *Environment Now! v. Espy*, 877 F.Supp. 1397, 1421 (E.D.Cal.1994)). Plaintiffs accurately note that questions of law are generally reviewed *de novo*, however, the Secretary's decision here does not include pure legal questions. Plaintiffs' attacks on the validity of the Rule require a review of the reasonableness of agency action, viewing the record as a whole. *See, e.g.*, *Environment Now!*, 877 F.Supp. at 1421; *Samaritan Hospital*, 609 F.2d at 951.

Reasonableness is necessarily a question of fact. *See, e.g.*, *California Dental Ass'n v. F.T.C.*, 224 F.3d 942, 958 (9th Cir.2000); *Continental T.V., Inc. v. G.T.E. Sylvania Inc.*, 694 F.2d 1132, 1135 (9th Cir.1982); *Betaseed, Inc. v. U & I, Inc.*, 681 F.2d 1203, 1228–29 (9th Cir.1982); and *Donnelly v. U.S.*, 201 F.2d 826, 829 (9th Cir.1953). The issues raised present mixed questions of law and fact. The reasonableness

of the USDA's actions must be considered in the context of the legal requirements of the applicable statutes (the APA, PPA, RFA and NEPA) to determine whether promulgation of the Rule was arbitrary and capricious, beyond the agency's authority, and/or in violation of procedures required by law.

A standard of *de novo* review does not govern here, as recognized in *Estate of Merchant v. C.I.R.*, 947 F.2d 1390, 1392–93 (9th Cir.1991) (citing *Pierce v. Underwood*, 487 U.S. 552, 557–63, 108 S.Ct. 2541, 101 L.Ed.2d 490 (1988)); abrogating the *de novo* review standard of *McConney*, 728 F.2d at 1201). *Estate of Merchant* holds that when a district court reviews agency action, questions of whether the agency was “substantially justified,” or “unreasonable” in taking the final action, are governed by the principle that substantial deference should be accorded the agency as finder of fact and review is for “abuse of discretion.” *See Merchant*, 947 F.2d at 1392–93 (citing *Pierce*, 487 U.S. at 557–63, 108 S.Ct. 2541). *Pierce* observed that a trial court's determination of whether agency action was “substantially justified” was neither a clear question of law or of fact and, therefore, was most fairly treated as a question of fact, entitled to deference upon review. *Pierce*, 487 U.S. at 559–60, 108 S.Ct. 2541.

The agency action here requires determination of whether the USDA's investigatory procedures, compilation of data, and scientific analyses were reasonable, competent, informed and properly applied to support the decision to resume importation of Spanish clementines. *Environment Now*, 877 F.Supp. at 1421, recognizes that “[a]gency action will be set aside as arbitrary and capricious if the agency lacked *1096 support in the administrative record for its factual assumptions or otherwise abused its discretion...” 877 F.Supp. at 1421 (citing *Ass'n of Data Processing v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683 (D.C.Cir.1984)). *Marathon Oil Co. v. United States*, 807 F.2d 759, 765 (9th Cir.1986), reiterates the standard of review in the district court under 5 U.S.C. § 706; substantial deference to agency decisions and the court is limited to determine whether “a clear error of judgment has occurred and whether the agency based its decision upon consideration of relevant factors.” *Id.* (citing *Overton Park*, 401 U.S. at 416, 91 S.Ct. 814). Reasonableness is judged by taking the administrative record as a whole. *Id.* at 766 (citing *Continental Oil Co. v. United States*, 184 F.2d 802, 820–21

(9th Cir.1950) and [Ashland Oil, Inc. v. Phillips Petroleum Co.](#), 554 F.2d 381, 387–88 (10th Cir.1975)).

“[T]he court is not empowered to substitute its judgment for that of the agency.” [Citizens to Preserve Overton Park, Inc. v. Volpe](#), 401 U.S. 402, 414, 416, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971), *overruled on other grounds*, [Califano v. Sanders](#), 430 U.S. 99, 105, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977). This circuit recognizes a narrow scope of review applicable to agency action: “Assuming that statutory procedures meet constitutional requirements, the court is limited to a determination of whether the agency substantially complied with its statutory and regulatory procedures, whether its factual determinations were supported by substantial evidence, and whether its action was arbitrary, capricious or an abuse of discretion.” [Toohey v. Nitze](#), 429 F.2d 1332, 1334 (9th Cir.1970), *cert denied*, 400 U.S. 1022, 91 S.Ct. 585, 27 L.Ed.2d 633 (1971). *See also* [Briggs v. Dalton](#), 939 F.Supp. 753, 760 (D.Hawai‘i 1996) (accord). Despite this “narrow” scope of review, the court is still expected to make a “thorough, probing, in-depth review” of the administrative record to ensure the validity of the agency action, [Overton Park](#), 401 U.S. at 415, 91 S.Ct. 814, and “must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” [Id.](#) at 416, 91 S.Ct. 814 (citing L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 359 at 182 (1965); [McBee v. Bomar](#), 296 F.2d 235, 237 (6th Cir.1961); [In re Josephson](#), 218 F.2d 174, 182 (1st Cir.1954); [Western Addition Community Organization v. Weaver](#), 294 F.Supp. 433 (N.D.Cal.1968); and [Wong Wing Hang v. Immigration and Naturalization Serv.](#), 360 F.2d 715, 719 (2nd Cir.1966)).

IV. ANALYSIS

A. JUDICIAL NOTICE

Federal Defendants request judicial notice of a published report of the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) entitled “Spanish Clementine Data Report and Analysis 2002–2003 Season” (the “2002–2003 Data Report”). Doc. 34 filed Apr. 28, 2003. Plaintiffs object to judicial notice of the 2002–2003 Data Report on the basis that it is irrelevant to the issues presented in the pending litigation because it was

prepared after and is not part of the administrative record and it appears to have been prepared for the litigation making the validity of its contents suspect. Doc. 35, Objection to Judicial Notice, filed May 1, 2003, at 2. Intervenor Defendants support Federal Defendants request for judicial notice of the 2002–2003 Data Report, arguing that it is a relevant, self-authenticating government publication reflecting scientific data, factors considered, and acts taken by the USDA and supports the validity and correctness of USDA assumptions *1097 made in the underlying administrative proceeding and promulgation of the October 15th Final Rule. Doc. 36, Intervenor Defendant's Memorandum in Support of Federal Defendant's Request for Judicial Notice, filed May 8, 2003, at 2–3.

Intervenor Defendants seek judicial notice of a published government letter entitled “Clementine Stakeholder Letter” (the “Stakeholder Letter”). Doc. 39, Intervenor's Request for Judicial Notice, filed Jun. 10, 2003 at 2.

Plaintiffs object to Intervenor Defendants' request for judicial notice of the Stakeholder Letter on the basis of relevancy as it is not part of the administrative record, was prepared after the Rule was published, and has questionable reliability. Doc. 40, Plaintiffs' Objection to Judicial Notice, filed Jun. 16, 2003 at 2. In support of their request for judicial notice, Federal Defendants cite [Clappier v. Flynn](#), 605 F.2d 519 (10th Cir.1979) and [Mobil Oil Corp. v. TVA](#), 387 F.Supp. 498 (D.Ala.1974). In [Clappier](#), 605 F.2d at 535, the Tenth Circuit held that judicial notice was properly taken of an official government publication in the Federal Registry relating to hospital rates and charges concerning medical care furnished by the United States in an action for injuries whereby Plaintiff was treated at a government hospital. In [Mobil Oil](#), 387 F.Supp. at 500, *fn. 1*, the Alabama district court held that an agency's annual reports were proper subjects for judicial notice.

Rule 902 of the Federal Rules of Evidence provides that the following documents are self-authenticating:

...

(4) Certified copies of public records. A copy of an official record or report or entry therein, or of a document authorized by law to be recorded or filed and actually recorded or filed in a public office, including data compilations in any form, certified as correct by the custodian or other person authorized to make the

certification, by certificate complying with paragraph (1), (2), or (3) of this rule or complying with any Act of Congress or rule prescribed by the Supreme Court pursuant to statutory authority.

(5) Official publications. Books, pamphlets, or other publications purporting to be issued by public authority.

...

(11) Certified Domestic Records of Regularly Conducted Activity. The original or a duplicate of a domestic record of regularly conducted activity that would be admissible under Rule 803(6) if accompanied by a written declaration of its custodian or other qualified person, in a manner complying with any Act of Congress or rule prescribed by the Supreme Court pursuant to statutory authority, certifying that the record-

(A) was made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, a person with knowledge of those matters;

(B) was kept in the course of the regularly conducted activity; and

(C) was made by the regularly conducted activity as a regular practice.

A party intending to offer a record into evidence under this paragraph must provide written notice of that intention to all adverse parties, and must make the record and declaration available for inspection sufficiently in advance of their offer into evidence to provide an adverse party with a fair opportunity to challenge them.

...

[Fed.R.Evid. Rule 902.](#)

[Fed.R.Evid. Rule 1005](#) provides:

***1098** The contents of an official record, or of a document authorized to be recorded or filed and actually recorded or filed, including data compilations in any form, if otherwise admissible, may be proved by copy, certified as correct in accordance with [rule 902](#) or testified to be correct by a witness who has compared it with the

original. If a copy which complies with the foregoing cannot be obtained by the exercise of reasonable diligence, then other evidence of the contents may be given.

[Fed.R.Evid. Rule 1005.](#)

[Rule 44 of the Federal Rules of Civil Procedure](#) provides:

An official record kept within the United States, or any state, district, or commonwealth, or within a territory subject to the administrative or judicial jurisdiction of the United States, or an entry therein, when admissible for any purpose, may be evidenced by an official publication thereof or by a copy attested by the officer having the legal custody of the record, or by the officer's deputy, and accompanied by a certificate that such officer has the custody. The certificate may be made by a judge of a court of record of the district or political subdivision in which the record is kept, authenticated by the seal of the court, or may be made by any public officer having a seal of office and having official duties in the district or political subdivision in which the record is kept, authenticated by the seal of the officer's office.

[Fed.R.Civ.Proc. Rule 44\(a\)\(1\).](#)

In *Woolsey v. National Transp. Safety Bd.*, 993 F.2d 516, 520 (5th Cir.1993) *rehearing denied* 3 F.3d 441, *cert. denied* 511 U.S. 1081, 114 S.Ct. 1829, 128 L.Ed.2d 459, articles and self-promotional statements made by an air transport company in a weekly magazine were admissible as self-authenticating documents. *See also*, [Dallas County v. Commercial Union Assur. Co.](#), 286 F.2d 388, 391-92 (5th Cir.1961) (newspaper article admissible as secondary evidence); [D.L. v. Unified School Dist. # 497](#), 270 F.Supp.2d 1217, 1235 (D.Kan.2002) (newspaper articles

admissible to show fact of publication and as evidence of an agent's statement); [Nestle Co., Inc. v. Chester's Market, Inc.](#), 571 F.Supp. 763, (D.C.Conn.1983) *reversed on other grounds*, [756 F.2d 280](#), *on remand* 609 F.Supp. 588 (media articles were self-authenticating and admissible to show public perception and usage); [U.S. v. Leal](#), 509 F.2d 122, 125–26 (9th Cir.1975) (foreign hotel registration forms were self-authenticating when prepared by public officials in carrying out duties of their office); [U.S. v. Saputski](#), 496 F.2d 140, 142 (9th Cir.1974) (business records were self-authenticating so that signature was not prerequisite to admissibility in embezzlement lawsuit). See [Fed.R.Evid. 803\(8\)](#).

[3] A matter is not properly subject to judicial notice by the court if it involves a central and disputed issue. [U.S. v. Baker](#), 641 F.2d 1311 (9th Cir.1981). However, a court may properly take notice of public facts and public documents. [Greeson v. Imperial Irr. Dist.](#), 59 F.2d 529, 531 (9th Cir.1932). Public records, such as census data, is appropriate subject matter for judicial notice. [United States v. Esquivel](#), 75 F.3d 545, 549 (9th Cir.1996). *But see*, [Carley v. Wheeled Coach](#), 991 F.2d 1117, 1126 (3rd Cir.1993) (refusing to take notice of government's testing of vehicle rollovers as not "readily provable through a source whose accuracy cannot be reasonably questioned") and [Cofield v. Alabama Pub. Serv. Comm'n](#), 936 F.2d 512, 517 (11th Cir.1991) (refusing to take judicial notice of newspaper publication as source that establishes facts as indisputable).


In [Gafoor v. I.N.S.](#), 231 F.3d 645, 655–56 (9th Cir.2000) judicial notice was taken of *1099 evidence outside the Board of Immigration Appeals' administrative record, where such evidence was not previously available because the events had not yet occurred when the agency action was taken. [Rankin v. DeSarno](#), 89 F.3d 1123, 1126 fn. 3 (3rd Cir.1996), took judicial notice of a financial publication's reporting of the prime rate. In [Texas & Pac. Ry. Co. v. Pottorff](#), 291 U.S. 245, 254 fn. 4, 54 S.Ct. 416, 78 L.Ed. 777 (1934), judicial notice of various reports, treatises, textbooks, and other publications issued by the U.S. Comptroller of the Currency as evidence of good banking practices. See also, [Clemmons v. Bohannon](#), 956 F.2d 1523, 1532 & fn. 2 (10th Cir.1992) (Seymour, J., dissent) (judicial notice of



government reports), [Pueblo of Sandia v. U.S.](#), 50 F.3d 856, 861 fn. 6 (10th Cir.1995)(*accord*). Courts will also take judicial notice of historical happenings and events. [Akira Ono v. U.S.](#), 267 F. 359, 362 (9th Cir.1920).




[4] [George W. v. U.S. Dept. of Educ.](#), 149 F.Supp.2d 1195, 1199 (E.D.Cal.2000), recognizes a court may take judicial notice of a public record which has a "direct relation to the matters at issue," but only of the *existence* of those matters of public record (the existence of a public document or of representations in the document) but not of the *veracity* of arguments or disputed facts in the document. *Id.* (quoting [Robinson](#), 971 F.2d at 248).





In [George W.](#), a defendant sought judicial notice that a co-defendants' filed pleading be deemed its own. *Id.* The request for judicial notice of the contents and arguments of the motion was rejected, "[a] motion is a legal brief, advancing a partisan position in litigation, not a judicially noticeable fact." *Id.* The existence and authenticity of a document which is a matter of public record is judicially noticeable such as the authenticity and existence of a particular order, pleading, public proceeding, or census report, which are matters of public record, but the veracity and validity of their contents (the underlying arguments made by the parties, disputed facts, and conclusions of fact) are not. See, e.g., [Lee v. City of Los Angeles](#), 250 F.3d 668, 690 (9th Cir.2001)(a court may take judicial notice of another court's opinion, but not of the truth of the facts recited therein); [Asdar Group v. Pillsbury, Madison & Sutro](#), 99 F.3d 289, 290, fn. 1 (9th Cir.1996) (court may take judicial notice of the pleadings and court orders in earlier related proceedings); [Wyatt v. Terhune](#), 315 F.3d 1108, 1114 (9th Cir.2003).

Even where, under the doctrine of *stare decisis*, a court is generally compelled to abide by conclusions of law made in prior proceedings of higher courts, a court cannot take judicial notice of another court's determination of the truth of those facts. [Lee](#), 250 F.3d at 690 (citing [Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group, Ltd.](#), 181 F.3d 410, 426–27 (3rd Cir.1999)).¹⁹ See also, [Wyatt v. Terhune](#), 315 F.3d 1108, 1114 (9th Cir.2003) (while a court may judicially notice another court's order, it may not accept that court's findings of fact as true). *Lee* found that the district court properly took judicial notice of *the fact* that a waiver was signed in a prior proceeding, [Lee](#), 250 F.3d at 689–90,

but reversed the incorrect judicial notice of the *validity of that waiver*, *1100 a disputed fact yet unproved.  *Id.* at 690.

While the court may take judicial notice of the fact of filing or existence and the general meaning of words, phrases, and legal expressions, documents are judicially noticeable only for the purpose of determining what statements have been made, not to prove the truth of the contents. *See, e.g.,*  *Hennessy v. Penril Datacomm Networks, Inc.* 69 F.3d 1344, 1354–55 (7th Cir.1995);  *Wilshire Westwood Assocs. v. Atlantic Richfield Corp.*, 881 F.2d 801, 803 (9th Cir.1989).




“Judicial notice is taken of the existence and authenticity of the public and quasi public documents listed. To the extent their contents are in dispute, such matters of controversy are not appropriate subjects for judicial notice.”  *Del Puerto Water Dist. v. U.S. Bureau of Reclamation*, 271 F.Supp.2d 1224, 1234 (E.D.Cal.2003). *See also, California ex rel. RoNo, LLC v. Altus Finance S.A.*, 344 F.3d 920, 931 (9th Cir.2003) (“requests for judicial notice are GRANTED to the extent that they are compatible with FED. RULE EVID. 201 and do not require the acceptance of facts ‘subject to reasonable dispute.’ ” Quoting  *Lee*, 250 F.3d at 690);  *Kent v. Daimlerchrysler Corp.*, 200 F.Supp.2d 1208, 1219 (N.D.Cal.2002).

[5] On the separate issue of relevancy, the fact the government publications have been created and reflect continuing focus on the efficacy of the Rule is relevant, even if the contents could not have informed the Rule. No request to augment the record was made and there is no way to evaluate the probative value and accuracy of the contents of these public documents. However, the fact of follow-up data collection bears on active experience with operation of the Rule.  *Amoco Oil Co. v. Environmental Protection Agency*, 501 F.2d 722, 729 fn. 10 (D.C.Cir.1974);  *American Petroleum Institute v. Environmental Protection Agency*, 540 F.2d 1023, 1034 (10th Cir.1976) questioned by  *Airport Communities Coalition v. Graves*, 280 F.Supp.2d 1207, 1212–13 (W.D.Wash.2003) (no “Monday morning quarterbacking”) citing  *Rybachek v. U.S. Environmental Protection Agency*, 904 F.2d 1276, 1296 (9th Cir.1990) (not appropriate for party to use post-decision information to sustain or attack agency’s decision). The post-record submissions have only limited

applicability to confirm the plausibility of predictions under the Rule or the truth or falsity of predictions.

Federal Defendants’ motion for judicial notice of the fact of existence and authenticity of the 2002–2003 Data Report as created and published by the Department of Agriculture is GRANTED. To the extent Federal Defendants seek judicial notice of the accuracy and validity of the contents of the 2002–2003 Data Report, matters disputed by the Plaintiffs, Federal Defendants’ request for judicial notice is DENIED. Intervenor Defendants’ motion for judicial notice of the authenticity and existence of the Stakeholder Letter, as a self-authenticating government publication issued by the Department in the furtherance of its responsibilities, is GRANTED. To the extent Intervenor Defendants’ seek judicial notice of the veracity and/or accuracy of any of the Letter’s statements, disputed facts or conclusions of law, Intervenor Defendants’ motion for judicial notice of the Stakeholder Letter is DENIED.

B. THE USDA HAD AUTHORITY TO PROMULGATE THE OCTOBER 15, 2002 FINAL RULE

The first inquiry is whether the agency acted within the scope of its authority to promulgate the Rule. *See, e.g.,*  *1101 *Schilling v. Rogers*, 363 U.S. 666, 676–77, 80 S.Ct. 1288, 4 L.Ed.2d 1478 (1960);  *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415–16, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971). A reviewing court must decide whether the agency properly construed its authority on the particular facts and circumstances presented.  *Id.* at 416, 91 S.Ct. 814. APHIS invokes the Plant Protection Act as authority to promulgate the October 15 Final Rule, permitting importation of Spanish clementines to resume. “APHIS believes that its decisionmaking is tied directly to the authority given to the Secretary of Agriculture by the Plant Protection Act.” 67 F.R. 64702–01. The Plant Protection Act delineates the scope of the Secretary’s authority and discretion:

The Secretary [of Agriculture] may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or

restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.

7 U.S.C. § 7712(a). PPA sub (c) describes the method by which the Secretary may enforce its powers:

The Secretary may issue regulations to implement subsection (a) of this section, including regulations requiring that any plant, plant product, biological control organism, noxious weed, article or means of conveyance imported, entered, to be exported, or moved in interstate commerce-

- (1) be accompanied by a permit issued by the Secretary prior to the importation, entry, exportation, or movement in interstate commerce;
- (2) be accompanied by a certificate of inspection issued (in a manner and form required by the Secretary) by appropriate officials of the country or State from which the plant, plant product, biological control organism, noxious weed, article, or means of conveyance is to be moved;
- (3) be subject to remedial measures the Secretary determines to be necessary to prevent the spread of plant pests or noxious weeds; and
- (4) with respect to plants or biological control organisms, be grown or handled under post-entry quarantine conditions by or under the supervision of the Secretary for the purposes of determining whether the plant or biological control organism may be infested with plant pests or may be a plant pest or noxious weed.

7 U.S.C. § 7712(c).


Due to increasing concern over biological terrorism, APHIS's authority was further expanded by **7 U.S.C. § 8320**, enacted in June of 2002, which provides in relevant part:


The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to -






- (1) increase the inspection capacity of the Service at international points of origin;




- (2) improve surveillance at ports of entry and customs;
- (3) enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists;
- (4) develop new and improve existing strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism ***1102** or from unintentional introduction, including -
 - (A) establishing cooperative agreements among Veterinary Services of the Animal and Plant Health Inspection Service, State animal health commissions and regulatory agencies for livestock and poultry health, and private veterinary practitioners to enhance the preparedness and ability of Veterinary Services and the commissions and agencies to respond to outbreaks of such animal diseases; and
 - (B) strengthening planning and coordination with State and local agencies, including—
 - (i) State animal health commissions and regulatory agencies for livestock and poultry health; and
 - (ii) State agriculture departments; and
- (5) otherwise improve the capacity of the Service to protect against the threat of bioterrorism.


7 U.S.C. § 8320(a).

The Secretary of Agriculture's responsibilities for plant protection and quarantine have been delegated to APHIS and the Deputy Administrator of Plant Protection and Quarantine. **7 C.F.R. § 371.3**. The PPA grants APHIS wide discretion to properly effect its statutory purpose. **7 U.S.C. § 7712(a)** and **(c)**. A decision lies beyond the scope of agency authority where its exercise of discretion is contrary to law. "The scope of an agency's discretion is bounded by law; an agency cannot justify a decision by reference to its discretionary authority, if the decision lies beyond the scope of the agency's discretion."  *Farmworker Justice Fund, Inc. v. Brock*, 811 F.2d 613, 619–20 (D.C.Cir.) *vacated as moot*, 817 F.2d 890 (D.C.Cir.1987).




[6] The agency must consider all necessary and relevant factors to afford substantial justification for the Rule. *See, e.g.,*  *State of Tex. v. EPA*, 499 F.2d 289, 297 (5th Cir.1974);

  *Historic Green Springs, Inc. v. Bergland*, 497 F.Supp. 839, 845 (E.D.Va.1980);  *Fund for Animals v. Babbitt*, 903 F.Supp. 96, 105 (D.D.C.1995);  *Western Oil & Gas Ass'n v. Air Resources Board*, 37 Cal.3d 502, 208 Cal.Rptr. 850, 853, 691 P.2d 606 (1984). An agency should articulate the reasoning behind its findings but need not prepare formal findings of fact in support of its decision.  *Id.* at 853–54, 691 P.2d 606.

[7] [8] “An agency is entitled to select any reasonable methodology and to resolve conflicts in expert opinion and studies in its best reasoned judgment based on the evidence before it.” *Intercitrus, Ibertrade Commercial Corp. v. United States Dept. of Agriculture*, 2002 WL 1870467, *2 (E.D.Pa.) (citing *Hughes River Watershed v. Johnson*, 165 F.3d 283, 289–90 (4th Cir.1999) and  *Oregon Environmental Council v. Kunzman*, 817 F.2d 484, 496 (9th Cir.1987)). The complaining party bears the burden of a “clear showing” that the action exceeded the agency’s authority. *International Drilling & Energy Corp. v. Watkins*, 920 F.2d 14, 19 (C.A.Em.App.1990). Plaintiffs concede that APHIS “has discretion in determining what prohibition or restriction is necessary to prevent the introduction of a plant pest into the United States.” Doc. 24 at 16. Plaintiffs complain that APHIS has taken “unfettered license to exercise its discretion arbitrarily and without articulating a transparent standard,” as required by  *Harlan Land Co. v. U.S. Dept. of Agriculture*, 186 F.Supp.2d 1076, 1086–87 (E.D.Cal.2001) and  *Ober v. Whitman*, 243 F.3d 1190, 1195 (9th Cir.2001). *Id.* at 15–16.

Based on the completeness of APHIS’s investigation into the causes of Medfly larvae *1103 importation into the United States,²⁰ and according due deference to the agency’s findings of fact, determinations of reasonableness, practicality, and supporting scientific conclusions,²¹ APHIS acted within the scope of its authority to issue protective rules under the Plant Protection Act in adopting the Rule. The new Medfly larvae prevention methodology and additional safeguards on Spanish clementine imports is a reasonable method of protecting the United States and its agriculturists from Medfly importation and threat of infestation. “Scrutiny of the facts does not end, however, with the determination that the Secretary has acted within the scope of his statutory authority.”  *Overton Park*, 401 U.S. at 416, 91 S.Ct. 814.

C. *THE RULE IS NOT ARBITRARY AND CAPRICIOUS*
Plaintiffs claim that APHIS’s promulgation of the Rule was arbitrary and capricious because the “information, analysis, and explanation that APHIS has offered in support of the Rule are insufficient to provide assurance that a ‘catastrophic failure of the APHIS import program, will not occur.’” Doc. 24 at 3–4. The government responds that the agency’s ten month analysis and argument among its scientists on likely cause for the 2001 Medfly presence fully satisfy 7 U.S.C. § 7701’s “sound science” requirement. Plaintiffs argue that the agency was required to establish a definitive numeric threshold of minimum risk as part of the Rule. The government rejoins that this is an issue implicating the Secretary’s rulemaking authority, subject to judicial deference.

The Administrative Procedure Act (APA),  5 U.S.C. § 553, establishes the procedural requirements applicable to notice and comment for an agency’s rule-making authority.  *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 523–24, 98 S.Ct. 1197, 55 L.Ed.2d 460 (1978). A reviewing court must assure that the agency has given adequate consideration to all relevant factors in the administrative record in making its decision.  *Overton Park*, 401 U.S. at 416, 91 S.Ct. 814. “Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.” *Id.* The PPA, 7 U.S.C. § 7701(3), contains an express grant of discretionary authority to the Secretary to promulgate the Rule:

... to facilitate exports, *imports*, and interstate commerce in agricultural products and other products that pose a risk of harboring a risk of plant pests... in ways that will reduce to *the extent practicable as determined by the Secretary*, the risk of dissemination of plant pests...

7 U.S.C. § 7701(3)(*emphasis added*).

[9]  *Confederated Tribes of the Umatilla Indian Reservation v. Bonneville Power Administration*, 342 F.3d

924, 928 (9th Cir.2003) recognized that agency action is arbitrary and capricious where: (1) the agency relies on factors which Congress did not intend the agency to consider, (2) the agency entirely fails to consider particularly relevant factors, (3) the agency provides an explanation for the decision which is contradicted by the evidence, or (4) the agency decision is so implausible that it cannot be said to be a mere difference of interpretation or the product of the agency's expertise. *Id.* (quoting [Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.](#), 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)).

Judicial review of an agency's findings of fact proceeds under the rubric of "substantial evidence" set forth in [5 U.S.C. § 706\(2\)\(E\)](#). See [Information Providers' Coalition for Defense of the First Amendment v. F.C.C.](#), 928 F.2d 866, 869–70 (9th Cir.1991). Substantial evidence "does not mean a large or considerable amount of evidence, but rather only 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Id.* at 870 (quoting [Pierce v. Underwood](#), 487 U.S. 552, 564–65, 108 S.Ct. 2541, 101 L.Ed.2d 490 (1988) and [Consolidated Edison Co. v. NLRB](#), 305 U.S. 197, 229, 59 S.Ct. 206, 83 L.Ed. 126 (1938)). See also, [Tiger International, Inc. v. CAB](#), 554 F.2d 926, 935–36 (9th Cir.1977); [Camp v. Pitts](#), 411 U.S. 138, 141, 93 S.Ct. 1241, 36 L.Ed.2d 106 (1973); [California Citizens Band Ass'n v. U.S.](#), 375 F.2d 43, 53–54 (9th Cir.) *cert denied*, 389 U.S. 844, 88 S.Ct. 96, 19 L.Ed.2d 112 (1967); [Hughes Air Corp. v. CAB](#), 482 F.2d 143 (9th Cir.1973).

[Substantial evidence] is something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.

[Consolo v. Federal Maritime Commission](#), 383 U.S. 607, 620, 86 S.Ct. 1018, 16 L.Ed.2d 131 (1966).

"The agency must articulate a 'rational connection between the facts found and the choice made.'" [Bowman Transportation v. Arkansas–Best Freight System, Inc.](#), 419 U.S. 281, 285, 95 S.Ct. 438, 42 L.Ed.2d 447 (1974)(quoting [Burlington Truck Lines v. U.S.](#), 371 U.S. 156, 168, 83 S.Ct. 239, 9 L.Ed.2d 207 (1962)). "While we may not supply a reasoned basis for the agency's action that the agency itself has not given, [SEC v. Chenery Corp.](#), 332 U.S. 194, 196, 67 S.Ct. 1575, 91 L.Ed. 1995 (1947), we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." [419 U.S. at 285–86](#), 95 S.Ct. 438 (citing [Colorado Interstate Gas Co. v. FPC](#), 324 U.S. 581, 595, 65 S.Ct. 829, 89 L.Ed. 1206 (1945)). Because the administrative record reflects that APHIS adequately addressed the relevant facts, engaged in sufficient scientific analysis, and reasonably applied its investigatory conclusions in the process that created the Rule, the agency did not act arbitrarily or capriciously in promulgating the Final Clementine Re-import Rule.

i. Adequacy of the Administrative Record

[10] The starting point for judicial review of agency action is the administrative record already in existence, not a new record made initially in the reviewing court. [Southwest Center for Biological Diversity v. U.S. Forest Service](#), 100 F.3d 1443, 1450 (9th Cir.1996); [Asarco, Inc. v. U.S. EPA](#), 616 F.2d 1153, 1159 (9th Cir.1980). The court may, however, consider evidence outside the administrative record for certain limited purposes, e.g., to explain the agency's decisions, or to determine whether the agency's course of inquiry was insufficient or inadequate. See *id.*; [Love v. Thomas](#), 858 F.2d 1347, 1356 (9th Cir.1988), *cert. denied*, 490 U.S. 1035, 109 S.Ct. 1932, 104 L.Ed.2d 403 (1989); [Animal Defense Council v. Hodel](#), 840 F.2d 1432, 1436 (9th Cir.1988).²² The agency's follow-up reflected in its submission accompanying the Request for Judicial Notice seeks to explain and demonstrate sufficiency of the administrative record investigations and decision-making. A court, in certain instances, may require supplementation of the record or allow a party challenging agency action to engage in limited discovery. [Southwest Center](#), 100 F.3d at 1450. In [Public Power Council v. Johnson](#), 674 F.2d 791 (9th Cir.1982), the Ninth Circuit isolated four instances where supplementation or discovery may be justified:

- (1) when the record need be expanded to explain agency action;
- (2) when the agency has relied upon documents or materials not included in the record;
- (3) to explain or clarify technical matter involved in the agency action and
- (4) where there has been a strong showing in support of a claim of bad faith or improper behavior on the part of the agency decision makers.

Id. Supplementation of an administrative record is the exception, not the rule. See [San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission](#), 751 F.2d 1287, 1324 (D.C.Cir.1984). “If the administrative record is inadequate to explain the action taken, the preferred practice is to remand to the agency for amplification.” [Sears Sav. Bank v. Fed. Sav. and Loan Ins. Corp.](#), 775 F.2d 1028, 1030 (9th Cir.1985)(citing [Public Power Council v. Johnson](#), 674 F.2d 791, 794 (9th Cir.1982) and [Overton Park](#), 401 U.S. at 420, 91 S.Ct. 814). The A.R. here consists of twelve volumes, and over three thousand (3,421) pages of scientific testing, application and analysis, risk assessments, environmental assessments, economic assessments, national and international impact assessments and cumulative, well-reasoned explanations for the “how” and the “why” underlying APHIS's promulgation of the Final Rule. See A.R. 1282–1319, [67 Fed.Reg. 64702–64739](#). Other than the judicial notice requests, only following year results have been offered beyond the administrative record.

ii. *Distinguishing Harlan Land Co. v. U.S.D.A.*

Plaintiffs contend that, under the doctrine of *stare decisis*, [Harlan Land Co. v. U.S. Dept. of Agriculture](#), 186 F.Supp.2d 1076 (E.D.Cal.2001) compels a finding that APHIS's promulgation of the Rule is arbitrary and capricious because the agency failed to define “an acceptable level of risk.” Doc. 24 at 12–15. Plaintiffs misconstrue the application of *stare decisis* in ascribing a precedential effect to *Harlan Land* and fail to distinguish the administrative record in this case from the *Harlan* administrative record.

[11] “The doctrine of *stare decisis* does not compel one district court judge to follow the decision of another.”

[Starbuck v. City of San Francisco](#), 556 F.2d 450, 457 n. 13 (9th Cir.1977). See also, [*1106 People of Territory of Guam v. Yang](#), 800 F.2d 945, 949 (9th Cir.1986); [Dougherty v. Golden Gate Bridge](#), 31 F.Supp.2d 724, 730 (N.D.Cal.1998); [Willner v. Budig](#), 848 F.2d 1032, 1035 (10th Cir.1988) *cert denied*, 488 U.S. 1031, 109 S.Ct. 840, 102 L.Ed.2d 972 (1989); [Threadgill v. Armstrong World Indus., Inc.](#), 928 F.2d 1366, 1371, n. 7 (3rd Cir.1991). Rather, “[s]uch decisions will normally be entitled to no more weight than their intrinsic persuasiveness [on the] merits ... because the responsibility for maintaining the law's uniformity is a responsibility of the appellate rather than trial judges...” [Colby v. J.C. Penney Company, Inc.](#), 811 F.2d 1119, 1124 (7th Cir.1987). No trial court decision is binding precedent. [Hart v. Massanari](#), 266 F.3d 1155, 1163 (9th Cir.2001); [In re Executive Office of the President](#), 215 F.3d 20, 24 (D.C.Cir.2000) (district court decisions do not establish law of the district).

The administrative record in *Harlan Land* raised different issues based on an entirely different agency rule. It does not control the validity of the Rule challenged here. The administrative record underlying APHIS's October 15th Final Rule deals *exclusively* with the importation of clementines from Spain and prevention of Medfly infestation, which is supported by an extensive record of scientific inquiry and analysis by the agency. *Harlan Land* addressed a different APHIS rule which dealt exclusively with the importation of citrus from Argentina. The *Harlan* focus was on prevention of introduction into the United States of citrus black spot and sweet orange scab. There, as here, there was dispute whether sound science was reasonably employed in the promulgation of that rule. [186 F.Supp.2d at 1079–80](#). There, substantial evidence showed the apparent unreliability or inconsistency in testing by the agricultural authority for Argentina.

The *Harlan Land* administrative record did not explain what constituted an acceptable “negligible” level of risk, but rather concluded, *without* supporting scientific justification, that the risk posed by the proposed rule would be “negligible.” [186 F.Supp.2d at 1080](#). *Harlan Land* held that the administrative record did not reflect the scientific analysis employed to reach the agency's conclusion, which left the court without any method to review the reasonableness of that conclusion. *Id.* “An agency must cite to information to support its position;

without data the court owes no deference to an agency's line-drawing." *Id.* (citing [Ober v. Whitman](#), 243 F.3d 1190, 1195 (9th Cir.2001)). The administrative record must contain sufficient reliance on sound science to support the reasonableness of the agency's final action.

An administrative record which fails to identify or reflect what scientific investigation and analysis has been applied to create a final rule leaves the court with nothing but the agency's conclusions to analyze. *Harlan Land* concluded the absence of record information prevented verification that a reliable basis existed for the Agency to conclude the risk posed by that proposed rule was "negligible," especially where there was contradictory scientific evidence. *Id.* at 1086. When an agency fails to justify, through the utilization of sound science, how and why a proposed rule will achieve its proposed objectives, "the court has no basis for determining whether [the agency's] decision is arbitrary, capricious or an abuse of discretion [.]” *Id.*

[12] By contrast, the administrative record for the Rule here, concerning prevention of Medfly infestation from importation of Spanish clementines, includes extensive *1107 timely scientific studies²³ and analyses²⁴ which the agency expressly relied upon to explain how it reached its conclusion.²⁵ The studies include temperature control and cold treatment protocols, prior experience in eliminating Medflies, supported by statistical studies of success rates for temperature control and cold treatment testing to establish a prohibit 9 mortality as a zero tolerance target. The law mandates deference to APHIS's technical expertise and experience in conducting these analyses and the efficacy of the resulting findings, unless Plaintiff can cast doubt on its reliability by contrary science. [Friends of the Clearwater v. Dombeck](#), 222 F.3d 552, 556 (9th Cir.2000); [United States v. Alpine Land and Reservoir Co.](#), 887 F.2d 207, 213 (9th Cir.1989).

iii. *Ober v. Whitman*

Plaintiffs cite [Ober v. Whitman](#), 243 F.3d 1190, 1195 (9th Cir.2001) to support their contention that APHIS's explanation and application of science did not quantify an acceptable measure of risk and that such failure is fatal to the validity of the October 15th Final Rule. Doc. 24 at 15–17. In *Ober*, Arizona residents challenged the EPA's adoption of a Clean Air Act, 42 U.S.C. § 7401, *et seq.*, implementation plan which exempted from control, as *de minimis*, i.e., a "negligible contribution," airborne particulate matter under

ten microns (PM–10). [243 F.3d at 1192, 1194](#). The rule was upheld because EPA met its burden to examine relevant data and articulate a satisfactory explanation, rationally connecting facts found and choices made. The agency fully explained its adoption of *de minimis* controls based on negligible contributions to the overall air pollution levels and the effect of applying those controls to sources of pollution. [Id. at 1194–95](#) (citing [57 Fed.Reg. at 13,541](#)). *1108 *Ober* upheld the "de minimis" exemption on the basis that it would be unreasonable to require agency control over such minute sources of pollution. *Id.* (citing [57 Fed.Reg. at 13,541](#) and [Alabama Power Co. v. Costle](#), 636 F.2d 323, 360 (D.C.Cir.1979)).

It is commonplace, of course, that the law does not

concern itself with trifling matters, and this principle has often found application in the administrative context. Courts should be reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort... The ability ... to exempt *de minimis* situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design.

Ober at 1194 (quoting [Alabama Power](#), 636 F.2d at 360 and citing [Industrial Union Dept., AFL–CIO v. American Petroleum Inst.](#), 448 U.S. 607, 663–64, 100 S.Ct. 2844, 65 L.Ed.2d 1010 (1980) (also citing *Alabama Power*)).

The October 15th Final Rule does not seek to exempt any Medfly or Spanish clementine importation from the new and more stringent preventative safeguards required: "[O]ur actual target infestation level of fruit is zero..." [67 Fed.Reg. 64712](#), A.R. 1292. APHIS's goal is to *absolutely prevent* Medfly larvae infestation from occurring in the United States. A.R. 1283, [67 Fed.Reg. 64703](#).²⁶ The Final Rule achieves this stated purpose through methods which, according to APHIS's investigation and scientific analyses, will reasonably



minimize the risk of importation of live larvae to a probit 9 mortality²⁷ level. A.R. 1283, 67 Fed.Reg. 64703.

APHIS's risk analysis for the October 15th Final Rule is only one aspect of the rule-adopting process. The record explains that the very minute risk of importation of larvae that might actually survive the Final Rule's protective measures is further reduced by domestic preventative measures (upon importation to the United States). Sampling and quarantine minimize the chances that any surviving larvae that reach the U.S. could mature into adults or adults capable of reproduction. A.R. 1222. APHIS's research and scientific studies show that a single Medfly larva able to survive the Rule's measures must *also* be capable of maturing, becoming reproductive, and *then* meeting *another* larva that was able to survive the preventative measures (one in two thousand years), and still be able to mature, become reproductive, and mate, before a Medfly infestation is possible. *Id.* The likelihood of this “perfect risk” scenario, while scientifically possible, is more remote considering the hard scientific data about the effectiveness of more cold treatment and the Rule's extensions of cold treatment minimum time-length requirements. A.R. 1215.²⁸

*1109 Plaintiffs argue that Defendants' failure to set an exact numeric threshold of what they deem “acceptable risk” constitutes unreasonable acquiescence in and acceptance of the risk: that two Medfly larvae able to survive the Rule's preventative measures, both still maintaining their capability to simultaneously mature into reproductive adults, despite the cold treatment, *at approximately the same level of development and in the same vicinity* could find each other and actually reproduce, and thereafter not be detected in time, to cause an actual infestation. A.R. 328, 330–31. This risk scenario is so hypothetically remote as to be *de minimis* in the sense *Ober* recognizes. Such a “risk” need not be “numerically quantified” because the level of acceptable risk is set at zero. APHIS does not seek to exempt from regulation and allow the importation into the U.S. of a *de minimis* or negligible amount of Medfly larvae. Rather, APHIS seeks to entirely eliminate the risk of Medfly infestation, to the extent practical through known science. A.R. 1292. The PPA does not require setting a “numeric risk” threshold, which would be artificial and uncalled for under the totality of the circumstances.



The agency has explained and defined how its analyses, studies, and procedures that support the Final Rule, and how the use of inspection, field treatment or sampling, quarantine,

extended cold treatment, arrival point inspection and testing will eliminate risk and operate to achieve the goal of probit 9 mortality. A “negligible risk” standard is a non sequitur in the context of the Rule. Plaintiffs do not have the power to impose their views to rewrite the Rule, or to interpret the Rule to say what it does not. The Final Rule has no tolerance for any introduction of Medfly larvae; rather it seeks to eliminate all risks of introduction *to the extent practical through sound science*. There is no level of “acceptable” risk or “numeric threshold” to quantify. The law does not require idle acts.

APHIS reasonably explained the risks of Medfly importation, the means sought to minimize those risks to the extent practical through sound science, and reasonably incorporates its analyses into the justification of the Rule. The process was open to the public. APHIS is entitled to deference in interpreting the PPA and in using its expertise to promulgate a rule to achieve PPA statutory objectives. *See, e.g.*,  *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 556 (9th Cir.2000); *United States v. Alpine Land and Reservoir Co.*, 887 F.2d 207, 213 (9th Cir.1989);  *Mt. Graham Red Squirrel v. Espy*, 986 F.2d 1568, 1571 (9th Cir.1993).

APHIS has no obligation to create a numeric threshold to represent a level of risk that Plaintiffs seek to define. Where no risk is acceptable, the competence of the Rule to achieve that objective is measured by the cumulative circumstances and the science and technology available at the time of the final action. That has been done. Neither law nor logic requires an *1110 agency to quantify a numeric threshold of “acceptable risk” every time risk prevention is sought to be achieved by an agency rule.

iv. *Pearson v. Shalala*

 *Pearson v. Shalala*, 164 F.3d 650 (D.C.Cir.1999), requires an agency to “define the criteria it is applying,” when engaging in a discretionary rule-making determination.  *Id.* at 660. In *Pearson*, the FDA rejected applications for approval of statements contained in dietary supplement labeling on the basis that the proposed statements were not supported by “significant scientific agreement.” *Id.* *Pearson* found that the FDA's conclusory explanation that the proposed dietary labeling was not supported by “significant scientific agreement,” *without more*, was not a reasonable explanation for the FDA's rejection: “[W]e agree with appellants that the APA requires the agency to explain why it rejects their proposed health claims—to do so adequately necessarily

implies giving some definitional content to the phrase ‘significant scientific agreement.’ ” [164 F.3d at 660](#). *Pearson* found that the FDA could not simply rely upon the statement that the labels’ statements lacked “significant scientific agreement” as justification for their rejection, without providing some explanation as to what criteria was considered in reaching that conclusion. *Id.*

Here, APHIS does not merely state, as justification for the Final Rule, that the Rule is reasonable, “because it minimizes the risk to an acceptable level.” Rather, APHIS provides a series of analyses which show *how*, *why*, and *to what extent*, the new import requirements of the Final Rule will eliminate the risk of Medfly infestation to as reasonable a degree of certainty as practical utilizing sound science and available technology. A.R. 1222. To require more would place an undue burden on APHIS to apply science and/or technology not yet recognized, or in the alternative, require APHIS to unnecessarily restrict trade on the basis that all risk is not (nor may it ever be) capable of being eliminated *entirely*.²⁹

v. Shalala v. Guernsey Memorial Hospital

It is not the court’s function to direct an agency’s rule-making. The circumstances surrounding APHIS’s promulgation of the Rule, permitting importation of Spanish clementines to resume subject to new preventative measures aimed at eliminating the risk of Medfly introduction, are also subject to the Supreme Court’s approach in [Shalala v. Guernsey Memorial Hospital](#), 514 U.S. 87, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995).

In *Guernsey Memorial Hospital*, a Medicare provider (the “Hospital”) sought reimbursement for defeasance losses on the issuance of new bonds to be fully recognized within the year of refinancing. [Id. at 90](#), 115 S.Ct. 1232. The Secretary of Health and Human Services ruled that reimbursement for such losses should be amortized over the life of the old bonds. *Id.* The Hospital argued that the Secretary’s ruling contradicted “generally accepted accounting principles” with which she was required to comply under an applicable regulation.³⁰ [Id. at 90–91](#), 115 S.Ct. 1232. The Hospital challenged the Secretary’s ruling on the basis that she failed to demonstrate that amortization was supported by “generally accepted accounting principles.” *Id.* The Sixth Circuit reversed the District Court decision upholding the Secretary’s position, because the governing regulations contained “a ‘flat

statement’ that generally accepted accounting principles ‘are followed’ in determining Medicare reimbursements.” [Id. at 91](#), 115 S.Ct. 1232 (citing [Guernsey Memorial Hospital v. Secretary of Health and Human Services](#), 996 F.2d 830, 833 (6th Cir.1993) (quoting [42 C.F.R. § 413.20\(a\)](#))).

The Supreme Court reversed, holding that [42 C.F.R. § 413.20\(a\)](#)’s requirement that “generally accepted accounting principles” be utilized for “[s]tandardized definitions, accounting, statistics, and reporting practices,” did *not* limit the Secretary’s discretion in making reimbursement decisions. [Id. at 93](#), 115 S.Ct. 1232.

The Secretary’s reading of her regulations is consistent with the Medicare statute. Rather than requiring adherence to GAAP, the statute merely instructs the Secretary, in establishing the methods for determining reimbursable costs, to ‘consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment ... to providers of services.’ Nor is there any basis for suggesting that the Secretary has a statutory duty to promulgate regulations that, either by default rule or by specification, address every conceivable question in the process of determining equitable reimbursement.

[Id. at 95–96](#), 115 S.Ct. 1232 (quoting [42 U.S.C. § 1395](#)).

To determine an agency’s obligations under a particular set of statutes or regulations, the Court looks not only to the text of the statutes and regulations, but also to “the overall structure of the regulations.” *Id.* So long as the agency’s interpretations of the overall structure of the authoritative statutes and regulations are reasonable, a Court must defer to the agency’s determinations. [Id. at 94–95](#), 115 S.Ct. 1232 (citing [Thomas Jefferson Univ. v. Shalala](#), 512 U.S. 504, 512, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994); quoting [Martin v. Occupational Safety and Health Review Comm’n](#), 499 U.S. 144, 151, 111 S.Ct. 1171, 113 L.Ed.2d 117 (1991) and [Lyng v. Payne](#), 476 U.S. 926, 939, 106 S.Ct. 2333, 90 L.Ed.2d 921 (1986)).

The specialized expertise of a particular agency often requires deference to its discretionary functions, particularly when

an agency's responsibilities involve regulation of an ever-evolving field.

Because applying an agency's regulation to complex or changing circumstances calls upon the agency's unique expertise and policymaking prerogatives, we presume that the power authoritatively to interpret its own regulations is a component of the agency's delegated lawmaking powers[.]

Id. at 95, 115 S.Ct. 1232, quoting *Martin*, 499 U.S. at 151, 111 S.Ct. 1171.

Where the enabling statutes defer to agency discretion, such discretion should be upheld unless contradictory to the stated purpose of the regulation or otherwise contrary to law. *See, e.g., Hunt v. CIA*, 981 F.2d 1116, 1119 (9th Cir.1992) (in evaluating Central Intelligence Agency's claim of exemption from Freedom of Information Act, court must give substantial weight to CIA's affidavits); *Matney v. Sullivan*, 981 F.2d 1016, 1019 (9th Cir.1992) (Secretary of Health and Human Service's denial of social security benefits is conclusive and will not be overturned absent lack of substantial evidence or legal error); and *1112 *U.S. v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir.1989), *cert denied*, 498 U.S. 817, 111 S.Ct. 60, 112 L.Ed.2d 35, (deference to agency expertise is especially warranted for scientific matters).

Here, the statutory authority and applicable standard to which APHIS must adhere is expressly set forth in 7 U.S.C. § 7701. “The rule that, where the statute contains no ambiguity, it must be taken literally and given effect according to its language, is a sound one not to be put aside to avoid hardships that may sometimes result from giving effect to the legislative purpose.” *Capoeman v. United States*, 194 Ct.Cl. 664, 440 F.2d 1002, 1007 (1971). *See also, Commr. of Immigration v. Gottlieb*, 265 U.S. 310, 313, 44 S.Ct. 528, 68 L.Ed. 1031 (1924).

APHIS has reasonably interpreted its responsibilities under 7 U.S.C. § 7711(b) to “ensure that the processes used in developing regulations” for fruit imports that will prevent the introduction of Medfly into the United States are “based

on sound science and are transparent and accessible.” The express standard Congress set forth in 7 U.S.C. § 7701, regarding the Secretary's execution of her duties under the PPA requires only that the Secretary “facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, *to the extent practicable, as determined by the Secretary*, the risk of dissemination of plant pests or noxious weeds,” and “decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science.” 7 U.S.C. § 7701(3) and (4). To read a numeric threshold risk requirement into the statute would require the court to disregard common principles of statutory construction,³¹ and would abrogate the PPA's clear grant of discretion to the Secretary to reduce risks of plant pests and noxious weeds “to the extent practicable.” As discussed below Plaintiffs have provided no scientific reason to disregard the Secretary's analyses, interpretations, and scientific judgments used to establish the Rule. 7 U.S.C. § 7701(3).

The Secretary conducted tests and analyses to conclude the likelihood of a mated Medfly pair “reaching suitable host material,” as opposed to establishing a Medfly population, was so rare as to be unlikely to occur with a probability of less than once every 2,000 years, adopting the most conservative probability. Based on all the control measures prescribed by the Rule, the Secretary reasonably concluded that the Rule's protections “reduced to the extent practicable” the risk of Medfly introduction. Judicial deference to the Rule is justified on the totality of the record. *Environmental Defense Center, Inc. v. United States Environmental Protection Agency*, 344 F.3d 832, 858 fn. 36 (citing *Washington v. Daley*, 173 F.3d 1158, 1169 (9th Cir.1999)).

vi. Plaintiffs' Lack of Experts

Plaintiffs have not provided any expert evidence or persuasive scientific analysis to explain or contradict the Agency's science that appears in the A.R., nor that calls into questions the accuracy of the Secretary's conclusions. To support their position that the science underlying the October 15th Final Rule is faulty and/or insufficient to support the Rule, Plaintiffs' counsel picks at the APHIS team's expert *1113 studies and commentary and criticizes its interpretation of the data as applied in the Rule. *See, e.g., Doc. 24* at p. 21 (citing A.R. at 1481) and pp. 22–38.

Plaintiffs' criticism of the legitimacy of APHIS's proposed methods is based on abandoned, inadequate measures in effect during the Medfly outbreak in 2001. They complain APHIS scientists were unable to definitively conclude the precise source of the outbreak. APHIS scientists' studies reasonably concluded that the probable source of the 2001 Medfly larvae importation resulted from the combination of an anomalous growth in Spain's Medfly population, exacerbated by: atypically warm weather and a longer growing season; inadequacy and variability of cold treatment measures; insufficient grower phytosanitary practices; and inadequate destination point testing. A.R. 989, 1072, 1283, 1395, and 1789. *See also*, 67 Fed.Reg. at 64703. After a thorough investigation, APHIS determined that the Final Rule adequately addresses each of the potential causes of the 2001 outbreak. "We believe the system we have designed addresses all possible explanations for the problem." A.R. 1283; 67 Fed.Reg. at 64703.

The uncontradicted weight of the data shows that in 23 extensive trials, 3 of 985, 322 Medfly larvae survived cold treatment of 34 to 36 degrees Fahrenheit over 14–18 days. The agency's conclusion that the final cold treatment schedule will achieve probit 9 mortality is justified by the record of testing. Had Plaintiffs provided expert evidence to challenge the validity of the scientific studies or the general scientific framework of the administrative record, the court could evaluate Plaintiffs' argument that either the science, or the agency's application of it, is somehow inaccurate, insufficient or unreliable. Instead, Plaintiffs' challenge to the science underlying the Rule and the conclusions the Agency reached, is no more than unfounded lay opinion of what other experts should or would have done or concluded. This is a failure of proof. It is reasonable to draw the evidentiary inference that Plaintiffs did not provide expert testimony because it would have been adverse. *United States v. Tory*, 52 F.3d 207, 211 (9th Cir.1995).

Plaintiffs' suggestion there is a need for further study of lower temperature-short duration treatments is unavailing, because the Rule no longer permits low temperature-short duration treatments. Even if, *arguendo*, further study is desirable, the agency's judgment that the existing data is sufficient to support probit 9 level of security, 67 Fed.Reg. at 64708, is reasonable and entitled to deference.

Even if Plaintiffs provided expert evidence to challenge the scientific basis for the Rule which contradicted the Agency's

experts, in a "battle of the experts," judicial deference must be accorded the agency's experts unless their opinions are unsupported or wrong. *See, e.g.*, *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378, 109 S.Ct. 1851, 104 L.Ed.2d 377 (1989); *Price Road Neighborhood Ass'n, Inc. v. U.S. Dept. of Transp.*, 113 F.3d 1505, 1511 (9th Cir.1997); *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1332 (9th Cir.1992); *Oregon Environmental Council v. Kunzman*, 817 F.2d 484, 496 (9th Cir.1987). Plaintiffs have no evidence to show the agency's experts' opinions are unsupported or wrong. APHIS has broad discretion to select data and its method of calculation. *B.P. Exploration & Oil, Inc. (93-3310) v. U.S.E.P.A.*, 66 F.3d 784, 804 (6th Cir.1995). An agency's discretion is especially broad when it involves highly scientific or technical considerations. *Id.* at 804, citing *Reynolds Metals Co. v. U.S. Environmental Protection Agency*, 760 F.2d 549, 565 (4th Cir.1985).

*1114 D. THE FINAL RULE COMPLIED WITH EXISTING LAW

"The final inquiry [on judicial review of agency action] is whether the Secretary's action followed the necessary procedural requirements." *Overton Park*, 401 U.S. at 417, 91 S.Ct. 814. Here, Plaintiffs allege that APHIS did not follow procedures required by the Regulatory Flexibility Act (RFA),³² the Plant Protection Act (PPA),³³ and the National Environmental Policy Act (NEPA).³⁴

1. THE RULE DOES NOT VIOLATE PROCEDURES REQUIRED UNDER THE REGULATORY FLEXIBILITY ACT

The Regulatory Flexibility Act (RFA) requires an agency to undertake a cost-efficiency analysis, to identify the most cost-efficient method of attaining the agency's statutory objectives and requires the agency to review the proposed rule's effect on small businesses. *See* 5 U.S.C. §§ 601, *et seq.* Before 1996 amendments to the RFA, unless an agency's noncompliance with the RFA was so unreasonable as to be arbitrary and capricious, judicial review of agency compliance with the RFA was generally not available. *See, e.g.*, *State of Michigan v. Thomas*, 805 F.2d 176, 188 (6th Cir.1986); *Thompson v. Clark*, 741 F.2d 401, 405 (D.C.Cir.1984); *Small Refiner Lead Phase-Down Task Force v. U.S. EPA*, 705 F.2d 506, 539 (D.C.Cir.1983).

While the Office of Advocacy is charged with the primary responsibility of monitoring agency compliance with the RFA,³⁵ due to growing concerns over agency compliance, Congress passed the Small Business Regulatory Enforcement Fairness Act (SBREFA) in the Spring of 1996 which amended 5 U.S.C. § 611(a)(1) to provide an aggrieved party judicial review of agency compliance with sections 601, 604,³⁶ 605(b), 607, 608(b), 609(a) and 610 of the RFA. See Pub.L. 104–121, § 242.

When an agency promulgates a final rule under 5 U.S.C. § 553, the RFA, 5 U.S.C. § 604, directs the agency to prepare a final regulatory flexibility analysis that contains:

- (1) a succinct statement of the need for, and objectives of, the rule;
- (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
- (5) a description of the steps the agency has taken to minimize the significant economic impact on small entities *1115 consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

5 U.S.C. § 604(a)(1)-(5).


Courts have interpreted the RFA to require nothing more than a good faith effort to assess the impact of a regulation on small businesses. See, e.g. *U.S. Cellular Corp. v. F.C.C.*, 254 F.3d 78, 88 (D.C.Cir.2001); *Alenco Communications, Inc. v. F.C.C.*, 201 F.3d 608, 624–25 (5th Cir.2000); *Ashley County Medical Center v. Thompson*, 205 F.Supp.2d 1026, 1066–67 (E.D.Ark.2002); *Hall v. Evans*, 165 F.Supp.2d 114, 145 (D.R.I.2001).

The filing of a regulatory flexibility statement under 5 U.S.C. § 604 is not required where an agency certifies that a rule will not have a significant impact upon a substantial number of small entities. See 5 U.S.C. § 605(b). Such a certification must be made by the head of the agency and the agency is required to publish that certification in the Federal Register at the time of publication “along with a statement providing the factual basis for such certification.” *Id.*

[13] The agency's 5 U.S.C. § 605(b) certification that “the regulations will likely not have a significant economic impact on a substantial number of small entities of Medfly host crop producers in the United States,” or on “small entities,” is found at A.R. 1317, 67 Fed.Reg. 64737–38. This certification is supported by an analytical statement:

- 1) There are approximately 15 Spanish clementine importers in the United States, three of which provide the majority of clementine importation;
- 2) Individuals in foreign countries own at least two of the import companies in “this list;”
- 3) The SBA deems small entities as fresh fruit and vegetable wholesalers with 100 employees or less;
- 4) Small wholesalers include wholesalers and grocery stores with annual sales of \$23 million or less;
- 5) Small wholesalers include warehouse clubs and superstores with annual sales of \$23 million or less;
- 6) Small wholesalers include fruit and vegetable markets with annual sales of \$6 million or less;
- 7) The percentage of income derived from the sale of clementines by wholesalers is “likely to be low” so that these regulations will not have a significant negative impact on small wholesalers; and

8) Small importers and wholesalers will likely be “better off” under the proposed regulations when compared to their status under the current ban on importation of clementines altogether as well as compared to the less strict conditions imposed prior to that ban.

The agency's statement in support of its  5 U.S.C. § 605(b) certification recognizes:

“We do not know whether the majority of producers of Medfly host crops to the U.S. are designated as small entities;” and

“the number of small wholesalers potentially affected by the regulations is not known.” A.R. 1265.

However, the Agency concludes that regulatory costs on producers of Medfly host crops will more than likely not be significant because “Medfly introduction costs are low under the regulations, regardless *1116 of Medfly pest pressure and field control in Spain.” As to the 15 clementine importers in the United States, three of which import the majority of the fruit, it is unclear whether such importers are “small entities,” (fruit and vegetable wholesalers with 100 employees or less).

The number of small wholesalers potentially affected by the regulations is not known. Small wholesalers include wholesalers and other grocery stores with annual sales receipts of \$23 million or less; warehouse clubs and superstores with annual sales receipts of \$23 million or less; and fruit and vegetable markets with annual sales receipts of \$6 million or less. Overall, the percentage of income derived from the sale of Clementines by all U.S. wholesalers is likely to be low, preventing the regulations from having significant negative impact relative to either baseline. Small importers and wholesalers are likely to be better off under regulations where they will have product to sell and better off than under the previous program, due to increased controls. A.R. 1237.

Import levels are projected to increase with the average of 2.5 days of additional cold treatment. Expenditures borne by Spanish exporters (the recall amount was 1.42% of average export value during 1999 and 2000) will likely not lead to significant price increases even if it is assumed all the additional cost is borne by U.S. importers. Due to inelasticity of demand in historical European markets, it is unlikely that extra cold treatment will increase exports to non-U.S. markets and increased U.S. exports will be reduced by higher

levels of diversion of clementines in peak Medfly season under increased controls, which should reduce U.S. imports, increase import prices and reduce regulatory gains for small U.S. importers over the prior import program. In the initial season, due to lower level imports, it is not expected that importers and wholesalers will realize regulatory gains equal to the previous import program due to reduced volume.

The agency's statement that small importers and wholesalers will likely be “better off” under the proposed regulations when compared to their status under a total ban on importation of clementines or compared to the less stringent conditions that prevailed prior to the ban, is based on import increases over time without increase in regulatory costs to importers. A.R. 1236–38, 1317.

The agency prediction that the “import levels will more than likely increase under the regulations,” is obvious because any imports will be an increase over no imports. The agency opines that “clementine imports will more than likely be lower during the first shipping season...,” A.R. 1318, due to increased regulation. This follows as the program measures are put into effect in Spain and the United States, there will be fewer qualifying clementines that will satisfy import criteria. To the extent other foreign markets have less stringent import controls, Spanish producers may divert product to such market. The agency relies on other analyses supporting its overall conclusion that the rule itself will result in a sufficiently high probability that Medfly infestation will not occur to conclude that any impact the new rule will have on small entities, will be positive rather than negative, negating the need for a regulatory flexibility analysis. See Doc. 32 at 48–52. This argument is not without merit.

Following the events of 2001, Plaintiffs have not provided any analysis that a consumer actually found a live Medfly larva, or that the worst case 1.5% hypothetical Risk Management Analysis (RMA) infestation rate actually was experienced in the 2002 import season. Arguing post-record issues invites consideration of the 2002–03 *1117 season data. Plaintiffs have not shown with scientific evidence that their assumed value of 7 rather than 3 surviving larvae makes any difference as to the values selected for the RMA.

Plaintiffs suggest the Risk Management Analysis has discrepancies from the Regulatory Impact Analysis (RIA). Both the RMA, A.R. 1225–1280, and the RIA provide a realistic analysis of the costs and benefits of importing clementines. The RMA utilizes a risk minimization review

based on conservative values to assess risk. The RIA looks at a worst-case analysis to measure costs and benefits. Given the minimal to non-existent risk of Medfly presence from imported clementines in the United States, Plaintiffs' predicted 1.5 billion dollar catastrophe is hyperbole, premised on a no-action hypothesis. No such catastrophe occurred in 2001 in an actual Medfly "outbreak." There is no indication Interior would not act immediately if presented with a new "outbreak." The cost of the successful 2001 Medfly eradication programs was about 14 million dollars. No other potential harm or cost to Plaintiffs is suggested; except the risk of competition, a risk Plaintiffs have accommodated through the years clementines have been imported.

2. THE RULE DOES NOT VIOLATE PROCEDURES REQUIRED UNDER THE PLANT PROTECTION ACT

[14] The Plant Protection Act (PPA) was enacted in 2000 to provide agriculturists with regulatory protection from "plant pests" or "noxious weeds" whose importation posed risks of devastating consequences for domestic agriculture. 7 U.S.C. §§ 7712 to 7716. Under the Act, the Secretary of Agriculture may restrict importation or interstate movement of any plant or plant product, including citrus fruit, to prevent the introduction of harmful pests or weeds which could harm domestic agriculture. 7 U.S.C. § 7712(a) and (c). In order to carry out this policy, the PPA authorizes the Secretary of Agriculture to issue regulations,³⁷ order the destruction or quarantine of harmful organisms,³⁸ create an integrated management plan for any geographical area or ecological range in the country,³⁹ and/or, without a warrant, stop and inspect any person or means of conveyance of importation into the country or in interstate commerce to determine whether the person or conveyance is carrying any plant, pest, or noxious weed and, with a warrant, to enter any premises and investigate for plant pests or noxious weeds.⁴⁰

The PPA provides the Secretary with meaningful enforcement measures and wide discretion to effectuate its policies. Title 7 § 7711(b) specifies the only PPA procedure with which the agency is expressly required to comply: "[t]he Secretary shall ensure that the processes used in developing regulations under subsection (a)⁴¹ of this section governing consideration *1118 of import requests are based on sound science and are transparent and accessible." Title 7 U.S.C. § 7712(b) provides, "[t]he Secretary shall ensure that processes used in developing regulations under this section governing consideration of import requests are based

on sound science and are transparent and accessible." By conducting various scientific studies⁴² and analyses⁴³ which the agency expressly relied upon, analyzed, and discussed in reaching its conclusion,⁴⁴ the Secretary has complied with the existing procedural law required by the PPA. The agency has "discretion to rely on the reasonable opinions of its own qualified experts." *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378, 109 S.Ct. 1851, 104 L.Ed.2d 377 (1989). Plaintiffs had the burden of producing evidence or by identifying evidence in the A.R. that shows the science employed was not sound. They have not done so. The agency's decisions that the Rule is effective to control risk and that its protections reasonably reduce the likelihood of a mated pair of Medflies in the U.S. in fruit from Spain present in suitable habitat, to less than one in two thousand years, considering the 95th percentile of distribution, are not arbitrary, capricious, or contrary to law. A.R. at 1394.

3. THE RULE DOES NOT VIOLATE PROCEDURES REQUIRED UNDER THE NATIONAL ENVIRONMENTAL PROTECTION ACT

Neither party has provided in-depth analysis of the NEPA claim. "The purpose of NEPA is 'to inject environmental considerations into the federal agency's decision-making *1119 process' and 'to inform the public that an agency has considered environmental concerns in its decision-making process.'" *Forelaws on Board v. Johnson*, 743 F.2d 677, 686 (9th Cir.1984) citing *Catholic Action of Hawaii*, 454 U.S. at 143, 102 S.Ct. 197; see also 40 C.F.R. § 1502.1. "NEPA's effectiveness depends entirely on involving environmental considerations in the initial decisionmaking process." See 40 C.F.R. §§ 1501.2, 1502.5; see also *Methow Valley*, 490 U.S. at 349, 109 S.Ct. 1835, 104 L.Ed.2d 351 (explaining that NEPA 'ensures that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts'). *Metcalf v. Daley*, 214 F.3d 1135, 1145 (9th Cir.2000).

The NEPA requires agencies to prepare a detailed Environmental Impact Statement (EIS) when the proposed legislation will "significantly affect[] the quality of the human environment." 42 U.S.C. § 4332. An EIS shall identify and set forth:

- (i) the environmental impact of the proposed action,
- (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
- (iii) alternatives to the proposed action,
- (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
- (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

42 U.S.C. § 4332(C).

[15] While in some instances, regulations for plant pest eradication by the Department of Agriculture may require the preparation of an EIS,⁴⁵ APHIS has adequately demonstrated that the Rule does not pose a colorable risk of affecting the quality of health or the human environment. See “Office of Risk Assessment and Cost Benefit Analysis” (“ORACBA Analysis”) at A.R. 1461–1479 and “Regulatory Impact Analysis,” A.R. 1320–91.

Title 7 C.F.R. § 372.5 classifies those agency actions which normally require an EIS and those which do not. Agency actions which normally require an environmental assessment but not necessarily an EIS are those actions which:

may involve the agency as a whole or an entire program, but generally is related to a more discrete program component and is characterized by its limited scope (particular sites, species, or activities) and potential effect (impacting relatively few environmental values or systems). Individuals and systems that may be affected can be identified.

7 C.F.R. § 372.5(b). The Final Rule impacts, most directly, U.S. citrus growers, importers to the U.S., and consumers who purchase Spanish clementines. The Defendants contend the Rule falls within that category of agency action which does not necessarily require an EIS as specified by 7 C.F.R. §

372.5, and that APHIS's election not to file an EIS was within the scope of its authority and in compliance with the NEPA, because the administrative record supports its assessment that the Final Rule will not “significantly affect[] the quality of the human environment,” under 42 U.S.C. § 4332 as contemplated by 7 C.F.R. § 372.5. A.R. 1307.

The Secretary argues that neither an EIS, nor an Environmental Assessment (EA), is required here because the Rule *1120 falls under 7 C.F.R. § 372.5(c)'s categorical exclusions from any further environmental analysis. A.R. at 1307, 67 Fed.Reg. 64727. Title 7 C.F.R. § 372.5(c) categorically excludes agency action from the EIS or EA requirements where “the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the actions themselves.” *Id.* The USDA has promulgated a non-exclusive list of categorical exclusions from the EIS and EA requirements which have been codified at 7 C.F.R. 1b.3(a),⁴⁶ and include research activities and studies, such as data collection, which are clearly limited in context and intensity.

Title 7 C.F.R. 372.5(c)(1) provides categorical exclusions from EIS or EA requirements for agency actions consisting of routine measures, “such as identifications, inspections, surveys, sampling that does not cause physical alteration of the environment, testing, seizures, quarantines, removals, sanitizing, inoculations, control, and monitoring employed by agency programs to pursue their missions and functions.” 7 C.F.R. § 372.5(c)(1)(i) (*emphasis added*).⁴⁷ Title 7 C.F.R. § 372.5(c)(2) provides categorical exclusions from EIS or EA requirements for agency actions consisting of research and development activities, “that are carried out in laboratories, facilities, or other areas designed to eliminate the potential for harmful environmental effects—internal or external—and to provide for lawful waste disposal.”⁴⁸

Title 7 C.F.R. § 372.5(c)(3) provides categorical exclusions from EIS or EA requirements for agency actions consisting of the following licensing, permitting, or authorization activities:

...

*1121 (iii) Permitting of:

(A) Importation of nonindigenous species into containment facilities,

(B) Interstate movement of nonindigenous species between containment facilities, or

(C) Releases into a State's environment of pure cultures of organisms that are either native or are established introductions.

Title 7 C.F.R. § 372.5(c)(4) provides categorical exclusions from EIS or EA requirements for agency actions consisting of the “[r]ehabilitation of existing laboratories and other APHIS facilities, functional replacement of parts and equipment, and minor additions to such existing APHIS facilities.”

The Secretary argues that it is excluded from providing an EIS or EA here because:

the means through which adverse environmental impacts are avoided has been built into the rule itself... [by][] design[ing] a regulatory approach that results in a very low probability that a mated pair of Medflies could enter the United States via imported Spanish clementines... [and where] [t]he only adverse environmental impacts that could be associated with the importation of Spanish clementines relate to the potential introduction of a pest via that commodity...

A.R. at 1307, 67 Fed.Reg. 64727.

Substantial deference must be accorded an agency's interpretation of the meaning of its own categorical exclusions from the NEPA's EIS and EA requirements unless it is plainly erroneous. See *Alaska Center for the Environment v. U.S. Forest Service*, 189 F.3d 851, 857 (9th Cir.1999) (citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 510–12, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994) and *United States v. McKittrick*, 142 F.3d 1170, 1173 (9th Cir.1998)). Moreover:

An agency satisfies NEPA if it applies its categorical exclusions and determines that neither an EA nor an EIS is required, so long as the application of the exclusions to the facts of the particular action is not arbitrary and capricious.


Bicycle Trails Council v. Babbitt, 82 F.3d 1445, 1456, fn. 5 (9th Cir.1996). Accord, *Committee for Idaho's High Desert v. Collinge*, 148 F.Supp.2d 1097 (D.Idaho 2001).

Collinge considered the Wildlife Service's predator control program aimed at protecting an endangered bird, the sage grouse, which entailed the killing and trapping of predators such as black bears, mountain lions, bobcats, raccoons, magpies, ravens, foxes, coyotes, badgers and skunks, via poisonous eggs, leghold traps, snares, denning, calling and shooting, and aerial hunting. *Collinge*, 148 F.Supp.2d at 1100. The *Collinge* plaintiffs sought to enjoin the Wildlife Service from executing its predator control program on the basis that its environmental assessments (EA) were insufficient and outdated and because an environmental impact statement (EIS) had not been prepared in violation of NEPA. *Id.* The Wildlife Service's response that its predator control program was categorically excluded from the EIS or EA requirements of the NEPA under 7 C.F.R. § 372.5(c)(2), was rejected for failure to specifically demonstrate how the asserted exclusions applied to the program. *Id.* at 1102. The Wildlife Service's “general statement [that the program was categorically excluded] says nothing about whether the particular predation control proposal at issue here falls within the specific terms *1122 of a categorical exclusion established by regulation.” *Id.*

California v. Norton, 311 F.3d 1162, 1176 (9th Cir.2002) rejected Interior's argument that it was entitled to a categorical exclusion from the NEPA's EIS and/or EA requirements because it failed to provide “contemporaneous documentation” to show that the agency considered the environmental consequences of its action. *Id.* “Post hoc invocation of a categorical exclusion does not provide assurance that the agency actually considered the

environmental effects of its action before the decision was made.” *Id.* (citing *Collinge, supra*, at 1103).

Here, by contrast, the nature and purpose of the Rule itself, aimed at the prevention of Medfly introduction into the United States, is designed to protect human health and the environment. Its risk analyses adequately address all issues of environmental concern, particularly the threat of the spread of Medflies, the risk to plant life (crops), and the risk to consumers who could encounter larvae in a fruit. Any additional study as to the environmental impact of Medfly introduction would be repetitive of the agency's 2001 Environmental Assessment and resulting statement.

Plaintiffs have not shown that the Secretary's assertion of categorical exclusions, supported by substantial record evidence, requires the Secretary's further explanation under NEPA or what such an explanation would address.  See *Norton*, 311 F.3d at 1177. The Rule itself is aimed at effectively preventing Medfly importation into the United States, to protect human health and the environment. The Rule's corrective measures do not pose new environmental hazards (such as the application of new or untested pesticides post-entry); rather, the environmental impact of the Rule itself is salutary. Phytosanitary practices are to be implemented in Spain; cold storage will be supplied in Spain, in transit, and in the U.S.; sampling and testing of fruit will be conducted at all stages from production in the field, through import and ultimate delivery to the consumer.

The “hard look” analysis required by the NEPA is unnecessary and inapplicable because the Rule's design and its overall purpose is protection of the environment and human health. Even assuming a “hard look” must be taken, the Secretary has done so. The agency correctly relies on applicable categorical exclusions from the NEPA's EIS and EA requirements. Plaintiffs have provided no factual evidence or law to show the inapplicability of the exclusions or the applicability of any exceptions to the exclusions. The Secretary's interpretation of the categorical exclusions has not been challenged in any meaningful substantive way. Deference must be accorded to the Secretary's NEPA findings.

V. CONCLUSION

For all the reasons stated above, IT IS ORDERED:

1. Federal Defendants' request for judicial notice of the existence and authenticity of the 2002–2003 Data Report as being created and published by the Department of Agriculture is GRANTED;

2. Federal Defendants' request for judicial notice of the accuracy and validity of the contents of the 2002–2003 Data report is DENIED, however, judicial notice is taken that the data was assembled, analysis performed, and no Medfly detections were made;

*1123 3. Intervenor Defendants' request for judicial notice of the authenticity and existence of the Department's Stakeholder Letter is GRANTED;

4. Intervenor Defendants' request for judicial notice of the veracity and/or accuracy of any of the statements, disputed facts, or conclusions of fact contained in the Stakeholder Letter is DENIED;

5. The Department's October 15th Final Rule providing for importation of clementines from Spain to resume, subject to revised conditions and additional preventative measures, is reasonably supported by the administrative record, adequately justified through the agency's transparent application of sound science, within the scope of the agency's authority under the PPA, and in full compliance with existing law.

6. Defendants' motion for summary judgment is GRANTED; and

7. Defendants shall submit a form of judgment in conformity with this decision within the next five (5) days following service of this decision by the Clerk.

SO ORDERED.

All Citations

346 F.Supp.2d 1075

Footnotes

- 1 Plaintiffs' motion for summary judgment was defective for failure to attach a signed proof of service. See Doc. 23. Plaintiffs have filed separate proofs of service for their summary judgment motion. See Doc. 28, filed Apr. 3, 2003; see Doc. 29, Proof of Service for Motion for Summary Judgment on AUSA Catherine on March 26, 2003, filed Apr. 3, 2003.
- 2 The submitted document was found deficient for failure to attach a signed proof of service form. See Doc. 25. On April 3, 2003, Plaintiffs submitted a proof of service of the statement of stipulated facts on AUSA Catherine Cerna on March 24, 2003. See Doc. 27. While no proof of service document exists for Intervenor–Defendants, the statement of stipulated facts was signed by Brian C. Leighton, Esq., attorney for Intervenor–Defendants. See Doc. 25.
Local Rule 56–260(c) states: “All interested parties may jointly file a stipulation setting forth a statement of stipulated facts to which all interested parties agree. As to any stipulated facts, the parties so stipulating may state that their stipulations are entered into only for the purposes of the motion for summary judgment and are not intended to be otherwise binding.”
- 3 This document does not conform to Local Rule 7–130's requirement that “[e]ach page shall be numbered consecutively at the bottom.” See Local Rule 7–130. The court is not limited to the parties' citations of the AR.
- 4 The administrative record (“A.R.”) filed by Federal Defendants on February 14, 2003 omitted the first page of the A.R. containing the Final Rule authorizing the re-importation of Spanish Clementines into the United States. See Doc. 19.
- 5 The larvae detected in Avon, North Carolina, was found in “Nadel” brand Spanish clementines and was purchased for personal consumption on November 17, 2001. See A.R. 87.
- 6 “Pupae” are “insect[s] in the stage of development between the larval and adult forms.” WEBSTERS NEW WORLD DICTIONARY, COLLEGE ED., 1966.
- 7 It was later discovered that cold treatment records from the M/V Green Maloy had “met or surpassed the fruit temperature requirements of 33 degrees Fahrenheit/or 0.55 degrees Celsius/11 day schedule provided under the U.S. Code of Federal Regulations (C.F.R.) 319.56, treatment schedule T–107a.” See A.R. 120.
- 8 The autonomous community of Valencia, situated on Spain's Mediterranean coast, accounts for 67 per cent of Spain's total citrus production. In Valencia, there are over 100,000 growers of citrus, whose respective groves and orchards total 183,000 hectares. See A.R. at 1793–94.
- 9 **7 U.S.C. § 7712(e)** states in relevant part:
The Secretary shall conduct a study of the role for and application of systems approaches designed to guard against the introduction of plant pathogens into the United States associated with proposals to import plants or plant products into the United States...shall ensure the participation by scientists from State departments of agriculture, colleges and universities, the private sector, and the Agricultural Research Service... [and] [n]ot later than 2 years after June 20, 2000, the Secretary shall submit a report on the results of the study conducted under this section to the Committee on Agriculture, Nutrition, and Forestry of the Senate and the Committee on Agriculture of the House of Representatives.
According to Dr. Gadh, the APHIS team “could not come up with the exact cause of the problem, but identified many key factors that they believe contributed to the problem. And those were based on the data they got from Spanish officials of their trapping activities there.” See A.R. 982; see *also*, A.R. 1056.
- 10 Prior to implementation of 7 C.F.R. § 319.56–2jj **7 C.F.R. § 319.56–2jj**, there had been no particular regulation devoted to the importation of clementines from Spain, rather, importation was permitted under the more generalized regulations set forth at **7 C.F.R. § 319.56–2(e)**. **7 C.F.R. § 319.56–2(e)** authorized the importation of any otherwise unrestricted fruit or vegetable which was found by the USDA Administrator to comply with the treatment procedure listed by the Plant Protection and Quarantine Manual (**7 C.F.R. § 300.1**), which required fruit to be held at the following temperatures:

32°F or below	10	lines
33°F or below	11	
34°F or below	12	
35°F or below	13	
36°F or below	14	

See 7 C.F.R. § 300.1. Nothing more than compliance with this procedure was required. Any additional preventative measures were taken only on a voluntary basis.

- 11 The purpose behind this random “sample and cut” aspect of the Rule is to minimize the possibility of importing any lots with massive infestation.
- 12 “Given a large enough volume of infested fruit imports, even the probit 9 level of security could be overwhelmed.” A.R. 1222 (excerpt, page 15, ORACBA “Quantitative Analysis of Available Data on the Efficacy of Cold Treatment against Mediterranean Fruit Fly Larvae,” by Mark Powell).
- 13 The rule amends the PPQ Treatment Manual with this revised cold treatment schedule only with regard to clementines imported from Spain. See A.R. 1134, 67 Fed.Reg. 45927.
- 14 A.R. at 1400–01. This portion of the analysis evaluated the amount of fruit exported per container (less than 166,294) as well as the amount of total fruit exported from Spain to the United States in one year (ca. 80,000 tons based on the 1999–2000 season). These figures were gathered in cumulative reliance upon: USDA, *Tropical products transport handbook*, No. 668 (1987); personal communication with William Thomas, USDA APHIS PPQ, Supervisor, Port of Philadelphia, PA; personal communication with Ernest Santaballa, Coordinador Regional Inspeccion Sanidad Vegetal, MAPA, Valencia; personal communication with Wilmer Snell, APHIS PPQ PIM and Donna West, APHIS PPQ PIM; Central Limit Theorem, N; MAPA, *Anuario de estadísticas agroalimentarias*, pp. 280–88, (1999); Landolt, P., D. Chambers, and V.Chew, *Alternative to the use of provit 9 mortality as a criterion for quarantine treatments of fruit fly (Diptera:Tephritidae)-infested fruit*, J.Econ.Entomol 77:285–287 (1984); Whyte,C.F., R.Baker, J.Cowley, and D.Harte, *Pest establishment, a quantitative method for calculating the probability of pest establishment from imported plants and plant products, as a part of pest risk assessment*, NZ Plant Protection Centre Publications, No. 4, ISSN 1173–6704 (1996); Wearing, C.H., J.Hansen, C.Whyte, C.E.Miller, J.Brown, *The potential for spread of codling moth (Lepidoptera: Tortricidae) via commercial sweet cherry fruit: a critical review and risk assessment*, Crop Protection 20: 465–488 (2001); Vail, P., J.Tebbetts, B.Mackey, and C.Curtis, *Quarantine treatments: a biological approach to decision-making for selected hosts of codling moth (Lepidoptera: Tortricidae)*, J.Econ.Entomol 86:70–77 (1993); Weems,H.V., *Mediterranean fruit fly, Ceratitis capitata (Wiedemann) (Diptera: Tephritidae)*, Entomol. Circ. 230, Florida Department of Agriculture and Consumer Services, Division of Plant Industry (1981); Steiner,L.F., Mitchell, W.C. and A.H.Baumhover, *Progress of fruit fly control by irradiation sterilization in Hawaii and Mariana Islands*, Internat.J.Appl. Rad.Isotopes 13:427–434 (1962); PNKTO (Pests Not Known to Occur in the United States of Limited Distribution) 18 (South American Fruit Fly), 26 (Mediterranean Fruit Fly).
- 15 A.R. at 1401–02. This portion of the analysis evaluated what proportion of fruit infested with Medfly in the field actually arrive at the packinghouse (ca. 5 per thousand). The fruit that arrives at the packinghouse represents that fruit which will be shipped and treated. This figure was accomplished based on cumulative reliance upon: AQIM (Agricultural quarantine inspection monitoring handbook), 2001; Steel, R. and J.Torrie, *Principles and Procedures of Statistics*, McGraw Hill, Inc., New York, NY, pp. 633 (1980); Vose,D., *Quantitative risk analysis*, J.Wiley and Sons, New York, pp. 418 (2000); Agusti,M., *Citricultura*, Ediciones Mundi–Prensa, Madrid, Spain, pp. 416 (2000); EPPO, *Data Sheet on Quarantine Organisms* (1979); personal communication with Ernest Santaballa, Coordinador Regional Inspeccion Sanidad Vegetal, MAPA, Valencia; Weems,H.V., *Mediterranean fruit fly, Ceratitis capitata (Wiedemann)(Diptera: Tephritidae)*, Entomol.Circ. 230, Florida Department of Agriculture and Consumer Services, Division of Plant Industry (1981); Planes, S. and J.M.Carrero, *Plagas del campo*, Ediciones Mundi–Prensa, Madrid, Spain, pp. 550 (1995); 2001 sampling results by USDA–APHIS–PPQ; Gould,W.P., *Probability of detecting Caribbean fruit fly (Diptera: Tephritidae) infestations by fruit dissection*, Florida Entomologist 78(3): 502–507 (1995); MAPA, *Maps, Medfly trap locations, research results and citrus phenology* (2001); and APHIS inspector's site visits to Spain.

- 16 A.R. at 1402–03. This component estimates the total number of medflies present per infested fruit (100 eggs or eight viable adults per fruit). This figure was accomplished based on cumulative reliance upon: Santabella, E., R. Laborda, M. Cerda, *Informe sobre tratamiento frigorífico de cuarentena contra Ceratitis capitata (Wied.) Para exportar mandarina clementines a Japon*, Univ. Polytechnica de Valencia, pp. 25 (1999); Leyva, J.L., H. Browning, and F. Gilstrap, *Development of A. ludens in several hosts*, *Environ. Entomol.* 20(4): 1160–1165 (1991); McDonald, P.T. and P.O. McInnis, *Ceratitidis capitata: effect of host fruit size on the numbers of eggs per clutch*, *Entomol. Ex. Appl.* 37:207–13 (1985); Gillot, (1980); PNKTO (Pests Not Known to Occur in the United States of Limited Distribution) 18 (South American Fruit Fly), 26 (Mediterranean Fruit Fly); personal communication with William Thomas, USDA APHIS PPQ, Supervisor, Port of Philadelphia, PA; and Gould, W.P., *Probability of detecting Caribbean fruit fly (Diptera: Tephritidae) infestations by fruit dissection*, *Florida Entomologist* 78(3):502–507 (1995).
- 17 A.R. at 1403–04. This component considers the rate of survival post-application of cold treatment to be at most 32 in a million (ca. .000032 larvae survive treatment). This figure was accomplished based on cumulative reliance upon: USDA's Treatment Manual (1998); Liquido, N., K. Vick, and R. Griffin, *Quarantine Security for Commodities*, In: Bartlett, P, Chaplin, G. And R. van Velson (eds), *Plant Quarantine Statistics: a review. Horticultural Research and Dev. Corp.*, Sydney, Australia (1996); personal communication with C.E. Miller; Robertson, J. and H. Preisler, *Pesticide Bioassays with Arthropods*, CRC Press (1992); Back, E. and C. Pemberton, *Effect of cold storage temperatures upon the pupae of the Mediterranean fruit fly*, *J. Agric. Res.* 6(7):251–260 (1916); Fares, F., *The effect of cold storage on the hatchability of the Mediterranean fruit fly*, *Agric. Res. Rev. (Cairo)* 51(1):57–58 (1973); Flitters, N.E. and P. Messenger, *Effect of temperature and humidity on the development and distribution of Hawaiian and Mexican fruit flies*, *J. Rio Grande Valley Hort. Soc.* 12:7–13 (1958); Hill, A., C. Rigney, and A. Sproul, *Cold storage of oranges as a disinfestation treatment against fruit flies Dacus tryoni and Ceratitis capitata*, *J. Econ. Entomol.* 81(1):257–260 (1988); Mason, A. and O. McBride, *Effect of low temperatures on the Mediterranean fruit fly in infested fruit*, *J. Econ. Entomol.* 28(5):297 (1934); Petty, F. and E. Griffiths, *Effective control of fruit fly by refrigeration*, *S. Afric. Dept. Agric. Sci. Bull.* 99 (1931); Nel, R.G., *The utilization of low temperatures in the sterilization of deciduous fruit infested with the immature stages of Mediterranean fruit fly, Ceratitis capitata*, *Union. S. Afric. Sci. Bull.* 155 (1936); Gould, W., J. Armstrong, J. Hansen, J. Cooley, *Cold Treatment recommendations* (2002); Baker, A.C., W.E. Stone, C.C. Plummer & M. McPhail, *A review of studies on the Mexican fruit fly and related Mexican species*, *USDA Misc. Publ.* 531:155 (1944); De Lima, C.P.F., A. Jessup, and R. McLauchlan, *Cold disinfestations of citrus using different temperature X time combinations*, *Hort. Australia Ltd. Project No. CT96020* (2002); and USDA Memo from M. Powell to D. Reeves (2002).
- 18 A.R. at 1404–06. This component considers the amount of fruit that actually represents a hazard (fruit that is not consumed and is discarded into a suitable environment) estimated to be 5% of any given container. This figure was accomplished based on cumulative reliance upon: Miller, C.E., *Risk Assessment, Mediterranean fruit fly. Planning and Risk Analysis Systems, Policy and Program Development*, USDA APHIS, pp. 113 (1992); USDA, *USDA plant hardiness zone map*, Agriculture Research Service, Misc. Pub. No. 1475 (1990); Smith, H.T., *Medfly cooperative eradication program, final environmental impact statement*, USDA APHIS, Hyattsville, MD. Pp. 45–75 (1993); Dominguez, F., *Plagas y enfermedades de las plantas cultivadas*, Ediciones Mundi-Prensa, Madrid, Spain, pp. 821 (1998); Baker, A.C., W.E. Stone, C.C. Plummer & M. McPhail, *A review of studies on the Mexican fruit fly and related Mexican species*, *USDA Misc. Publ.* 531:155 (1944); Wearing, C.H., J. Hansen, C. Whyte, C.E. Miller, J. Brown, *The potential for spread of codling moth (Lepidoptera: Tortricidae) via commercial sweet cherry fruit: a critical review and risk assessment*, *Crop Protection* 20:465–488 (2001); and Roberts, R., C. Hale, T. van der Zwet, C. Miller, S. Redlin, *The potential for spread of Erwinia amylovora and fire blight via commercial apple fruit; a critical review and risk assessment*, *Crop. Prot.* 17, 19–28 (1998).
- 19 Judicial notice is distinguished from res judicata and collateral estoppel whereby a party is prevented from raising a claim or issue which has already been sufficiently addressed and decided in a prior proceeding where that party's interest was adequately represented. See, e.g., [Robinson, 971 F.2d at 249–53](#); [Allen](#)

v. McCurry, 449 U.S. 90, 101 S.Ct. 411, 66 L.Ed.2d 308 (1980); *Thorley v. Superior Court*, 78 Cal.App.3d 900, 907, 144 Cal.Rptr. 557 (1978).

20 See *infra* Part C.v-vii.

21 See *infra* Part C.v.

22 *Animal Defense Council* states in relevant part:

When [] a failure to explain agency action effectively frustrates judicial review, the court may ‘obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary.’ *Camp v. Pitts*, 411 U.S. 138, 143, 93 S.Ct. 1241, 1244, 36 L.Ed.2d 106 (1973). The court’s inquiry outside the record is limited to determining whether the agency has considered all relevant factors or has explained its course of conduct or grounds of decision. *Hintz*, 800 F.2d at 829.

The district court may also inquire outside of the administrative record ‘when it appears the agency has relied on documents or materials not included in the record.’ *Id.* In addition, discovery may be permitted if supplementation of the record is necessary to explain technical terms or complex subject matter involved in the agency action. *Id.*

Id. 840 F.2d at 1436.

23 See, e.g., “Quantitative Analysis of Available Data on the Efficacy of Cold Treatment against Mediterranean Fruit Fly Larvae,” July 5, 2002, at A.R. 1207–1224; “Fruit Fly Cooperative Control Program, Final Environmental Impact Statement” (2001), 67 Fed.Reg. 64727, A.R. 1307 (available at <http://www.aphis.usda.gov/ppd/es/ppq/ffeis.pdf>); De Lima, C.P.F., A. Jessup, and R. McLauchlan.2002. “Cold disinfestations of citrus using different temperatures X time combinations.” *Horticulture Australia Ltd. Project Number: CT96020*, 67 Fed.Reg. 64708, A.R. 1288; Landolt, P., D. Chambers, and V. Chew.1984. “Alternative to the use of probit 9 mortality as a criterion for quarantine treatments of fruit fly (Diptera: Tephritidae)-infested fruit.” *J. Econ. Entomol* 77: 285–287, 67 Fed.Reg. 64717, A.R. 1297; Synopsis of APHIS review of cold treatment records of ports of Philadelphia, PA and Elizabeth, NJ; Synopsis of APHIS study tracing initial interceptions in 2001 to be traced to particular vessels, “M/V Japan Senator” and “M/V Green Maloy,” A.R. 1289.

24 See, e.g., “Risk Mitigation Analysis” at A.R. 1392–1460 (notice and comment provided at 67 Fed.Reg. 18578–79, and extended at 67 Fed.Reg. 36560–61); “Office of Risk Assessment and Cost Benefit Analysis” (“ORACBA Analysis”) at A.R. 1461–1479; “Regulatory Impact Analysis,” A.R. 1320–91; Wearing, C.H., J. Hansen, C. Whyte, C.E. Miller, J. Brown.2001. “The potential for spread of codling moth (Lepidoptera: Tortricidae) via commercial sweet cherry fruit: a critical review and risk assessment.” *Crop Protection* 20: 465–488, 67 Fed.Reg. 64717, A.R. 1297; Roberts, R.C. Hale, T. Van der Zwet, C.Miller, S. Redlin.1998. “The potential for spread of *Erwinia amylovora* and fire blight via commercial apple fruit; a critical review and risk assessment.” *Crop. Prot.* 19–28, *Id.*; Whyte, C.F., R. Baker, J. Cowley, and D. Harte.1996. “Pest establishment, a quantitative method for calculating the probability of pest establishment from imported plants and plant products, as a part of pest risk assessment.” *NZ Plant Protection Centre Publications, No. 4, ISSN 1173–6704. Lynfield, NZ., Id.*; Analyses of hypergeometric sampling rates and Confidence/percentage of infestation Chart at 67 Fed.Reg. 64712–13, A.R. 1292.

25 67 Fed.Reg. 64702–64739, A.R. 2182–1319.

26 APHIS explains that promulgation of the Final Rule “is based on the finding that the application of the remedial measures contained in this final rule *will prevent* the introduction or dissemination of plant pests into the United States.” 67 Fed.Reg. 64703. A.R. 1283.



27 “Probit 9 mortality” is described as “[a] level or percentage of mortality of target pests (i.e., 99.9968 percent mortality or 32 survivors out of a million) caused by a control measure.” 67 Fed.Reg. 64703, fn. 3.

28 Table 4 of the July 5, 2002, “Quantitative Analysis of Available Data on the Efficacy of Cold Treatment against Mediterranean Fruit Fly Larvae,” by Mark Powell, illustrates the recognized studies of cold treatment efficacy (Nel, 1936; Sproul, 1976; Hill, 1988; Jessup, 1993; Santaballa, 1999; and APHIS, 2002 survey study). Each

study tested different numbers of larvae against varying cold treatment applications where temperature and length of treatment factored into the overall efficacy of the treatments. Additionally, each study tested different host factors, i.e., lemons, nuts. The only study which involved cold treatment of clementines, Santabella (1999), tested a population range from 935 larvae to 10,376, each at 35.6 degrees Fahrenheit (2 degrees Celcius). The Santabella study revealed: (1) out of 935 larvae, 24 survived an eight day treatment; (2) out of 935 larvae, 10 survived a ten day treatment; (3) out of 935 larvae, 5 survived twelve days of treatment; (4) out of 935 larvae, 0 survived 14 days of treatment; (5) out of 11,317, 0 survived 16 days of treatment; (6) on another test involving 10,295 larvae, 0 survived 16 days of treatment; and (7) on another test involving 10,376 larvae, 0 survived 16 days of treatment. (Compare to the Hill (1988) study which treated 41,099 larvae for 16 days at 34.7 degrees Fahrenheit/1.5 degrees Celcius. Three (3) of the 41,099 larvae survived).

29 According to the October 4, 2002, Risk Mitigation Analysis, APHIS's analysis "showed that the likelihood of a mated pair in fruit from Spain was less than one in two thousand years, considering the 95th percentile of the distribution (less than one in more than 10,000 years using the mean of the distribution)." A.R. 1394.

30  42 C.F.R. § 413.20(a).



31 "Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvement." See  *TVA v. Hill*, 437 U.S. 153, 194–195, 98 S.Ct. 2279, 57 L.Ed.2d 117 (1978). Accord,  *Badaracco v. C.I.R.*, 464 U.S. 386, 398, 104 S.Ct. 756, 78 L.Ed.2d 549 (1984).

32 See Doc. 1, Complaint at 8, filed October 16, 2002; Doc. 24 at 38.

33 See Doc. 1 at 7.

34 See Doc. 1 at 9.

35 See  5 U.S.C. § 612.

36 The amended statute provides that "sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of  section 604."  5 U.S.C. § 611(a)(1).

37 See 7 U.S.C. § 7712.

38 See 7 U.S.C. § 7714(a) and (b).

39 See 7 U.S.C. § 7714(c).

40 See  7 U.S.C. § 7731 (probable cause required).



41 7 U.S.C. § 7711(a) prohibits plant pests from being imported/exported or otherwise moved through interstate commerce unless accompanied by a permit and in accordance with the Secretary's regulations under this title: "Except as provided in subsection (c) of this section, no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and is in accordance with such regulation as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States."

42 See, e.g., "Quantitative Analysis of Available Data on the Efficacy of Cold Treatment against Mediterranean Fruit Fly Larvae," July 5, 2002, at A.R. 1207–1224; "Fruit Fly Cooperative Control Program, Final Environmental Impact Statement" (2001), 67 Fed.Reg. 64727, A.R. 1307 (available at <http://www.aphis.usda.gov/ppd/es/ppq/fffeis.pdf>); De Lima, C.P.F., A. Jessup, and R. McLauchlan.2002. "Cold disinfestations of citrus using different temperatures X time combinations." *Horticulture Australia Ltd. Project Number: CT96020*, 67 Fed.Reg. 64708, A.R. 1288; Landolt, P., D. Chambers, and V. Chew.1984. "Alternative to the use of probit 9 mortality as a criterion for quarantine treatments of fruit fly (Diptera: Tephritidae)—infested fruit." *J. Econ. Entomol* 77: 285–287, 67 Fed.Reg. 64717, A.R. 1297; Synopsis of APHIS review of cold treatment records of ports of Philadelphia, PA and Elizabeth, NJ; Synopsis of APHIS study tracing initial interceptions in 2001 to be traced to particular vessels, "M/V Japan Senator" and "M/V Green Maloy," A.R. 1289.

43 See, e.g., "Risk Mitigation Analysis" at A.R. 1392–1460 (notice and comment provided at 67 Fed.Reg. 18578–79, and extended at 67 Fed.Reg. 36560–61); "Office of Risk Assessment and Cost Benefit

Analysis” (“ORACBA Analysis”) at A.R. 1461–1479; “Regulatory Impact Analysis,” A.R. 1320–91; Wearing, C.H., J. Hansen, C. Whyte, C.E. Miller, J. Brown.2001. “The potential for spread of codling moth (Lepidoptera: Tortricidae) via commercial sweet cherry fruit: a critical review and risk assessment.” *Crop Protection* 20: 465–488, 67 Fed.Reg. 64717, A.R. 1297; Roberts, R.C. Hale, T. Van der Zwet, C.Miller, S. Redlin.1998. “The potential for spread of Erwinia amylovora and fire blight via commercial apple fruit; a critical review and risk assessment.” *Crop. Prot.* 19–28, *Id.*; Whyte, C.F., R. Baker, J. Cowley, and D. Harte.1996. “Pest establishment, a quantitative method for calculating the probability of pest establishment from imported plants and plant products, as a part of pest risk assessment.” *NZ Plant Protection Centre Publications, No. 4, ISSN 1173–6704. Lynfield, NZ., Id.*; Analyses of hypergeometric sampling rates and Confidence/percentage of infestation Chart at 67 Fed.Reg. 64712–13, A.R. 1292.

44 67 Fed.Reg. 64702–64739, A.R. 2182–1319.

45  *Environmental Defense Fund v. Hardin*, 325 F.Supp. 1401 (D.D.C.1971);  *Save America's Vital Environment, Inc. (SAVE) v. Butz*, 347 F.Supp. 521 (N.D.Ga.1972).

46 7 C.F.R. § 1b.3(a) categorically excludes from the EA or EIS requirements the following agency activities:

- (1) Policy development, planning and implementation which relate to routine activities, such as personnel, organizational changes, or similar administrative functions;
- (2) Activities which deal solely with the funding of programs, such as program budget proposals, disbursements, and transfer or reprogramming of funds;
- (3) Inventories, *research activities, and studies, such as resource inventories and routine data collection when such actions are clearly limited in context and intensity*;
- (4) Educational and informational programs and activities;
- (5) Civil and criminal law enforcement and investigative activities;
- (6) Activities which are advisory and consultative to other agencies and public and private entities, such as legal counseling and representation;
- (7) Activities related to trade representation and market development activities abroad.

Id. (*emphasis added*).

47 7 C.F.R. § 372.5(c)(1)(ii) provides the following examples of “routine measures” categorically excluded from the EIS or EA requirement:

- (A) Inoculation or treatment of discrete herds of livestock or wildlife undertaken in contained areas (such as a barn or corral, a zoo, an exhibition, or an aviary);
- (B) Pesticide treatments applied to infested plants at a nursery; and
- (C) Isolated (for example, along a highway) weed control efforts.

48 7 C.F.R. § 372.5(c)(2)(ii) provides the following examples of “research and development activities” categorically excluded from the EIS or EA requirement:

- (ii) Examples of this category of actions include:
 - (A) The development and/or production (including formulation, repackaging, movement, and distribution) of previously approved and/or licensed program materials, devices, reagents, and biologics;
 - (B) Research, testing, and development of animal repellents; and
 - (C) Development and production of sterile insects.

National Telephone Co-op. Ass'n v. F.C.C., 563 F.3d 536 (2009)

385 U.S.App.D.C. 327, 47 Communications Reg. (P&F) 985



KeyCite Yellow Flag - Negative Treatment

Distinguished by [Delaware Dept. of Natural Resources and Environmental Control v. E.P.A.](#), D.C.Cir., May 1, 2015

563 F.3d 536

United States Court of Appeals,
District of Columbia Circuit.**NATIONAL TELEPHONE COOPERATIVE
ASSOCIATION**, Petitioner

v.

FEDERAL COMMUNICATIONS COMMISSION
and United States of America, Respondents
Qwest Communications
Corporation, et al., Intervenors.

No. 08-1071.

|
Argued Jan. 26, 2009.|
Decided April 28, 2009.**Synopsis**

Background: Non-profit association representing small and rural telephone cooperatives and commercial companies petitioned for review of Federal Communications Commission (FCC) intermodal portability order, which set conditions under which wireline telecommunications carriers were required to transfer telephone numbers to wireless carriers. The Court of Appeals, [Merrick B. Garland](#), Circuit Judge, [400 F.3d 29](#), stayed enforcement and remanded order because FCC failed to publish required analysis. On remand, [FCC issued analysis](#), [20 F.C.C.R. 8616](#), [2005 WL 937606](#), and association challenged it.

Holdings: The Court of Appeals, Kavanaugh, Circuit Judge, held that:

[1] FCC's analysis for issuance of order determination complied with requirements of Regulatory Flexibility Act (RFA);

[2] FCC's explanation of implementation costs was reasonable and reasonably explained;

[3] association's opposition regarding imposition of transport costs was misplaced;

[4] FCC reasonably concluded that mitigating measures were unnecessary; and

[5] FCC's explanation of its rejection of alternative policy options was reasonable and reasonably explained.

Petition denied.

West Headnotes (8)

[1] Telecommunications **Number portability**



Federal Communications Commission's (FCC's) analysis for issuance of intermodal portability order, which set conditions under which wireline telecommunications carriers were required to transfer telephone numbers to wireless carriers, complied with requirements of Regulatory Flexibility Act (RFA), where analysis addressed all of legally mandated subject areas. [5 U.S.C.A. § 604\(a\)\(5\)](#).

[6 Cases that cite this headnote](#)**[2] Administrative Law and Procedure** **Statement of economic or social impact**


Requirements of Regulatory Flexibility Act (RFA) are purely procedural, even though it directs agencies to state, summarize, and describe reasons for determination; RFA imposes no substantive constraint on agency decisionmaking, but merely requires agencies to publish analyses that address certain legally delineated topics. [5 U.S.C.A. § 601, et seq.](#)

[10 Cases that cite this headnote](#)**[3] Administrative Law and Procedure** **Statement of economic or social impact**

Agency's analysis, as required by Regulatory Flexibility Act (RFA), satisfies requirement, under Administrative Procedure Act (APA) and RFA, that impact of agency's rule on

small businesses be reasonable and reasonably explained.  5 U.S.C.A. §§ 601, et seq.,  701, et seq.



[24 Cases that cite this headnote](#)

[4] **Administrative Law and Procedure**  **Arbitrariness and capriciousness; reasonableness**

Arbitrary-and-capricious review in agency rulemaking cases is highly deferential.



[26 Cases that cite this headnote](#)

[5] **Telecommunications**  **Number portability**



Federal Communication Commission's (FCC's) explanation of implementation costs related to intermodal portability order, which set conditions under which wireline telecommunications carriers were required to transfer telephone numbers to wireless carriers, was reasonable and reasonably explained; FCC found scant support for implementation cost estimates offered by commentators, and further concluded that estimates would not impose significant economic burden on small entities even if they were valid, and that order balanced impact of costs on small carriers and public interest benefits.  5 U.S.C.A. §§ 601, et seq.,  701, et seq.

[6] **Telecommunications**  **Proceedings**



Opposition of non-profit association representing small and rural telephone cooperatives and commercial company to Federal Communications Commission (FCC) intermodal portability order, which set conditions under which wireline telecommunications carriers were required to transfer telephone numbers to wireless carriers, alleging that order imposed burden on small businesses with significant and disproportionate transport costs, was misplaced in review of order; any problems associated with transport costs were not unique to intermodal porting, and thus FCC would address issue

comprehensively in separate pending inter-carrier compensation proceeding.  5 U.S.C.A. §§ 601, et seq.,  701, et seq.

[7] **Telecommunications**  **Number portability**

Federal Communications Commission (FCC) reasonably concluded that mitigating measures were unnecessary as to intermodal portability order, which set conditions under which wireline telecommunications carriers were required to transfer telephone numbers to wireless carriers, based on FCC determinations that order fulfilled statutory objectives by advancing both competition and interests of consumers, and would not impose significant implementation costs on small businesses.  5 U.S.C.A. §§ 601, et seq.,  701, et seq.

[8] **Telecommunications**  **Number portability**

Federal Communication Commission's (FCC's) explanation of its rejection of alternative policy options in issuing intermodal portability order, which set conditions under which wireline telecommunications carriers were required to transfer telephone numbers to wireless carriers, was reasonable and reasonably explained; FCC explained that issuing temporary stay of order's requirements for small wireline carriers or limiting scope of order's requirement would have denied many wireline consumers benefit of being able to port numbers to wireless carriers, and rejected partial or blanket exemption from order's requirements on ground that exemption would have discouraged competition and harmed consumers in small and rural areas.  5 U.S.C.A. §§ 601, et seq.,  701, et seq.

[2 Cases that cite this headnote](#)

*538 On Petition for Review of an Order of the Federal Communications Commission.

Attorneys and Law Firms

L. Marie Guillory argued the cause for petitioner. With her on the briefs were Daniel Mitchell, Jill Canfield, and Karlen J. Reed.

Joel Marcus, Counsel, Federal Communications Commission, argued the cause for respondent. With him on the brief were Thomas O. Barnett, Assistant Attorney General, U.S. Department of Justice, Catherine G. O'Sullivan and Nancy C. Garrison, Attorneys, Matthew B. Berry, General Counsel, Federal Communications Commission, Joseph R. Palmore, Deputy General Counsel, and Richard K. Welch, Acting Deputy Associate General Counsel.

Before: GINSBURG, GARLAND and KAVANAUGH, Circuit Judges.

Opinion

Opinion for the Court filed by Circuit Judge KAVANAUGH.

KAVANAUGH, Circuit Judge:

****329** The Regulatory Flexibility Act requires an agency issuing a final rule to publish an analysis of the rule's impact on small businesses.¹

***539 *330** In 2005, we stayed and remanded a Federal Communications Commission order because the agency had failed to publish the required analysis. [U.S. Telecom Ass'n v. FCC](#), 400 F.3d 29, 42–43 (D.C.Cir.2005). The FCC has now issued the analysis, but the National Telecommunications Cooperative Association challenges it as inconsistent with the Regulatory Flexibility Act and arbitrary and capricious under the Administrative Procedure Act. We deny NTCA's petition for review.

I

This case concerns “number portability”—the ability of telephone customers to keep a telephone number after switching service providers. In 1996, the Federal Communications Commission issued an order requiring “local exchange carriers”—that is, companies that provide telephone service, *see* [47 U.S.C. § 153\(26\)](#)—to ensure number portability to persons changing carriers but remaining

in the same physical location. So, for example, someone switching between two local telephone service providers can keep the same home telephone number. That requirement facilitates competition among wireline carriers by eliminating the inconvenience of having to switch numbers when changing carriers.

In 2003, the FCC issued a second order requiring local exchange carriers to port numbers to *wireless* carriers providing service in the same area. That new requirement—known as “intermodal portability”—means that local wireline carriers have to route telephone calls to wireless carriers. To accomplish this, local exchange carriers must transmit wireline telephone signals to what is known as a “point of interconnection”—a point where wireline signals are converted into wireless signals. Points of interconnection are sometimes far from local exchange carriers, however, and local exchange carriers must bear certain costs in routing signals over those distances.

Local exchange carriers challenged the FCC's Order on intermodal portability. They argued, among other things, that the FCC had violated the Regulatory Flexibility Act, which directs agencies to publish an analysis of how a rule will affect small businesses. *See* [5 U.S.C. § 604](#). The FCC responded that the Order in question was exempt from the Act because it constituted an interpretive rule. In 2005, this Court concluded that the intermodal portability Order was not exempt from the Act's requirements; we found that the Order was a legislative rule. We therefore granted the local exchange carriers' petitions for review with respect to their Regulatory Flexibility Act claim, stayed the intermodal portability Order until the FCC supplied the required regulatory flexibility analysis, and remanded the matter to the FCC. [U.S. Telecom Ass'n v. FCC](#), 400 F.3d 29, 43 (D.C.Cir.2005).

In 2008, the FCC published the analysis required by the Regulatory Flexibility Act, and the stay on enforcement of the intermodal portability Order accordingly expired. Now the National Telecommunications Cooperative Association—an association of rural telephone companies, *see* [47 U.S.C. § 153\(37\)](#)—challenges the Final Regulatory Flexibility Analysis that the FCC issued on remand. Citing the Order's effects on small businesses, NTCA argues that the FCC violated the Regulatory Flexibility Act and the Administrative Procedure Act.

**331 *540 II

B

A

The Regulatory Flexibility Act requires that agencies issuing rules under the Administrative Procedure Act publish a final regulatory flexibility analysis. See [5 U.S.C. § 604](#). Such an analysis must meet certain statutory requirements. It must state the purpose of the relevant rule and the estimated number of small businesses that the rule will affect, if such an estimate is available. In addition, each analysis must summarize comments filed in response to the agency's initial regulatory flexibility analysis, along with the agency's assessment of those comments. Finally, each analysis must include “a description of the steps the agency has taken to minimize the significant economic impact” that its rule will have on small businesses, “including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.” [§ 604\(a\)\(5\)](#).

[1] [2] According to NTCA, the analysis issued by the FCC does not comply with the Regulatory Flexibility Act. We disagree. As we have previously recognized, the Act's requirements are “[p]urely procedural.” [U.S. Cellular Corp. v. FCC](#), 254 F.3d 78, 88 (D.C.Cir.2001); see also [Aeronautical Repair Station Ass'n, Inc. v. FAA](#), 494 F.3d 161, 178 (D.C.Cir.2007) (“The RFA is a procedural statute setting out precise, specific steps an agency must take.”). Though it directs agencies to state, summarize, and describe, the Act in and of itself imposes no substantive constraint on agency decisionmaking. In effect, therefore, the Act requires agencies to publish analyses that address certain legally delineated topics. Because the analysis at issue here undoubtedly addressed all of the legally mandated subject areas, it complies with the Act. Cf. [U.S. Cellular Corp.](#), 254 F.3d at 88–89 (“Petitioners dispute neither that the Commission included a FRFA [final regulatory flexibility analysis] ... nor that this statement addresses all subjects required by the RFA.”).

NTCA also raises a related but distinct claim that the FCC's action is arbitrary and capricious under the APA because the agency did not reasonably address the Order's impact on small businesses.

[3] The APA's arbitrary-and-capricious standard requires that agency rules be reasonable and reasonably explained. Under *State Farm*, we must assess, among other things, whether the agency decision was based on “consideration of the relevant factors.” [Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.](#), 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) (internal quotation marks omitted). The Regulatory Flexibility Act makes the interests of small businesses a “relevant factor” for certain rules. Therefore, the APA together with the Regulatory Flexibility Act require that a rule's impact on small businesses be reasonable and reasonably explained. A regulatory flexibility analysis is, for APA purposes, part of an agency's explanation for its rule. See [Small Refiner Lead Phase-Down Task Force v. EPA](#), 705 F.2d 506, 539 (D.C.Cir.1983) (“a reviewing court should consider the regulatory flexibility analysis as part of its overall judgment whether a rule is reasonable”); see also [Thompson v. Clark](#), 741 F.2d 401, 405 (D.C.Cir.1984) (“Thus, if data in the regulatory flexibility analysis—or data anywhere else in the rulemaking record—demonstrates that the rule constitutes such an unreasonable assessment of social costs and benefits as to **332 *541 be arbitrary and capricious, the rule cannot stand.”) (citation omitted).

[4] As we have said many times before, arbitrary-and-capricious review in agency rulemaking cases is highly deferential. See [City of Portland, Oregon v. EPA](#), 507 F.3d 706, 713 (D.C.Cir.2007); [AT & T Corp. v. FCC](#), 448 F.3d 426, 431 (D.C.Cir.2006). In assessing whether a rule is reasonable and reasonably explained, our review is “narrow,” and we must not “substitute [our] judgment for that of the agency.” [State Farm](#), 463 U.S. at 43, 103 S.Ct. 2856. That is particularly true with regard to an agency's predictive judgments about the likely economic effects of a rule. See [Teledesic LLC v. FCC](#), 275 F.3d 75, 84 (D.C.Cir.2001).

In this case, NTCA raises four specific objections to the FCC's regulatory flexibility analysis, which we consider in turn.

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[5] *First*, NTCA contends that the intermodal portability Order causes small businesses to incur unreasonably high implementation costs. But the FCC found “scant support” for the implementation cost estimates offered by some commentators. *In re Telephone Number Requirements for IP-Enabled Services Providers*, 22 F.C.C.R. 19531, 19607 ¶ 5, 2007 WL 3306343 (2007). The agency noted, moreover, that the estimates would not impose “a significant economic burden on small entities,” even if they were “taken at face value.” *Id.* at 19606–07 ¶ 5. The FCC concluded that its chosen approach “best balances the impact of the costs that may be associated with the wireline-to-wireless intermodal porting rules for small carriers and the public interest benefits of those requirements.” *Id.* at 19610 ¶ 13. Although the FCC's explanation of implementation costs was not elaborate, we find its consideration of those costs reasonable and reasonably explained in light of the record in this case. *See In re Core Communications, Inc.*, 455 F.3d 267, 279 (D.C.Cir.2006); *United Parcel Service, Inc. v. U.S. Postal Service*, 184 F.3d 827, 839–40 (D.C.Cir.1999).

[6] *Second*, according to NTCA, the FCC's intermodal portability Order also burdens small businesses with significant and disproportionate transport costs—that is, costs incurred by routing a telephone call from one carrier to another.² The agency here pointed out that any problems associated with transport costs are not unique to intermodal porting; the agency said it therefore would address the issue comprehensively rather than piecemeal. The FCC is now considering transport costs in a separate rulemaking proceeding, the intercarrier compensation proceeding. Because this Order is not the source of the transport costs problem, and because the FCC is already performing the review of transport cost issues that NTCA asks us to mandate, NTCA's opposition is misplaced and should be raised in the intercarrier compensation proceeding. We reached the same conclusion under similar circumstances in *Central Texas Telephone Co-op., Inc. v. FCC*, 402 F.3d 205 (D.C.Cir.2005). There, in a case involving number portability, we found no APA violation where the FCC similarly postponed consideration of transport cost issues that had already been “raised ... in other proceedings”—namely, in the intercarrier compensation proceeding. *Id.* at 215 (internal quotation marks omitted); *see also Toca Producers v. FERC*, 411 F.3d 262, 264 (D.C.Cir.2005) **333 *542 (dismissing petition as unripe where petitioner may obtain its requested remedy “in a

proceeding now pending before the Commission”); *U.S. Air Tour Ass'n. v. FAA*, 298 F.3d 997, 1010–11 (D.C.Cir.2002) (agency “reasonably put off” consideration in RFA case where it represented that it would address the matter in future rulemaking).

As NTCA points out, the separate intercarrier compensation proceeding has been pending for several years. We assume the Commission will complete its work soon. If not, an appropriate party may of course file a petition for mandamus. *Cf. In re Core Communications, Inc.*, 531 F.3d 849 (D.C.Cir.2008); *Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70 (D.C.Cir.1984).

[7] *Third*, NTCA argues that the FCC should have imposed additional mitigating measures to lighten the burden of the Order on small businesses. We have limited capacity or capability to second-guess how an agency weighs a rule's possible impact on small businesses against other statutory objectives. We similarly have limited ability to dispute an agency's assessment of how best to minimize a rule's impact on small businesses. Those are precisely the type of issues that rest “within the expertise” of the FCC “and upon which a reviewing court must be most hesitant to intrude.” *State Farm*, 463 U.S. at 53, 103 S.Ct. 2856. In this case, given the FCC's reasonable determinations that the intermodal portability Order (i) fulfilled statutory objectives by advancing both competition and the interests of consumers and (ii) would not impose significant implementation costs on small businesses, the FCC reasonably concluded that mitigating measures were unnecessary. *See In re Telephone Number Requirements*, 22 F.C.C.R. at 19606–07 ¶ 5, 19611 ¶ 16.

[8] *Fourth*, NTCA alleges that the FCC inadequately addressed alternative policy options. Courts may not “broadly require an agency to consider all policy alternatives in reaching [a] decision.” *State Farm*, 463 U.S. at 51, 103 S.Ct. 2856. Here, NTCA says the FCC could have either (i) issued a temporary stay of the intermodal porting requirements for small wireline carriers until the conclusion of the intercarrier compensation proceeding or (ii) limited the scope of the intermodal portability requirement so that wireline carriers would have to port only to wireless carriers with nearby points of interconnection. The FCC, however, persuasively explained that such approaches would have the effect of denying many wireline consumers “the benefit of

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being able to port their numbers to wireless carriers.” *In re Telephone Number Requirements*, 22 F.C.C.R. at 19610 ¶ 14. In addition, NTCA suggests that the agency could have created “a partial or blanket exemption from the wireline-to-wireless intermodal porting requirements for small entities.” *Id.* at 19611 ¶ 16. But the FCC rejected such exemptions on the ground that they would discourage competition and “would harm consumers in small and rural areas across the country by preventing them from being able to port on a permanent basis.” *Id.* The agency’s rejection of these alternative approaches was both reasonable and reasonably explained.

* * *


We deny the petition for review.

*So ordered.***All Citations**

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Footnotes

1  [Section 604 of Title 5](#) reads in full:

(a) When an agency promulgates a final rule under  [section 553](#) of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in section 603(a), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain—

- (1) a succinct statement of the need for, and objectives of, the rule;
- (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
- (5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

2 Contrary to the FCC’s suggestion, NTCA’s transport costs argument is not an untimely challenge to the merits of the FCC’s underlying Order. *Cf. Cellular Telecomms. & Internet Ass’n v. FCC*, 330 F.3d 502, 508 (D.C.Cir.2003). NTCA has timely challenged the reasonableness of the regulatory flexibility analysis after our remand in  [United States Telecom Ass’n](#), 400 F.3d at 43.

National Women, Infants, and Children Grocers Ass'n v...., 416 F.Supp.2d 92 (2006)

26 A.L.R. Fed. 2d 683



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416 F.Supp.2d 92
United States District Court,
District of Columbia.

NATIONAL WOMEN, INFANTS, AND CHILDREN
GROCERS ASSOCIATION et al., Plaintiffs,

v.

FOOD AND NUTRITION SERVICE, Defendant.

No. CIV.A.05-2432(EGS).

|
Feb. 23, 2006.

Synopsis

Background: Trade organization and small businesses brought action challenging an interim rule issued by Food and Nutrition Service (FNS) implementing provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Parties filed cross motions for summary judgment.

Holdings: The District Court, [Sullivan, J.](#), held that:

[1] interim rule was not contrary to the vendor cost containment provision of Child Nutrition and WIC Reauthorization Act;

[2] FNS established “good cause” to forego notice and comment procedures in promulgating interim rule; and

[3] FNS properly certified under Regulatory Flexibility Act (RFA) that the interim rule would not have a significant impact upon a substantial number of small entities.

Defendant's motion granted.

Procedural Posture(s): Motion for Summary Judgment.

West Headnotes (12)

[1] **Public Assistance** Meal and nutrition programs

Food and Nutrition Service's (FNS) interim rule implementing provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), which required state agencies to “compare the average cost of each type of food instrument redeemed by [WIC-only vendors] against the average cost of the same type of food instrument redeemed by regular vendors,” was not contrary to the vendor cost containment provision of Child Nutrition and WIC Reauthorization Act requiring that food costs remain the same whether or not WIC-participants redeemed their vouchers at WIC-only vendors or at regular vendors; statute did not require WIC-only vendors to be compared with other comparable vendors, rather than with all regular vendors. Child Nutrition Act of 1966, § 17(h)(11)(A)(i)(III), 42 U.S.C.A. § 1786(h)(11)(A)(i)(III); 7 C.F.R. § 246.12(g)(4)(i)(D).

[2] **Statutes** Express mention and implied exclusion; *expressio unius est exclusio alterius*


Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.

2 Cases that cite this headnote

[3] **Public Assistance** Meal and nutrition programs

Participant access provision of Food and Nutrition Service's (FNS) interim rule implementing provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was based on a permissible construction of Child Nutrition and WIC Reauthorization Act. Child Nutrition Act of 1966, § 17(h)(11)(B)(ii), (C)(iii), 42 U.S.C.A. § 1786(h)(11)(B)(ii), (C)(iii); 7 C.F.R. § 246.12(g)(4).

[4] **Public Assistance** Administrative proceedings


Although Food and Nutrition Service's (FNS) interim rule implementing provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was otherwise exempt from notice and comment procedures because it related to public grants, U.S. Department of Agriculture (USDA) bound itself to the procedural requirements of the Administrative Procedure Act (APA) by issuing a policy statement providing that it would give notice of proposed rulemaking and invite the public to participate in rulemaking where not required by law, including rulemaking relating to grants and benefits.  5 U.S.C.A. § 553(a)(2).

[5] **Administrative Law and Procedure**  Exceptions to Rulemaking Procedures

Agency attempts to avoid the notice and comment procedure under the Administrative Procedure Act (APA) are closely scrutinized.


 5 U.S.C.A. § 553.

[6] **Public Assistance**  Administrative proceedings

Food and Nutrition Service's (FNS) established “good cause” to forego notice and comment procedures in promulgating interim rule implementing provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); Congress granted the agency some discretion to issue an interim rule without first providing notice and comment in order to ensure that a rule was in place by the effective date of Child Nutrition and WIC Reauthorization Act, it would have been difficult for the FNS to have set aside a period of time to undertake notice and comment, there was a compelling need to have a rule in effect by statute's effective date, and rule was only temporary.  5 U.S.C.A. § 553(b)(B).

[3 Cases that cite this headnote](#)


[7] **Administrative Law and Procedure**  Discretionary powers or acts

Administrative Law and Procedure  Discretion of agency; abuse of discretion


When a statute uses a permissive term such as “may” rather than a mandatory term such as “shall,” that choice of language suggests that Congress intends to confer some discretion on the agency, and that courts should accordingly show deference to the agency's determination.


[1 Cases that cite this headnote](#)


[8] **Administrative Law and Procedure**  Impracticable or unnecessary; time constraints



Generally, strict congressionally imposed deadlines, without more, do not warrant invocation of the good cause exception to Administrative Procedure Act's (APA) notice and comment procedures.  5 U.S.C.A. § 553(b)(B).


[4 Cases that cite this headnote](#)



[9] **Administrative Law and Procedure**  Requirements of notice and comment in general

An agency's failure to engage in pre-promulgation notice and comment can be partially cured when there is an opportunity for post-promulgation comment.  5 U.S.C.A. § 553.

[10] **Administrative Law and Procedure**  Rules, Regulations, and Other Policymaking


Agencies need only engage in a “reasonable” and “good faith effort” to carry out the mandate of Regulatory Flexibility Act (RFA).  5 U.S.C.A. §§ 601– 604.

[11] **Administrative Law and Procedure**  **Compliance with constitution or law in general**

Failure to comply with Regulatory Flexibility Act (RFA) may be, but does not have to be, grounds for overturning a rule.  5 U.S.C.A. §§ 601– 604.

1 Cases that cite this headnote

[12] **Public Assistance**  **Administrative proceedings**

Because interim rule implementing provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was directed toward the states and regulated state agencies' actions, Food and Nutrition Service (FNS) properly certified under Regulatory Flexibility Act (RFA) that the interim rule would not have a significant impact upon a substantial number of small entities.  5 U.S.C.A. § 605(b).

Attorneys and Law Firms


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[Amy E. Powell](#), [James J. Gilligan](#), U.S. Department of Justice, Washington, DC, for Defendant.

MEMORANDUM OPINION

SULLIVAN, District Judge.

I. INTRODUCTION




Plaintiffs bring this action to challenge the interim rule issued by defendant Food and Nutrition Service (“FNS”), an agency of the U.S. Department of Agriculture (“USDA”). The interim rule implements provisions of the Special Supplemental Nutrition Program for Women, Infants, and Children (“WIC”).  42 U.S.C. § 1786. Plaintiffs argue that in promulgating the interim rule, the FNS failed to abide by the notice and comment rulemaking requirements


of the Administrative Procedure Act (“APA”),  5 U.S.C. § 553(b), and failed to conduct an analysis consistent with the requirements of the Regulatory Flexibility Act (“RFA”),  5 U.S.C. § 601 *et seq.* Plaintiffs also argue that the interim rule is contrary to the underlying statute and to Congressional intent. *See* Pls.' Mot. for Summ. J. at 1–2. Pending before the Court are the parties' cross motions for summary judgment. A hearing on the motions was held on January 26, 2006. Upon careful consideration of the parties' cross motions, the responses, replies and supplemental motions thereto, oral arguments, and the entire record, the Court *95 DENIES plaintiffs' Motion for Summary Judgment and GRANTS defendant's Motion for Summary Judgment. Accordingly, plaintiffs' claims are DISMISSED WITH PREJUDICE.

II. BACKGROUND

A. The Special Supplemental Nutrition Program for Women, Infants, and Children (“WIC”)

Plaintiffs are National Women, Infants, and Children Grocers Association (“NWGA”), Nutritional Food Distributors, Inc., County Food Services, Inc., and Dillard Foods, Inc. NWGA is a small, voluntary, not-for-profit trade organization. Complaint ¶ 4. The other named plaintiffs are small businesses operating in Arkansas and Oklahoma. Complaint ¶¶ 5–7.

The Special Supplemental Nutrition Program for Women, Infants, and Children (“WIC”) is a nation-wide federal program that provides supplemental foods and nutrition education to lower-income pregnant, breast-feeding, and postpartum women, and infants and children who are at nutritional risk. *See*  42 U.S.C. § 1786(a). The Secretary of Agriculture (“Secretary”) is authorized to carry out WIC,  42 U.S.C. § 1786(c)(1), and the Secretary has delegated the administration of WIC to the Food and Nutrition Service (“FNS”). 7 C.F.R. § 246.3(a). In  2005, WIC served approximately 8 million participants, including approximately 1.9 million women, 2.1 million infants, and 4 million children ages five and under. *See* Complaint ¶ 11. WIC is expected to serve roughly 8.5 million participants in 2006. *Id.*

WIC is a federal grant-in-aid program.  42 U.S.C. § 1786(c)(1). Through WIC, states receive grants to provide supplemental foods and nutrition education to lower-

income women, infants and children who are determined by a competent professional authority to be at nutritional risk. *Id.* Individual state agencies are responsible for implementing WIC within their states. State agencies are required to authorize the participation of retail food stores (“authorized vendors”), create vendor agreements that govern the contractual relationship between the state and authorized vendors, establish price limitations for paying authorized vendors, train authorized vendors, and monitor compliance. *See* Complaint ¶ 28; 7 C.F.R. §§ 246.3(b) and 246.12.

The women and children eligible to participate in the program receive “food instruments” or vouchers from state and local agencies which they can exchange for supplemental food packages that are tailored to meet their needs. 42 U.S.C. § 1786(d); Complaint ¶ 29. For example, in exchange for her voucher, a pregnant woman may receive a food package that includes fluid milk, eggs, cereal, juice, and dry beans. 7 C.F.R. § 246.10(c)(5). WIC participants must redeem their vouchers at retail food vendors who have received prior authorization from respective state agencies to carry pre-approved supplemental foods. Complaint ¶ 15, 28. These preauthorized vendors then submit the vouchers for reimbursement from the states. *Id.*

There are approximately 45,000 retail vendors authorized to redeem WIC vouchers. Complaint ¶ 15. Generally, authorized vendors are corner grocery stores, neighborhood supermarkets, and big box stores such as Target and Walmart. *See* Transcript of Hearing on Motion for Summary Judgment (Jan. 26, 2006) (“01/26/06 Tr.”) at 4. Of the 45,000 authorized vendors, there are approximately 1,200 vendors who specialize in redeeming WIC *96 vouchers.¹ Complaint ¶ 15. These vendors are known in the industry as “WIC-only” vendors. *See* 01/26/06 Tr. at 4. Only 20 states have WIC-only vendors. Complaint ¶ 15. WIC-only vendors focus on WIC participants' varied needs and offer them specialized services. Complaint ¶ 17–23. WIC-only stores often hire current and former WIC participants who are knowledgeable about the Program and can help shoppers identify what size package of which authorized brands to get under their particular voucher. *Id.*

B. The Child Nutrition and WIC Reauthorization Act of 2004

On June 30, 2004, Congress passed the Child Nutrition and WIC Reauthorization Act of 2004 (“Reauthorization

Act”). Pub.L. No. 108–265. This law reauthorized WIC through 2009 and made a number of substantive changes to the underlying statute. Congress imposed cost containment measures on state agencies in order to constrain rising program costs. *See* 42 U.S.C. § 1786(h)(11).

These cost containment measures were designed to control rising food costs associated with WIC-only vendors. *See* 01/26/06 Tr. at 72–74. The cost containment provision addresses Congress's concern that WIC-only vendors, unlike regular food retail vendors, operate outside of the competitive market forces because WIC-only vendors do not need to keep their food prices low and competitive in order to attract non-WIC customers. *See* S.Rep. No. 108–279, at 53–57, 2004 U.S.C.C.A.N. 668, at 714–718. Since WIC customers pay in government vouchers, they are not likely to be as sensitive to food prices. *Id.* WIC customers will receive what is denoted on their voucher regardless of the food price. *Id.* The Senate Report accompanying the Senate version of the Reauthorization Act states:

This [cost containment] provision is designed to respond to a new type of store in the WIC program, so-called WIC-only stores.... Available evidence suggests that WIC-only stores, on average, tend to charge much higher prices for WIC food items than do regular grocery stores, resulting in significantly higher costs to the federal government and creating long-term cost-containment problems in the WIC program.... [Because WIC-only stores] have no need to attract non-WIC customers... [they] have no incentive to set prices that are determined by market forces.... In order to ensure sound stewardship of taxpayer dollars, the Child Nutrition and WIC Reauthorization Act of 2004 includes several provisions designed to ensure that the WIC program continues to rely on market forces to contain food costs and that WIC-only stores do not charge higher prices than other stores leading to waste of federal funds.... It also requires the state agency to ensure

that WIC-only stores are cost neutral to the WIC program.... [S.Rep. No. 108–279, at 54–55](#), 2004 U.S.C.C.A.N. 668 at 715–716.

Congress established certain important deadlines for the implementation of the cost containment provision of the Reauthorization Act. Congress provided: (1) States “shall comply” with the cost containment provision by December 30, 2005, [42 U.S.C. § 1786\(h\)\(11\)\(G\)](#); (2) the Secretary “shall” issue guidance to state agencies “as soon as practicable,” [42 U.S.C. § 1758](#) Notes; (3) the Secretary “shall” promulgate a final regulation by June 30, *97 2006, *Id.*; and (4) the Secretary “may” promulgate interim final regulations to implement the cost containment provision (no date specified), *Id.* The first three deadlines are congressionally mandated, whereas Congress used the permissive term “may” with regard to the interim final rule.

C. Procedural History

On November 29, 2005, the FNS published the interim rule in the Federal Register. *See* [70 Fed.Reg. 71708](#). The interim rule was to go into effect on December 29, 2005, a day before the states were required to implement the cost containment provisions. *Id.* On December 16, 2005, plaintiffs moved for a temporary restraining order asking the Court to enjoin the implementation of the interim rule. A hearing on the motion was held on December 28, 2005, and the Court granted plaintiffs’ motion. The Court provided a brief explanation for its ruling in open court the following day, and stated that it was not persuaded at that juncture that the FNS had complied with the notice and comment requirements under [§ 553](#) of the Administrative Procedure Act (“APA”); nor was the Court persuaded that the government was not required to conduct an analysis under the Regulatory Flexibility Act (“RFA”). *See* Transcript of Hearing on Motion for Temporary Restraining Order (Dec. 29, 2005) (“12/29/06 Tr.”) at 5–6. Thus, the Court enjoined the FNS through February 9, 2006, from taking any enforcement actions against the named plaintiff businesses and the members of the named plaintiff trade organization under [7 C.F.R. § 246.12\(g\)\(4\)\(i\)\(D\)](#) and [§ 246.12\(g\)\(4\)\(vi\)](#). *See National Women v. Food and Nutrition Service*, 2005 WL 3576840 (D.D.C. Dec. 29, 2005). With regard to [7 C.F.R. § 246.12\(g\)\(4\)\(vi\)](#), the Court specified that its injunction was “only to the extent that sentences two and three of that provision may be construed to require States to

compare average payments per food instrument to above–50–percent vendors (WIC-only stores) to average payments per food instrument made to all other WIC vendors rather than to other comparable WIC vendors.” *Id.* On January 26, 2006, pursuant to a request of the Court and with the consent of the parties, the temporary restraining order was extended through February 23, 2006, to afford the Court a reasonable period of time within which to resolve the pending motions.

III. STANDARD OF REVIEW

Pursuant to [Federal Rule of Civil Procedure 56](#), summary judgment should be granted only if the moving party has shown that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law.

[Fed.R.Civ.P. 56](#); [Celotex Corp. v. Catrett](#), 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); [Waterhouse v. District of Columbia](#), 298 F.3d 989, 991 (D.C.Cir.2002). In ruling on cross-motions for summary judgment, the Court shall grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not genuinely disputed. [Rhoads v. McFerran](#), 517 F.2d 66, 67 (2d Cir.1975). Further, in APA review cases, whether agency action was contrary to law is a legal issue that a Court resolves on the basis of the administrative record. [American Bioscience, Inc. v. Thompson](#), 269 F.3d 1077, 1083 (D.C.Cir.2001).

Moreover, review of an agency’s construction of the statute which it administers is a two-fold inquiry under [Chevron v. Natural Resources Defense Council, Inc.](#), 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). “First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent *98 of Congress is clear, that is the end of the matter.... [the Court] must give effect to the unambiguously expressed intent of Congress.” [Chevron](#), 467 U.S. at 842–3, 104 S.Ct. 2778. The Court must look at the statutory provision in context when determining whether it speaks directly to the question at issue. [Food and Drug Admin. v. Brown & Williamson Tobacco Corp.](#), 529 U.S. 120, 132–33, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000). However, if the statute is “silent or ambiguous,” the next question for the Court is “whether the agency’s answer is based on a permissible construction of the statute.” [Chevron](#), 467 U.S. at 843, 104 S.Ct. 2778. Further, “[t]he Court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction”

in order to conclude that the agency's construction was reasonable. [Id.](#) at 843 n. 11.

IV. STATUTORY CONSTRUCTION CHALLENGE

A. The Vendor Cost Containment Provision

The vendor cost containment provision of the Reauthorization Act has two distinct cost-containment goals. “First, each State must ensure that its aggregate WIC food costs are no higher if WIC participants choose to shop at WIC-only stores than if they shop at regular competitive stores. Second, each State must ensure that average prices, referred to as ‘average payments per voucher’ in WIC-only stores are no higher than average prices in comparable competitive stores.” [150 Cong. Rec. S7244–01](#), 7248 (June 23, 2004) (Statement of Sen. Harkin) (presenting the WIC Reauthorization bill to the Senate). The first goal (aggregate cost neutrality) is codified in [42 U.S.C. § 1786\(h\)\(11\)\(A\)\(i\)\(III\)\(bb\)](#) (“subsection (bb)”) and the second goal (comparability) is codified in [42 U.S.C. § 1786\(h\)\(11\)\(E\)](#) (“subsection (E)”).

With these dual goals in mind, the vendor cost containment provision requires the following. First, the cost containment provision requires state agencies to “establish a vendor peer group system” for all authorized WIC vendors in their respective states and to “establish competitive price criteria and allowable reimbursement levels for each vendor peer group.” [42 U.S.C. § 1786\(h\)\(11\)\(A\)\(i\)](#). In these vendor peer group systems, state agencies compare vendors to similarly situated vendors to ensure that their pricing is competitive. *Id.* When establishing vendor peer groups, the cost containment provision requires WIC-only vendors to be distinguished from other regular vendors. [Id.](#) [§ 1786\(h\)\(11\)\(A\)\(i\)\(III\)\(aa\)](#). State agencies can do this in one of two ways: (1) by creating a separate peer group composed of WIC-only vendors; or (2) by establishing separate price criteria and reimbursement levels for WIC-only vendors if they are in a peer group with regular vendors. [Id.](#) [§ 1786\(h\)\(11\)\(A\)\(i\)\(III\)\(aa\)\(AA\), \(BB\)](#).

Second, the cost containment provision requires state agencies to establish competitive price criteria and reimbursement levels that “do not result in higher food costs if program participants redeem supplemental food vouchers at [WIC-only vendors] rather than at vendors other than [WIC-only vendors].” [Id.](#) [§ 1786\(h\)\(11\)\(A\)\(i\)\(III\)\(bb\)](#)

(“subsection (bb)”). As explained above, subsection (bb)'s goal is to keep food costs neutral, regardless of whether WIC participants patronize WIC-only vendors or regular vendors.

Third, the cost containment provision does not “compel” state agencies “to achieve lower food costs” if WIC participants choose to shop at WIC-only vendors ⁹⁹ rather than at regular vendors. [Id.](#) [§ 1786\(11\)\(A\)](#) (last paragraph).

Fourth, a state need not authorize any WIC-only vendors to participate in the program at all. [42 U.S.C. § 1786\(h\)\(11\)\(A\)\(i\)\(III\)](#). If it chooses to do so, however, it must satisfy an additional cost containment comparability provision found at [§ 1786\(h\)\(11\)\(E\)](#) (“subsection (E)”). This section provides that if WIC-only vendors are authorized then the state agency must ensure that “the competitive price criteria and allowable reimbursement levels [for WIC-only vendors] do not result in average payments per voucher to [WIC-only vendors] that are higher” than average payment to comparable regular vendors. [Id.](#) [§ 1786\(h\)\(11\)\(E\)](#).

B. The Interim Rule

The FNS promulgated the interim rule on November 29, 2005. [70 Fed.Reg. 70708](#). In accordance with [§ 1786\(h\)\(11\)\(A\)\(i\)](#), the rule states that a “state agency must establish a vendor peer group system and distinct competitive price criteria and allowable reimbursement levels for each peer group.” [7 C.F.R. § 246.12\(g\)\(4\)](#). In accordance with [§ 1786\(h\)\(11\)\(A\)\(i\)\(III\)\(aa\)](#), the interim rule provides for two ways to distinguish WIC-only vendors within an established peer group. A state agency can establish a separate peer group for WIC-only vendors, or if it does not establish WIC-only peer groups, the agency must establish distinct competitive price selection and reimbursement criteria for WIC-only vendors within a peer group with regular vendors. [Id.](#) [§ 246.12\(g\)\(4\)\(i\)\(A\)](#).

Turning to subsection (bb), which articulates the aggregate cost neutrality goal of the cost containment provision, the interim rule requires state agencies to “compare the average cost of each type of food instrument redeemed by [WIC-only vendors] against the average cost of the same type of food instrument redeemed by regular vendors.” [Id.](#) [§ 246.12\(g\)\(4\)\(i\)\(D\)](#). In other words, the interim rule compares WIC-only vendors with *all* WIC vendors.

Finally, under the interim rule, prior to authorizing any WIC-only vendors, a state agency must receive FNS certification of its vendor cost containment system. *Id.* § 246.12(g)(4)(vi). In accordance with subsection (E), which articulates the comparability goal of the cost containment provision, § 246.12(g)(4)(vi) of the rule provides that states must “demonstrate that its competitive price criteria and allowable reimbursement levels do not result in average payments per food instrument to [WIC-only vendors] that are higher than average payments per food instrument to comparable [regular] vendors.” Here, WIC-only vendors are being compared with all *comparable* WIC vendors. The rule then explains how the states are to arrive at their average payment calculations. *Id.* § 246.12(g)(4)(vi).

C. Plaintiffs' Statutory Construction Challenge

Plaintiffs challenge § 246.12(g)(4)(i)(D) of the rule as being inconsistent with the plain language and purpose of subsection (bb) of the statute under step one of *Chevron*. Plaintiffs argue that the interim rule's comparison of WIC-only vendors with *all* WIC vendors is contrary to the plain language of the statute. Further, plaintiffs argue that the interim rule's comparison of the average costs of vouchers redeemed at WIC-only vendors with the average costs of vouchers redeemed at *all* WIC vendors is contrary to the last paragraph of § 1786(h)(11)(A)'s prohibition on achieving lower food costs if WIC participants shop at WIC-only stores. Finally, plaintiffs contend that the interim rule's retroactive recoupment and participant access *100 provisions are not based on a permissible construction of the statute under step two of *Chevron*.

D. The Word “Comparable” is Not Found in § 1786(h)(11)(A)(i)(III)(bb)

[1] To achieve the aggregate cost neutrality goal of subsection (bb), the interim rule requires state agencies to “compare the average cost of each type of food instrument redeemed by [WIC-only vendors] against the average cost of the same type of food instrument redeemed by regular vendors.” 7 C.F.R. § 246.12(g)(4)(i)(D). Plaintiffs argue that the interim rule's interpretation is contrary to the plain language of subsection (bb) and that the statute requires WIC-only vendors to be compared with other *comparable* vendors and not with all regular vendors. In arriving at this reading of subsection (bb), plaintiffs would have the Court import the word “comparable” to subsection (bb) where no such word is found. The only section of the statute where the word

“comparable” appears is in subsection (E), which provides that average payments to WIC-only vendors are not to be higher than average payments to comparable vendors. § 42 U.S.C. § 1786(h)(11)(E).

[2] Under the law of statutory construction, “[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”

§ *Russello v. United States*, 464 U.S. 16, 23, 104 S.Ct. 296, 78 L.Ed.2d 17 (1983). The Court will not read into subsection (bb) what is not stated therein, nor will the Court ignore the plain language of subsection (bb). The most natural reading of subsection (bb) is that food costs must remain the same whether or not WIC-participants redeem their vouchers at WIC-only vendors or at regular vendors. Any attempt to import the word “comparable” into subsection (bb) to limit the basis of the comparison would distort Congress's clearly expressed intent. While the plain language of subsection (E) requires comparison of WIC-only vendors to *comparable* regular vendors for the purpose of establishing average payments, the plain language of subsection (bb) requires comparison of WIC-only vendors to all regular vendors in order to keep food costs low.

E. Last Paragraph of § 1786(h)(11)(A) Must be Read in Context

Plaintiffs also argue that if subsection (bb) is to be read and understood as suggested by the interim rule then that provision would violate the last paragraph of § 1786(h)(11)(A), which provides that “[n]othing in this paragraph shall be construed to compel a State agency to achieve lower food costs if program participants redeem supplemental food vouchers at [WIC-only vendors] rather than at vendors other than [WIC-only vendors].” Plaintiffs contend that if WIC-only vendors are compared with all regular vendors, the interim rule would compel state agencies to achieve lower food costs when WIC participants redeem their vouchers at WIC-only stores in direct contravention of the last paragraph of § 1786(h)(11)(A).

Plaintiffs' construction of the statute ignores the plain language of the statute and takes the language out of context.

When the last paragraph of § 1786(h)(11)(A) is read together with the preceding subparagraphs, the meaning of

that section becomes plainly clear—state agencies cannot be forced to achieve lower average prices at WIC-only vendors than the average prices at all other vendors. Cost containment *101 and neutrality are the goals of the Reauthorization Act, thus, state agencies are directed to ensure that WIC-only vendors' costs are not higher, but at the same time not forced to be any lower, than the average costs of regular vendors.

F. Plaintiffs' Reading of the Statute Would Create a Loophole Unintended by Congress

Plaintiffs further argue that since subsection (bb) is found under a section entitled “Peer Groups,” price and cost comparisons based on subsection (bb) should be between peer groups rather than between WIC-only stores and regular vendors. If the statute is to be read as suggested by the plaintiffs, however, a loophole would be created in subsection (bb). As noted above, § 1786(h)(11)(A)(i) provides states with the option of establishing vendor peer groups that contain just WIC-only vendors. If, as suggested by the plaintiffs, subsection (bb) requires average prices of WIC-only vendors to be compared with the average prices of other vendors in their peer group, subsection (bb) would impose no limit at all on the prices of WIC-only vendors in states that elect to have WIC-only peer groups. The Court is not persuaded that Congress intended to enact such a loophole that would allow state agencies to evade the cost containment requirements. Despite the artful arguments of plaintiffs, the plain language of subsection (bb) requires comparison of WIC-only vendors with all regular vendors.

G. Participant Access

[3] Finally, plaintiffs contend that the interim rule provides inadequate guidance for § 1786(h)(11)(C)(iii).² Specifically, *102 plaintiffs contend that the rule is invalid under *Chevron* step two because the FNS unreasonably interpreted the statute's requirement that participant access be a critical factor in establishing vendor peer groups, competitive price criteria and reimbursement level. *See* Pl.'s Mot. for Summ. J. at 36 (“[t]he Rule does not, but should, take into consideration where a WIC recipient would shop if the WIC-only stores were not an option.”). Contrary to plaintiffs' assertions, the interim rule directly implements the Reauthorization Act's demand that state agencies “consider participant access by geographic area.” 42 U.S.C. § 1786(h)(11)(B)(ii), (C)(iii).

Section 1786(h)(11)(C)(iii) provides, “[i]n establishing allowable reimbursement levels, the State agency shall consider participant access in a geographic area.” The interim rule directly implements this provision by closely tracking the language of § 1786(h)(11)(C)(iii). Section 246.12(g)(4) of the interim rule states that “[i]n establishing competitive price criteria and allowable reimbursement levels, the State agency must consider participant access by geographic area.” The interim rule is anything but unreasonable; it virtually echos the language of the statute.³

Further, defendant is correct to point out that in order to support their argument, plaintiffs rely on a provision of the interim rule that is inapposite. Plaintiffs direct the Court to 7 C.F.R. § 246.12(g)(4)(ii)(A) which mentions geography but only in the context of establishing peer groups. *See* Def.'s Opp. at 15; Pls.' Mot. for Summ. J. at 36; 7 C.F.R. § 246.12(g)(4)(ii)(A) (directing state agencies to use “[a]t least two criteria for establishing peer groups, one of which must be a measure of geography, such as metropolitan or other statistical areas that form distinct labor and product markets”). That provision of the rule does not implement nor does it purport to implement § 1786(h)(11)(C)(iii).

In conclusion, plaintiffs' challenge to the FNS' construction of the Reauthorization Act under step one and step two of *Chevron* fails as a matter of law.⁴ The cost *103 containment provisions of the interim rule are consistent with the plain language and purpose of the Reauthorization Act. Further, the interim rule relating to participant access is based on a permissible construction of the statute.

V. NOTICE AND COMMENT REQUIREMENT

UNDER THE ADMINISTRATIVE PROCEDURE ACT
Plaintiffs claim that the Secretary violated the notice and comment provision of the APA by not affording them a meaningful opportunity to comment on the interim rule prior to its promulgation. In response, defendant first argues that § 553 of the APA is not applicable to the interim rule because the interim rule relates to grants which are explicitly exempted from § 553. Second, even if § 533 is applicable, the FNS had “good cause” to forego the procedure.

Section 553 of the APA requires agencies to publish a “[g]eneral notice of proposed rule making” and “to

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give interested persons an opportunity to participate in the rulemaking...” 5 U.S.C. § 553(b), (c). The purpose of the statute is to “provide both notice and meaningful opportunity to comment.” *Asiana Airlines et al., v. Federal Aviation Administration*, 134 F.3d 393, 396 (D.C.Cir.1998).

The requirements of § 553, however, do not apply to rulemakings “relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.” 5 U.S.C. § 553(a)(2) (emphasis added); see also *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070, 1084 (D.C.Cir.1978) (noting that the § 553(a)(2) exception exists because where public benefits or entitlements are concerned “the congressional aim was to afford agencies procedural latitude regardless of the interest of affected parties and the public generally in contributing to formulation of the exempted rule”). Further, an agency may depart from notice and comment procedures for “good cause.” See 5 U.S.C. § 553(b)(B) (notice and comment does not apply “when the agency for good cause finds... that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest”).

*104 [4] The WIC Program does appear to relate to public “grants.” Therefore, the interim rule would appear to be exempt from the APA. However, in 1971, USDA issued a policy statement providing that USDA will “give notice of proposed rulemaking and ... invite the public to participate in rulemaking where not required by law,” including rulemaking relating to grants and benefits. Statement of Policy, 36 Fed.Reg. 13804 (“1971 Policy Statement”) (July 24, 1971).

Although the interim rule is exempt from § 553 of the APA, USDA’s 1971 Policy Statement fully binds the agency to the procedural requirements of the APA. See *Rodway v. United States Dept. of Agriculture*, 514 F.2d 809, 814 (D.C.Cir.1975) (“[i]t is, of course, well settled that validly issued administrative regulations have the force and effect of law. Thus, [the 1971 Policy Statement] fully bound the Secretary to comply thereafter with the procedural demands of the APA.”). In promulgating the interim rule, the FNS had to comply with the notice and comment procedure of § 553 of the APA as adopted by the 1971 Policy Statement, unless exempted from compliance.

As in § 553 of the APA, the 1971 Policy Statement allows for a “good cause” exemption. The 1971 Policy Statement

states that “where an agency [of USDA] finds for good cause that compliance would be impracticable, unnecessary or contrary to public interest,” it may depart from the notice and comment procedure, so long as the agency has a “substantial basis therefore.” 36 Fed.Reg. 13804.

The FNS contends that it had good cause to forego notice and comment and offers four reasons for its good cause determination. First, it was specifically authorized by Congress in the Reauthorization Act to issue an interim rule. Second, the FNS worked diligently to meet the congressionally-imposed deadline. Third, it had a compelling need to have the interim rule in place by December 30, 2005, the effective date of the Reauthorization Act. Finally, the interim rule is a temporary rule that allows for data collection and flexibility.

[5] Agency attempts to avoid the notice and comment procedure under the APA are closely scrutinized. See *New Jersey Dept. of Environmental Protection v. EPA*, 626 F.2d 1038, 1045 (D.C.Cir.1980) (holding that exceptions under § 553 must be “narrowly construed and only reluctantly countenanced” in order to assure that “an agency’s decisions will be informed and responsive”); *Asiana*, 134 F.3d at 396 (“[w]e have looked askance at agencies’ attempts to avoid the standard notice and comment procedures”); *Council of the Southern Mountains v. Donovan*, 653 F.2d 573, 580 (D.C.Cir.1981) (noting that the court had “recently admonished agencies that circumstances justifying reliance on [the good cause exception] are indeed rare and will be accepted only after the court has examined closely proffered rationales justifying the elimination of public procedures”). In fact, “just because the agency itself adopted the requirements of section 553(b) and (c) ... does not mean that it may follow the procedure arbitrarily, or use good cause to manipulate the procedures to its own uses.” *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir.1984). See also *Rodway*, 514 F.2d at 814. Therefore, the Court’s inquiry should be thorough, and the Court must look to the totality of the circumstances in order to determine whether the defendant justifiably invoked the good cause exception to notice and comment procedure. *Petry v. Block*, 737 F.2d 1193, 1200 (D.C.Cir.1984). See also *Mid-Tex Electric Coop., Inc. et al., v. Fed. Energy Regulatory Comm’n*, 822 F.2d 1123, 1132 (D.C.Cir.1987) (“good cause inquiry *105 is inevitably fact- or context-dependent”).

[6] Upon careful examination of the FNS' justifications for its decision to forego the notice and comment procedure, the Court concludes that the combination of four reasons advanced by defendant establishes the requisite good cause. This is not a case where an agency has engaged in dilatory tactics between the enactment of the statute and the publication of the interim rule, or simply waited until the day of a statutory deadline to raise the good cause banner and attempt to promulgate a rule without undertaking notice and comment. The totality of the circumstances of this case persuades the Court that the FNS has been diligent in its efforts to promulgate an interim rule to provide the guidance needed by the states to comply with the Reauthorization Act.

First, it is significant that Congress authorized the issuance of an interim rule. See [42 U.S.C. § 1758](#) Notes (“The Secretary may promulgate interim final regulations to implement [the Reauthorization Act].”). By using the word “may,” Congress granted the USDA some discretion to issue an interim rule without first providing notice and comment in order to ensure that a rule was in place by December 30, 2005, the effective date of the statute.⁵

[7] “When a statute uses a permissive term such as ‘may’ rather than a mandatory term such as ‘shall,’ this choice of language suggests that Congress intends to confer some discretion on the agency, and that courts should accordingly show deference to the agency's determination.”

[Dickson v. Secretary of Defense](#), 68 F.3d 1396, 1401 (D.C.Cir.1995). Although the Reauthorization Act required states to comply with the statute by December 30, 2005, the agency implementing the statute has until June 30, 2006, to promulgate final regulations. Thus, for six months states would be without any guidance as to how to implement the Reauthorization Act. Exercising its discretion, the FNS promulgated an interim rule to cover the period between enactment of the statute and promulgation of the final regulation. The FNS' decision to issue the interim rule to cover this period of six months should be given deference for the agency was exercising its discretion in a reasonable manner. In order for the states to receive federal funding under WIC, they must be in compliance with the Program's specific requirements. In the absence of a rule, state agencies would be at a loss as to how to implement the new provisions of the statute, how to continue demonstrating *106 their compliance with the requirements, and how to remain eligible for future funding.

Second, the FNS maintains that the specific time line set by Congress for implementation of the statute should be considered in the good cause determination. In conjunction with the tight time line, the FNS argues that it worked diligently to complete the interim rule and has not abused its discretion to forego prior notice and comment.

[8] “As a general matter, strict congressionally imposed deadlines, without more, by no means warrant invocation of the good cause exception. Nevertheless, deviation from APA requirements has been permitted where congressional deadlines are very tight and where the statute is particularly complicated.” [Methodist Hospital of Sacramento v. Shalala](#), 38 F.3d 1225, 1236 (D.C.Cir.1994). The congressional deadline in this case was not as pressing as in cases where good cause exception has been invoked and found to be appropriate. See, e.g., [Petry](#), 737 F.2d at 1200–01 (agency's decision to forego notice and comment was grounded in good cause when Congress provided the agency with 60 days to promulgate the regulation); [Philadelphia Citizens in Action v. Schweiker](#), 669 F.2d 877, 883 (3d Cir.1982) (the fact that Congress provided the agency with 49 days to promulgate and implement regulations constituted good cause). But see [Kollett v. Harris](#), 619 F.2d 134 (1st Cir.1980) (holding that the good cause exception did not apply given that 14 months intervened between the passage of the amendments and their effective date and no justification was advanced for the agency's failure to follow notice and comment within the time available); [Sharon Steel Corp. v. EPA](#), 597 F.2d 377 (3d Cir.1979) (the fact that the EPA had more than one year to implement the plans weighed against a good cause determination because the EPA could have complied with the notice and comment requirements); [U.S. Steel Corp. v. EPA](#), 595 F.2d 207, 213 (5th Cir.1979) (six-month Congressional deadline did not excuse agency failure to comply with prior notice and comment procedure). Here, the FNS had 18 months from enactment of the statute to the date of its implementation.

Although the time line available to the FNS was not severely constrained, the agency has demonstrated that it worked diligently to complete the interim rule while also attending to other demanding obligations. The Court accepts defendant's proffer that it would have been difficult for the FNS to have set aside a period of time to undertake notice and comment. The FNS has demonstrated that it has not been dilatory in

promulgating the interim rule during the period of June 2004 to November 2005.⁶ Clearly, a notice and *107 comment period prior to December 30, 2005, would have required not only several months of receiving and reviewing public comments to the interim rule, but also, if there were any resulting changes to the interim rule, the rule would have undergone a second internal review and clearance process.

Further, the Reauthorization Act includes over 60 pages of provisions affecting the WIC Program and the National School Breakfast and Lunch Programs. Vogel Decl. (Jan. 17, 2006) ¶ 5. The FNS issued a total of approximately 70 policy memoranda and 25 regulations related to the Reauthorization Act. *Id.* For the WIC Program alone, the FNS developed six policy memoranda and four other regulations. *Id.* at ¶ 18. Five FNS staffs were available to work primarily on the implementation of the WIC-related portions of the Reauthorization Act. *Id.* ¶ 5. See, e.g., [Petry](#), 737 F.2d at 1202 (noting that “while agency understaffing in a rulemaking process would not, without more, normally constitute grounds for the ‘good cause’ exception,” when considered with other factors in the case, good cause existed to bypass notice and comment). Therefore, the Court concludes that uncontroverted record evidence indicates that it is highly doubtful that the FNS could have published its interim rule by December 30, 2005, if it had undergone the notice and comment rulemaking procedure. See Vogel Decl. (Jan. 17, 2006). The constrained time frame plus FNS' demonstrated diligence certainly contributes to a good cause finding.

Third, the FNS argues that there was a compelling need to have a rule in effect by December 30, 2005, because on that date the states were required by Congress to be in compliance with the Reauthorization Act, and no one would have benefited if the states were left with no guidance on how to implement the new provisions of the WIC Program. Although this justification standing alone would not constitute good cause, the combined effect of this and other reasons suffice. Undoubtedly, states need to know from the agency responsible for implementing the statute how they can continue to receive federal funding. WIC is a multi-billion dollar federal program that directly affects the health and nutrition of millions of Americans.⁷ Without guidance, the statute could be applied ineffectively and inconsistently, and certainly the savings Congress had hoped to achieve by the Reauthorization Act could be lost.⁸

[9] Fourth, the FNS argues that the interim rule is exactly what it says—a temporary rule that is subject to amendment by public comment. The interim nature of a challenged rule is a “significant factor” in evaluating an agency's good cause claim. *Tenn. Gas Pipeline Co. v. Fed. Energy Regulatory Comm'n*, 969 F.2d 1141, 1144 (D.C.Cir.1992); [Mid-Tex Electric Coop.](#), 822 F.2d at 1132. Further, an agency's failure to engage in pre-promulgation notice and comment can be partially cured when there is an opportunity for post-promulgation comment. [Universal Health Services of McAllen, Inc. v. Sullivan](#), 770 F.Supp. 704, 721 (D.D.C.1991). Of course, an agency must remain *108 open at the later stage to consider the comments garnered. *Id.*

The FNS has displayed a willingness to incorporate public suggestions into its final rules in its preamble to the interim rule. See 70 Fed.Reg. at 71709 (the FNS “will be collecting and analyzing data from State agencies, in anticipation of issuing a final rule.”). Further, prior to publishing the interim rule in the Federal Register, the FNS issued a lengthy guidance to the states in July 2005, and it received and reviewed comments from the different state agencies, some of which were incorporated into the guidance. Vogel Decl. (Jan. 17, 2006) ¶ 16. The interim rule, temporally limited in scope, is necessary to assist the FNS develop better assessment and evaluation tools to ensure that the Reauthorization Act does indeed achieve its goals of cutting program costs and ensuring containment of costs among WIC-only vendors.

In conclusion, having examined the totality of circumstances in which the interim rule was promulgated, the Court finds that the FNS' invocation of the good cause exception is justified. The FNS had good cause to proceed without prior notice and public comment of the interim rule.

VI. REGULATORY FLEXIBILITY ACT ANALYSIS

Plaintiffs next argue that the FNS failed to conduct an adequate analysis under the Regulatory Flexibility Act (“RFA”) in promulgating the interim rule. The RFA requires agencies to consider the effect that their regulation will have on small entities, analyze effective alternatives that may minimize a regulation's impact on such entities, and make their analyses available for public comment. [5 U.S.C. §§ 601–604](#). Defendant argues that because the RFA requires an analysis of the impact on directly regulated businesses, it is not applicable here. The RFA does not require that an agency

assess the impact of a rule on all small entities that may be affected by the rule, but only those directly regulated.

[10] [11] The RFA was enacted by Congress “to encourage administrative agencies to consider the potential impact of nascent federal regulations on small businesses.” *Associated Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 111 (1st Cir.1997). Under the RFA, an agency describes the effect of the proposed rule on small businesses and discusses alternatives that might minimize adverse economic consequences. *Id.* Judicial review of agency compliance with the RFA is available. *Alenco Communications Inc., v. Fed. Communications Comm'n*, 201 F.3d 608, 625 (5th Cir.2000). Agencies need only engage in a “reasonable” and “good faith effort” to carry out the mandate of the RFA. *Id.* Further, the RFA is a purely procedural, as opposed to a substantive, mandate; RFA “requires nothing more than that the agency file a final regulatory flexibility analysis demonstrating a reasonable, good-faith effort to carry out the RFA’s mandate.” *United States Cellular Corp. v. Fed. Communications Comm'n*, 254 F.3d 78, 88 (D.C.Cir.2001). Moreover, “failure to comply with the RFA may be, but does not have to be, grounds for overturning a rule.” *Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855, 868 (D.C.Cir.2001).

[12] A regulatory flexibility analysis, however, is not required if the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” 5 U.S.C. § 605(b). The RFA “impose[es] no obligation upon an agency to conduct a small entity impact analysis of effects on entities which it does not regulate.” *American Trucking Ass'n, Inc. v. U.S. EPA*, 175 F.3d 1027, 1044 (D.C.Cir.1999). *109

See also *Cement Kiln*, 255 F.3d at 869 (“this court has consistently rejected the contention that the RFA applies to small businesses indirectly affected by the regulation of other entities....Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy.”).

The FNS certified that an RFA analysis was unnecessary because the interim rule would “not have a significant economic impact on a substantial number of small entities.” 70 Fed.Reg. at 71709. The FNS certification satisfies the standards set out in § 605(b) of the RFA. The FNS published its certification in the Federal Register and provided a factual basis for its certification. *Id.* Further, as in *American*

Trucking, the entities directly regulated by the interim rule are state agencies. The state agencies, not WIC-only vendors, are required to establish peer groups and competitive price criteria in order to receive federal funding.

In *American Trucking*, the Court held that the National Ambient Air Quality Standards (“NAAQS”) promulgated by the Environmental Protection Agency (“EPA”) do not in and of themselves impose regulations on small entities. Rather, “states regulate small entities through the state implementation plans that they are required by the Clean Air Act to develop.” 175 F.3d at 1044. The Court went on to say that the NAAQS only indirectly regulate small entities because the standards affect the planning decisions of the states. *Id.*

The situation in *American Trucking* is directly analogous to the situation in this case. The Reauthorization Act and the interim rule are directed toward the states and regulate state agencies’ actions—specifically, what state agencies need to do in order to contain WIC program costs. State agencies are required by the interim rule to produce a state plan that demonstrates to the FNS that they are in compliance with the cost containment provisions of the Reauthorization Act. 70 Fed.Reg. at 71721–22. Since the retail food market conditions and WIC participant access to vendors vary from state to state, the Reauthorization Act and the interim rule provide state agencies with significant discretion regarding how to establish vendor peer groups, competitive pricing, and allowable reimbursement levels to meet the requirements of the cost containment provision. 70 Fed.Reg. 71708. Depending on how vendor peer groups are established by the states, small business entities could be affected differently in every state.

Plaintiffs attempt to distinguish this case from *American Trucking* by urging the Court to look at the language in *Cement Kiln*.⁹ In that case, the Court stated that the RFA applies to “small entities which will be subject to the proposed regulation—that is, those small entities to which the proposed rule will apply.” *Cement Kiln*, 255 F.3d at 869 (quoting *Mid-Tex Elec. Coop.*, 773 F.2d at 342). Contrary to plaintiffs’ contentions, that language actually supports the defendant’s position. State agencies are the entities to *110 which the interim rule applies. Small business entities such as WIC-only vendors may be “targets” of the interim rule, but the interim rule actually applies to state agencies. See *Cement Kiln*, 255 F.3d at 869 (“application of the RFA does not

turn on whether particular entities are the ‘targets’ of a given rule”). The Court, therefore, concludes that the FNS properly certified that the interim rule would not have a significant impact upon a substantial number of small entities.

Finally, the Court notes that the FNS plans to “collect data on the implementation of this interim final rule and the options States select in order to better assess the impact for the final rulemaking and the Final Regulatory Flexibility Analysis and publish it for comments.” 70 Fed.Reg. at 71709.

For the foregoing reasons, plaintiffs’ Motion for Summary Judgment is DENIED and defendant’s Motion for Summary Judgment is GRANTED. The Court’s December 29, 2005 Order granting plaintiffs’ Motion for a Temporary Restraining Order is VACATED. An appropriate Order accompanies this Memorandum Opinion.

All Citations

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Footnotes

- 1 These vendors are defined as those who generate more than 50 percent of their annual revenue from the sale of supplemental foods to WIC participants. [42 U.S.C. § 1786\(11\)\(h\)\(D\)\(ii\)](#).
- 2 At the outset, defendant argues that plaintiffs do not have standing to challenge the rule on participant access grounds because they have not alleged any injury in fact that is fairly traceable to the challenged rule. Plaintiffs do not address this argument in their pleadings; however, the Court will address it briefly here. To satisfy the case or controversy requirement of Article III of the Constitution, a plaintiff must show (1) that it has suffered a concrete and particularized injury that is actual or imminent not merely conjectural or hypothetical, (2) that the injury is fairly traceable to the challenged action of the defendant, and (3) that injury is fairly redressable by a decision of this Court. See, e.g., [Friends of the Earth v. Laidlaw Environmental Services](#), 528 U.S. 167, 180–81, 120 S.Ct. 693, 145 L.Ed.2d 610 (2000); [Lujan v. Defenders of Wildlife](#), 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). The Court finds that the harm to the plaintiff trade organization and to its members as a result of the promulgation of the interim rule constitutes a real and actual injury that is fairly traceable to the rule. Further, an injunction preventing implementation of the rule would redress this injury. Defendant also argues that this claim should be rejected on ripeness grounds. Defendant contends that plaintiffs’ claim is not yet fit for decision because the challenged rule went into effect only weeks prior and no concrete effect of the rule is evident at this time. Further, plaintiffs have failed to identify a genuine hardship that would befall them if this claim was postponed. To determine whether an administrative action is ripe for review, courts must “evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration.” [National Park Hospitality Ass’n v. Department of Interior](#), 538 U.S. 803, 808, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003). Under the first prong, the Court must look to see whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency’s action is sufficiently final. [Nat’l Ass’n of Home Builders v. U.S. Army Corps of Engineers](#), 440 F.3d 459, —, 2006 WL 250234, at * 4 (D.C.Cir.2006). If the issues raised are purely legal, then a claim is “presumptively reviewable.” *Id.* Under the second prong, the Court must consider “not whether [the parties] have suffered any ‘direct hardship,’ but rather whether postponing judicial review would impose an undue burden on them or would benefit the court.” *Id.* If the Court sees no “significant agency or judicial interests militating in favor of delay” then “[lack of] hardship cannot tip the balance against judicial review.” *Id.* The Court concludes that plaintiffs have raised a purely legal claim. Plaintiffs are challenging the legality of the interim rule by alleging that the rule falls short of the statutory mandate and that defendant’s implementation




of the rule would violate the statute. Given the purely legal nature of plaintiffs' challenge to the interim rule, the Court concludes that the issue is fit for judicial resolution and that their participant access claim is ripe for review.

- 3 Since the participant access claim is challenging the the interim rule's scope, an argument could be made that plaintiffs are challenging the reasonableness of the interim rule, which is an inquiry under arbitrary and capricious review. See [Arent v. Shalala, 70 F.3d 610, 615–16 \(D.C.Cir.1995\)](#) (recognizing that “*Chevron* review and arbitrary and capricious review overlap at the margins”).

Under the arbitrary and capricious standard, a reviewing court must look to ensure that the agency did not rely “on factors which Congress has not intended it to consider, ... failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

 [Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 \(1983\)](#). When plaintiffs' challenge is analyzed under this standard, the Court finds the interim rule to be anything but arbitrary and capricious. The rule relies wholly on the factors Congress has intended it to consider.

- 4 Plaintiffs argue in their Motion for Summary Judgment that the retroactive recoupment of excess payments from states and their authorized vendors is an impermissible construction of the Reauthorization Act. The Court finds that this issue is moot in light of the fact that the FNS emphatically assured the Court and the plaintiffs during the January 26, 2006 hearing and in their Supplemental Memorandum in Support of Defendant's Motion for Summary Judgment that the recoupment provision of the interim rule is *not* retroactive. See Def.'s Supplemental. Mem. in Supp. of Mot. for Summ. J. at 5–7; 01/26/06 Tr. at 2, 10, 45–46. As stated by the FNS, if a state retroactively recouped its costs, it would be acting contrary to the law. 01/26/06 Tr. at 46. Although it was made abundantly clear at the January 26, 2006 hearing to all parties that retroactive recoupment is not an issue in this case, plaintiffs have again raised the issue in their Supplemental Motion in Support of Motion for Summary Judgment. Plaintiffs are clearly misconstruing what the interim rule means by recoupment of excess payments. The words “recouping excess payments” appear in a sentence discussing the different ways a state agency may enforce the cost containment requirement against WIC-only vendors who are *not* in compliance. [7 C.F.R. § 246.12\(g\)\(4\)\(i\)\(D\)](#). If WIC-only vendors are in compliance with the states' established competitive price range and reimbursement levels, then no recoupment is allowed. See Attach. to Vogel Decl. (Jan. 20, 2006) (a state agency is not permitted “to recoup any payment to a vendor that is within the established maximum allowable reimbursement level for that vendor... for cost containment purposes”); see *also* 01/26/06 Tr. at 84. Therefore, in light of the fact that plaintiffs have not raised any new arguments as to retroactive recoupment, that issue is moot. In any event, should states attempt to retroactively recoup costs—which is doubtful—plaintiffs can seek relief in courts of competent jurisdiction.

- 5 Plaintiffs argue that since the Reauthorization Act does not expressly authorize the USDA to forego prior notice and comment, the FNS is required to abide by  [§ 553](#). Congress can modify the requirements of prior notice and comment procedures under  [§ 553](#) of the APA when its intent to do so is stated expressly. See [5 U.S.C. § 559](#) (“[s]ubsequent statute may not be held to supersede or modify this subchapter...except to the extent that it does so expressly.”). Plaintiffs contend that the word “may” does not constitute an express authorization from Congress to forego notice and comment. Plaintiffs' argument misses the mark. In this case, notice and comment is not required by the APA but by the USDA's 1971 Policy Statement. Thus, Congress did not explicitly exempt rulemaking related to the Reauthorization Act from notice and comment because the APA is not applicable in the first instance. See  [Philadelphia Citizens in Action v. Schweiker, 669 F.2d 877, 885–86 \(3d Cir.1982\)](#) (explaining that “since Congress specifically does not require notice and comment where grants or benefits are involved [rather it is Health and Human Services own internal policy that requires it] Congress surely is not obliged to state explicitly that statutes it enacts fit within exceptions to regulations or policies formulated solely by an administrative agency.”).

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- 6 From July of 2004 through October of 2004, the FNS conducted congressional briefings and collected necessary data and information from state agencies relating to the vendor cost containment provision of the Reauthorization Act. Vogel Decl. (Jan. 17, 2006) ¶ 6–11. Between December 2004 and March 2005, the FNS had a working draft of the interim rule and conducted necessary regulatory analysis. *Id.* at ¶ 11. Between March 2005 and July 2005, the interim rule went through the formal clearance process within the FNS and USDA. *Id.* at ¶ 13–14. In July 2005, the FNS issued a draft guidance to state agencies. *Id.* at ¶ 16. In August 2005, the interim rule was presented to the Office of Management and Budget (“OMB”) for its 90 day review. *Id.* at ¶ 13. Between July 2005 and October 2005, the FNS trained state agencies in seven FNS regions. *Id.* at ¶ 16. At the end of September 2005, the OMB responded with 90 technical questions about the interim rule to which the FNS had to respond. *Id.* at ¶ 15. On November 7, 2005, the OMB cleared the rule. *Id.* On November 22, 2005, the interim rule was signed by the Deputy Undersecretary of FNS. *Id.* On November 29, 2005, the interim rule was published in the Federal Register. *Id.*
- 7 Congress has appropriated over \$5.2 billion to fund the program for fiscal year 2006. State agencies are expected to receive nearly \$2 billion in additional funding through statutorily mandated rebates from infant formula manufacturers. Complaint ¶ 13.
- 8 The FNS estimates that the Reauthorization Act will result in cost savings of approximately \$75 million annually. 70 Fed.Reg. at 71709.
- 9 Although the agency in *Cement Kiln* did not believe the RFA required it to conduct a regulatory flexibility analysis on the regulation's impact on generators of hazardous materials, the agency did so in the “spirit” of the RFA. 255 F.3d at 868. The petitioner challenged the adequacy of the agency's regulatory flexibility analysis, and the Court held that because the generators of the hazardous materials were not subject to the rule in question, RFA analysis was not necessary. *Id.* at 869. Since RFA analysis was not necessary in the first place, the Court did not address the question of whether the analysis undertaken was adequate. *Id.*

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North Carolina Fisheries Ass'n, Inc. v. Daley, 16 F.Supp.2d 647 (1997)

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KeyCite Yellow Flag - Negative Treatment

Distinguished by [Oregon Trollers Ass'n v. Gutierrez](#), 9th Cir.(Or.), July 6, 2006

16 F.Supp.2d 647
 United States District Court,
 E.D. Virginia,
 Norfolk Division.

NORTH CAROLINA FISHERIES ASSOCIATION,
 INC. and Georges Seafood, Inc., Plaintiffs,
 State of North Carolina, ex rel. James B.
 Hunt, Jr., Governor, and North Carolina
 Department of Environment, [Health and
 Natural Resources](#), Plaintiffs–Intervenors,
 v.

William M. DALEY, Secretary
 of Commerce, Defendant.

Civil Action No. 2:97CV339.

|
 Oct. 10, 1997.

Synopsis

Commercial fisherman and state fisheries association challenged quota set by National Marine Fisheries Service (NMFS) for summer flounder. State intervened. Motions for summary judgment were filed. The District Court, [Doumar, J.](#), held that: (1) Regulatory Flexibility Act was violated by determination of no significant economic impact on small entities based on fact recommended quota remained unchanged from prior year; (2) Magnuson-Stevens Act was violated as unchanged quota was based on quota prior to standard's enactment; (3) optimum yield was not the same as maximum yield; (4) audit of state's fisheries, and not other states, violated Magnuson-Stevens Act; but (5) fisherman were not prejudiced by quota determined set by audit numbers; and (6) Secretary of the Commerce had to publish final adjusted quota within reasonable period of time.

So ordered.

Procedural Posture(s): Motion for Summary Judgment.

West Headnotes (11)

[1] **Fish** Preservation and propagation

Secretary of Commerce's determination under Regulatory Flexibility Act, in setting summer flounder quotas, certifying that there would be no significant economic impact on small entities was arbitrary and capricious where factual basis for certification was that recommended quota was no different from previous year's quota; Secretary had to undertake analysis to determine whether quota had significant economic impact on fishery and statement did not provide factual basis as to why similar quotas would result in no impact. [5 U.S.C.A. § 605\(b\)](#).

1 Cases that cite this headnote

[2] **Fish** Preservation and propagation

In setting fishing quotas under Regulatory Flexibility Act, National Marine Fisheries Service (NMFS) must make some showing that it has at least considered potential effects of specific quota for specific year under consideration in determining there is no significant impact on small entities. [5 U.S.C.A. § 605\(b\)](#).

1 Cases that cite this headnote

[3] **Administrative Law and Procedure** Review for arbitrary, capricious, unreasonable, or illegal actions in general

Action may be considered arbitrary and capricious if the agency entirely failed to consider an important aspect of the problem. [5 U.S.C.A. § 701 et seq.](#)


[4] **Fish** Preservation and propagation

Setting fishery quota at same level as previous year's quota failed to comply with Magnuson-Stevens Act, and was arbitrary and capricious, where previous year's quota was published at time national standard to minimize adverse economic impact on fishing communities was not part of statute. Magnuson–Stevens Fishery

Conservation and Management Act, § 301(a)(8),


 16 U.S.C.A. § 1851(a)(8).

[2 Cases that cite this headnote](#)

[5] **Administrative Law and Procedure**  Power and authority of agency in general

Administrative agency's substantial discretion in determining how it will follow Congressional mandates does not include rewriting or ignoring statutes.

[6] **Fish**  Preservation and propagation

“Optimum yield” for a fishery under Magnuson-Stevens Act is not maximum yield; optimum yield is measured on a continuing basis and is not optimum yield in a single year. Magnuson-Stevens Fishery Conservation and Management Act, § 301(a)(8),  16 U.S.C.A. § 1851(a)(8).

[1 Cases that cite this headnote](#)

[7] **Fish**  Preservation and propagation

National Marine Fisheries Service (NMFS) violated Magnuson-Stevens Act in its audit of state's fishery information, even though audit brought state's numbers more in line with the actual number of fish caught, where NMFS was aware that its figures were inaccurate due to underreporting but did not audit any other state's fishery. Magnuson-Stevens Fishery Conservation and Management Act, § 301(a)(4),

 16 U.S.C.A. § 1851(a)(4).

[8] **Fish**  Preservation and propagation

Even though National Marine Fisheries Service (NMFS) violated Magnuson-Stevens Act by auditing only one state's fishery, and not other states' fisheries, commercial fishermen were not prejudiced in calculation of fishing quota where fishermen admitted there were overages and did not offer alternative, lower number for fishing quota calculation. Magnuson-Stevens Fishery

Conservation and Management Act, § 301(a)(4),

 16 U.S.C.A. § 1851(a)(4).

[9] **Fish**  Preservation and propagation


Application of fishing overage and adjustment to fishing quota was technically and legally correctly determined by subtraction of prior year's overage, where overage from two years earlier was subtracted in reaching prior year's adjusted quota and then prior year's overage was subtracted from quota being adjusted, even though, practically speaking, the timing of the quota adjustment essentially led to overage from two years earlier being applied to current quota. 50 C.F.R. § 648.100(d)(2).

[10] **Fish**  Preservation and propagation

Secretary of Commerce must fix each year's fishing quota, including adjustments, within a reasonable period of time so that states have a chance of making adjustments to their own fishery management schemes to enable them to comply with federal government's quota; since it is the federal government's responsibility to determine the quota from year to year and it has decided that overages for any given year will be subtracted from the succeeding year's quota, government must make determinations and make them within reasonable time.

[11] **Fish**  Preservation and propagation

Inclusion of amount of summer flounder overfished when calculating the stock assessment did not violate Magnuson-Stevens Act nor Administrative Procedure Act (APA), even if it amounted to “double counting,” as subtraction of overages was form of punishment meant to act as a deterrent to prevent overfishing in the future and ensure compliance with the quotas; overages were considered in determining stock assessment that set quota and were subtracted from the quota once it was set.

 5 U.S.C.A. § 701 et seq.; Magnuson-Stevens Fishery Conservation and Management Act, §

305(f),  16 U.S.C.A. § 1855(f); 50 C.F.R. § 648.100(d)(2).

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Richard Ernest John Slaney, Wolcott, Rivers, Wheary, Basnight & Kelly, P.C., Virginia Beach, VA, for Natural Resources Defense Council, Movant.

ORDER & OPINION

DOUMAR, District Judge.

In its simplest terms, this case is an effort by the fisherman of North Carolina to increase *649 the amount of summer flounder that they are authorized to land for the year 1997. Much of the problem centers on an overfishing of some 592,748 pounds of fish which they allegedly caught in excess of their quota in the year 1995. In addition, Plaintiffs and Intervenor–Plaintiffs raise problems with the National Marine Fisheries Service's computing of the catch, its timing in making determinations, and its consideration of the economic effects on the fisherman. The age old problem of the regulator

versus the regulated and the differing interpretations each places on certain factors is involved.

Using a combination of inputs, the Defendant Secretary fixes a quota for fisherman to land summer flounder. This quota applies to both recreational and commercial fisherman. Here, we are concerned with the commercial fisherman and their quota. The ceremonial courtroom was jam-packed with fisherman on the day of the hearing. Mostly these fisherman are from small communities in Eastern North Carolina bordering the sounds and barrier beaches.

This case is before the court on Plaintiffs', Intervenor–Plaintiffs' and Defendant's cross-motions for summary judgment. In summary, the Court finds for the Plaintiffs and Intervenor–Plaintiffs on Counts One, Six and Nine. The Court REMANDS the 1997 quota to the Secretary of Commerce and ORDERS the Secretary to conduct a level of economic analysis consistent with his obligations under the Regulatory Flexibility Act and National Standard 8 of the Magnuson–Stevens Act as discussed below. As to Count Nine, the Court ORDERS the Secretary to publish each year's adjusted quota within a reasonable period of time to enable fisherman to utilize the quota appropriately. The Court DISMISSES Counts Three and Five WITH PREJUDICE; and the Court GRANTS Defendant's motion for summary judgment on Counts Two, Four, Seven, Eight and Ten.

I. Background

The summer flounder fisheries on the East Coast are subject to a detailed management scheme which is designed to reduce the mortality rate of summer flounder. The fishery management plan (FMP) for summer flounder was initially adopted by the National Marine Fisheries Service in 1988. Several amendments to that plan have been made since that time. Part of this management scheme includes the establishment of a coastwide quota for summer flounder which is apportioned between the various states on the East Coast.

The quota is established by the National Marine Fisheries Services (NMFS) after considering the recommendations of the Summer Flounder Monitoring Committee.¹ In determining the quota, a stock assessment is calculated which is an assessment of the number of summer flounder in the entire fishery. This is established by considering many factors including the prior year's catch based on landings reported.

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In determining this figure, it is generally accepted that the landings will be under-reported by approximately 30%.² Therefore, the stock assessment for 1997 included a reduction of the final population estimate by the amount reported overfished in 1995 plus approximately 30% for under-reporting. In determining the 1997 quota and assessment, the figures for 1995 are highly determinative because the 1996 figures are not yet available when the agency begins its calculations. *See infra* note 14.

The quota is allocated between commercial and recreational fisheries. North Carolina is allocated slightly less than 27.5% of the coastwide commercial quota. 50 C.F.R. § 648.100(d) (1). NMFS is required by federal regulation to announce the proposed commercial quota for each year on October 15 of the previous year. 50 C.F.R. § 648.100(c). Furthermore, if a state overfishes in any *650 given year, the overages from that year must be deducted from that state's annual quota for the following year. 50 C.F.R. § 648.100(d)(2).

Dealers—persons or firms that receive summer flounder for a commercial purpose—submit weekly reports to NMFS stating the number of fish purchased and the name and permit number of the vessels from which the fish were purchased. Owners and operators also submit fishing vessel trip reports. In addition to collecting weekly summaries from dealers, NMFS also collects dealer purchase reports to verify the information contained on the weekly summaries. In 1995 and 1996, NMFS did not collect dealer purchase reports from dealers in North Carolina while it did collect these reports from dealers in other states.³

North Carolina's proposed quota for 1996 was published on November 28, 1995. The final quota was published on January 4, 1996. *See infra* Figure 1. North Carolina's 1996 quota was 3,049, 589 pounds of summer flounder. On December 10, 1996 close to the end of North Carolina's fishing season, the federal government adjusted North Carolina's 1996 quota downward by 592,748 pounds due to an overage from the 1995 season.⁴

On December 18, 1996, the federal government announced the proposed quota for 1997, over two months after it was required to do so. 50 C.F.R. § 648.100(c). Relying on this proposed quota and its meetings with the federal government, North Carolina closed its fishery on January 10, 1997, only ten days after the season opened, in order to reserve 30% of its quota for its fall fishery.

The final quota for 1997 was published on March 7, 1997. North Carolina's quota was again established at 3,049, 589 lbs. Then, as required by federal regulation, the federal government reduced North Carolina's quota by 1,237,149 which was North Carolina's overage for 1996. *See infra* discussion of Count Seven. North Carolina's 1997 quota was again adjusted downward on July 7, 1997 due to 538,835 pounds of additional overages discovered for 1996. Therefore, North Carolina's current adjusted quota for 1997 is 1,273,605.

Figure 1. This table outlines the actions taken in regard to the North Carolina summer flounder quota in 1996 and 1997.

Date	Action	Pounds of Flounder	Source
1/4/96	1996 NC quota set	3,049,859 lbs.	A.R. at 139
3/13/96	NC transfers fish to Virginia	(5,773) lbs.	61 Fed.Reg. 10286
	Adjusted 1996 NC quota	3,043,816 lbs.	61 Fed.Reg. 10286
4/5/96	States 1996 quotas adjusted for 1995 overage; <u>no adjustment for North Carolina</u>		A.R. at 169
12/10/96	NC quota adjusted for 1995 overage	(592,748) lbs.	A.R. at 645

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		Adjusted 1996 NC quota	2,451,068 lbs.	A.R. at 645
	12/18/96	1997 quota proposed	3,049,589 lbs.	A.R. at 658
	4/7/97	1997 NC quota set	3,049,589 lbs.	A.R. at 744
		NC quota adjusted for 1996 overage *	(1,237, 149) lbs.	A.R. at 744
		Adjusted 1997 NC quota	1,812,440 lbs.	A.R. at 744
	7/15/97	NC quota adjusted for additional overage discovered for 1996	(538, 835) lbs.	62 Fed.Reg. 37741
		Adjusted 1997 NC quota	1, 273, 605 lbs.	62 Fed.Reg. 37741

* 1996 overage is calculated by subtracting the adjusted 1996 quota from the 1996 landings:

1996 landings.....	3,688,217
Adjusted 1996 quota.....	(2,451,068)
1996 overage.....	(1,237,149)

*651 Plaintiffs, North Carolina Fisheries Association and Georges Seafood, Inc., filed a ten count complaint with this Court on April 4, 1997 alleging that the federal government violated the Regulatory Flexibility Act, the Magnuson–Stevens Act, the Administrative Procedure Act and various federal regulations in setting and adjusting the 1997 quota and in adjusting the 1996 quota. Defendant filed an answer on May 28, 1997. Intervenor–Plaintiffs, the State of North Carolina and the North Carolina Department of Environment, Health and Natural Resources, filed a complaint very similar to the Plaintiffs' complaint on August 26, 1997.⁵

All parties filed motions for summary judgment, and the court heard arguments on September 22, 1997. At that time, the Court determined that it was necessary to have an evidentiary hearing on September 29, 1997 to determine whether there was a sufficient economic impact such that the Secretary of Commerce needed to do more fact finding than was evident from the administrative record before determining that there was no significant impact on small businesses. More than 100 men and women who make their living fishing in the various coastal communities in North Carolina came to court willing to testify to the substantial effect that the quota had on their businesses.

II. Analysis

Standard of Review

Both the Regulatory Flexibility Act, 5 U.S.C. § 611, and the Magnuson–Stevens Act, 16 U.S.C. § 1855(f), provide for judicial review of agency actions. Agency actions under both statutes are to be reviewed for compliance in accordance with Administrative Procedure Act, 5 U.S.C. § 701 et seq. Regulatory Flexibility Act, 5 U.S.C. § 611(a)(2); Magnuson–Stevens Act, 16 U.S.C. § 1855, 16 U.S.C. § 1855(f)(1).

The Administrative Procedure Act (APA) states that a reviewing court shall “hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” 5 U.S.C. § 706(2)(A). Therefore, this Court will review the Secretary's actions in accordance with these standards. See *Fishermen's Dock Cooperative, Inc. v. Brown*, 75 F.3d 164, 167–68 (4th Cir.1996).

Count One

Plaintiffs allege in Count One of their complaint that NMFS's failure to conduct an initial regulatory flexibility analysis and final regulatory flexibility analysis when setting the 1997 quota violated §§ 603 & 604 of the Regulatory Flexibility Act and thus violated the Administrative Procedure Act.

[1] [2] Defendant argues that he complied with § 605(b) of the Regulatory Flexibility Act by certifying that there would be no significant economic impact on small entities.⁶ The Defendant did make a certification when he published the proposed rule: "The proposed measures would not have a *652 significant economic impact on a substantial number of small entities." 61 Fed.Reg. 66648 (1996), A.R. at 658. The Secretary also provided the "factual basis" for the certification: "The recommended 1997 quota is no different from the 1996 coastwide harvest limit of 18.51 million lb." *Id.* While this is a "statement," it does not provide a factual basis. There is no explanation why the fact that the quotas are the same means there will be no impact.⁷ While the federal government cannot be expected to explore every possible contingency before certifying that there is no significant impact, the government must make some showing that it has at least considered the potential effects of *this* quota, *this* year.⁸ There is no evidence in the Administrative Record that any such consideration was undertaken.⁹

The federal government did consider three possible quotas for the 1997 fishery, but the *653 government failed to do any significant analysis to support its conclusion that there would be no significant impact. The only justification provided by the government was that the quota remained the same from 1996 to 1997. There is no record whatsoever showing that the federal government did any comparison between conditions in 1996 and 1997. A simple conclusory statement that, because the quota was the same in 1997 as it was in 1996, there would be no significant impact, is not an analysis. It is evident to this Court from the some 100 North Carolina fisherman who appeared to testify that their businesses were significantly affected that there was a significant economic impact, and there must have been some change in conditions between the two years to cause such an impact.

[3] The United States Supreme Court has held that an action may be considered arbitrary and capricious if the agency "entirely failed to consider an important aspect of

the problem." *Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 2867, 77 L.Ed.2d 443 (1983). It is clear to this Court that the Secretary acted arbitrarily and capriciously in failing to give any significant consideration to the economic impact of the quota on the North Carolina fishery.

The Court will not substitute its findings for those of the Secretary of Commerce nor will the Court change the quota.¹⁰ Instead, the Court finds that the Secretary of Commerce violated the Regulatory Flexibility Act and REMANDS this quota to the Secretary and ORDERS him to undertake enough analysis to determine whether the quota had a significant economic impact on the North Carolina fishery. The Court further ORDERS the Secretary to include in his analysis whether the *adjusted* quota will have a significant economic impact on small entities in North Carolina. The Court ORDERS the Secretary to report the results to this Court by December 1, 1997. If the Secretary finds, after giving the matter a sufficient level of consideration and reducing that consideration to writing, that there is no significant economic effect on a substantial number of small entities, then so be it; but this Court will not stand by and allow the Secretary to attempt to achieve a desirable end by using illegal means.

Count Six

The Court addresses Count Six at this point in its opinion because Plaintiffs argued *654 this count collectively with Count One and the two counts are closely related. Plaintiffs argue in Count Six that Defendant failed to meet National Standard 8 of the Magnuson–Stevens Act, 16 U.S.C. § 1851(a)(8). Plaintiff's Complaint at ¶¶ 52–53. National Standard 8 provides,


Conservation and management measures shall, consistent with the conservation requirements of this Act (including the prevention of overfishing and rebuilding of overfished stocks), take into account the importance of fishery resources to fishing communities in order to (A) provide for the sustained participation of such communities, and (B) to the extent practicable, minimize

adverse economic impacts on such communities.

 16 U.S.C. § 1851(a)(8).


The Defendant argues that the quota is in line with his obligation to prevent overfishing and rebuild overfished stocks. It is clear that the Defendant has a duty to rebuild overfished stocks, but the defendant also has a statutory obligation to balance that duty with his responsibility to minimize the adverse impacts on fishing communities such as those in North Carolina.

[4] Defendant again attempts to rely on the fact that he set the 1997 quota at the same level as the 1996 quota as evidence that he complied with National Standard 8. This justification is ludicrous. When the 1996 quota was published, National Standard 8 was not part of the Magnuson–Stevens Act. There is no evidence that this quota complied with National Standard 8 in 1996. Therefore, even if no conditions changed between 1996 and 1997, which the Court highly doubts, there is no evidence that this quota complied with National Standard 8 in 1997. The very reason National Standard 8 was added to the Magnuson–Stevens Act was that there was no requirement in the Act that “fishery management councils ... try to minimize the adverse economic impacts of fisheries regulations on fishing communities.” 142 Cong. Rec. S10794–02, S10825 (daily ed. Sept. 18, 1996) (statement of Sen. Snowe).

[5] Defendant contends that “the Magnuson–Stevens Act does not require a thorough analysis of alternatives” and that a requirement that NMFS “consider a range of alternatives to the proposed rule setting the quota ... is without legal precedent.” Federal Defendant’s Response at 11. Certainly, it is without “legal precedent” as the law only came into effect within the last year. If the Court were to follow the Defendant’s line of reasoning, National Standard 8 would be written out of the statute by NMFS within that same short period of time. Granted, administrative agencies have a substantial amount of discretion in determining how they will follow Congressional mandates. That discretion, however, does not include rewriting or ignoring statutes. NMFS is required not only to “take into account the economic impact,” Federal Defendant’s Response at 11, but also, “to the extent practicable, minimize adverse economic impacts on such communities.”  16 U.S.C. § 1851(a)(8).

Accordingly, the Court finds that the Secretary acted arbitrarily and capriciously in failing to comply with National Standard 8 and REMANDS the quota to the Secretary and ORDERS the Secretary to perform a level of economic analysis sufficient to comply with National Standard 8 and “to the extent practicable, minimize the adverse economic impacts on [fishing] communities.” *Id.* Whether this analysis is done in conjunction with the analysis the Court has ordered in regard to the Regulatory Flexibility Act or separately is left to the discretion of the Secretary. Again, the Court ORDERS the Secretary to report the results to this Court by December 1, 1997.


Count Two

In Count Two, Plaintiffs argue that Defendant violated the APA because the 1997 summer flounder quota does not allow for the achievement of “optimum yield” on a continuing basis contrary to the requirements of National Standard 1 of the Magnuson–Stevens Act,  16 U.S.C. § 1851(a)(1). Plaintiff’s Complaint at ¶¶ 36–38.

[6] The crux of Plaintiffs’ argument seems to be that because less fish will be fished than the initial quota allows (because of the subtraction of the overages from the quota), optimum yield is not being achieved. *655 Plaintiffs’, however, misconstrue the term “optimum yield.” The District of Columbia Circuit has defined optimum yield as “maximum yield less whatever amount need be conserved for economic, social or ecological reasons.” *C & W Fish Co., Inc. v. Fox*, 931 F.2d 1556, 1563 (D.C.Cir.1991). This Court has also held that “ ‘optimum yield’ is not the same as ‘maximum yield.’ ” *J.H. Miles & Co. v. Brown*, 910 F.Supp. 1138, 1148 (E.D.Va.1995). Furthermore, optimum yield is measured on a continuing basis, therefore “management measures must aim to achieve, on a continuing basis, the optimum yield from each fishery, not the optimum yield in a single year.” *Id.*

The Court finds that the Secretary did not violate National Standard 1 and GRANTS the Secretary’s motion for summary judgment on Count Two.

Count Three

During oral argument, Plaintiffs withdrew Count Three which alleged that Defendant violated the APA because it failed to comply with National Standard 2 of the Magnuson–Stevens Act,  16 U.S.C. § 1851(a)(2), which requires that

conservation and management measures be based on the best scientific information available. Plaintiff's Complaint at ¶¶ 40–42. Therefore, Count Three is DISMISSED WITH PREJUDICE.

Count Four

In Count Four, Plaintiffs argue that Defendant violated the APA because the 1997 summer flounder quota for North Carolina discriminates between residents of different states in violation of National Standard 4 of the Magnuson–Stevens

Act, 16 U.S.C. § 1851(a)(4). Plaintiff's Complaint at ¶¶ 44–46.

Plaintiffs argue that NMFS used North Carolina's numbers in determining North Carolina's overage but used its own (NMFS's) numbers in calculating the overages of other states. The federal government claims that it used its own numbers in calculating North Carolina's overage for 1995; however, counsel for the Defendant could not point to an accounting of how NMFS arrived at the final number of 592,748 pounds. What is clear is that the federal government was alerted to the discrepancy between its numbers and North Carolina's numbers for 1995 by the State of North Carolina. At some point after being made aware of the discrepancy, NMFS decided, in economic parlance, to audit North Carolina's numbers in the agency's own fashion.

[7] The Mid–Atlantic Fishery Management Council noted in its discussions regarding the 1997 management measures that under-reporting in the various fisheries may be as high as 30%. Minutes of the Mid–Atlantic Fishery Management Council Meeting, September 17–19, 1997, at 6, 9, 58, A.R. at 307, 310, 359. Thus, presumably NMFS's audit of North Carolina brought North Carolina's numbers more in line with the actual number of fish caught. Despite NMFS's awareness that its figures are inaccurate and its knowing that there is approximately 30% under-reporting, NMFS did not audit any other fishery besides North Carolina's. The Court finds that NMFS's actions amount to a violation of National Standard 4.¹¹

[8] The Court finds, however, that this violation did not prejudice the Plaintiffs for two reasons. First, Plaintiffs admit there were overages and their own figures were higher than those ultimately arrived at by the federal government. Second, counsel for Plaintiffs conceded during oral arguments that “for the purposes of [Plaintiffs'] remedy” it was “willing to accept that there is a number of 592 thousand pounds

which they took as an overage which should not have been taken.” Excerpt of Proceedings, September 22, 1997 Hearing. Although focusing on the fact that the number was derived from North Carolina's figures, Plaintiffs never made a showing that the number was lower than 592,748 pounds. Therefore, because there is no prejudice shown by the Plaintiffs, the Court must uphold the Secretary's actions as they relate to National Standard 4 as it has no figure to substitute therefore. See *J.H. Miles & Co.*, 910 F.Supp. at 1146.

*656 Even though the Court finds for the Secretary, it questions NMFS's actions. Auditing only North Carolina and not any other state seems on its face to be extremely unfair because, when analyzing the stock assessment and setting the 1997 quota, under-reporting was assumed. Minutes of the Mid–Atlantic Fishery Management Council Meeting, September 17–19, 1997, at 6–11, A.R. at 307–12. The severely close auditing of North Carolina implies that there was some reason to hold North Carolina to a higher standard than other states. The fact that North Carolina has participated in other suits, see *Fishermen's Dock Cooperative*, 75 F.3d 164, should not cause NMFS to apply different standards to North Carolina than it applied to other states. If the agency desires in effect to audit North Carolina's records, then it should audit other states as well as it is a coastwide quota. Thus, although North Carolina was judged differently by the NMFS and the Secretary could not show the basis for NMFS's determination of the overage other than North Carolina's own figures, this Court cannot find prejudice from what Plaintiffs admit was an overage.

Count Five

Plaintiffs withdrew Count Five during oral argument. Count Five alleged that Defendant did not meet National Standard 6 of the Magnuson–Stevens Act, 16 U.S.C. § 1851(a)(6), requiring that conservation and management measures take into account and allow for variations among, and contingencies in fisheries, fishery resources, and catches. Plaintiff's Complaint at ¶¶ 48–50. Accordingly, this Court DISMISSES Count Five WITH PREJUDICE.

Count Seven

Plaintiffs argue that Defendant violated the APA because the 1997 fishing quota applied overages from 1995 and 1996 against the 1997 quota and therefore violated 50 C.F.R. § 648.100(d)(2). Plaintiff's Complaint at ¶¶ 56–60. Section

648.100(d)(2) of 50 C.F.R. states that, “[a]ny overages of the commercial quota landed in any state will be deducted from that state's annual quota for the following year.”

[9] The federal government complied with the letter of the law in a most undesirable fashion.¹² On December 10, 1996, the federal government subtracted the 1995 overage of 592,748 pounds from North Carolina's 1996 adjusted quota (adjusted from the transfer to Virginia, *see supra* note 4), to reach an adjusted 1996 quota of 2,451,068 pounds. North Carolina fisherman landed 3,688,217 pounds of fish in 1996; therefore, there was an overage of 1,237,149 pounds for 1996. This overage was subtracted from the 1997 quota of 3,049,589 to arrive at an adjusted 1997 quota of 1,812,440 pounds. *See supra* Fig.1. Although, practically speaking, the timing of the quota adjustment essentially led to 1995's overage being applied to 1997's quota, technically, and therefore, legally, the overage was applied to 1996 quota. Accordingly, the Courts GRANTS summary judgment to the Defendant on Count Seven.¹³

Count Eight

Plaintiffs argue that the adjusted quota was set in violation of the APA because 50 C.F.R. § 648.100(c) requires that the Regional Director of NMFS publish a proposed rule in the Federal Register by October 15 to *657 implement a coast wide commercial quota, but in 1996 the proposed rule was not published until December 18. Plaintiff's Complaint at ¶¶ 62–64.

Under the Magnuson–Stevens Act, a party challenging a regulation promulgated by the Secretary must do so within 30 days of promulgation or publication of the regulation.

16 U.S.C. § 1855(f). Therefore, while Plaintiffs are correct that the proposed rule was published more than two months after it was supposed to be, they are barred by the statute of limitations from raising this claim. The Court GRANTS the Secretary's motion for summary judgment on Count Eight.

Count Nine

In Count Nine, Plaintiffs allege that Defendant violated the APA and the Magnuson–Stevens Act because it failed to adequately police the federally-permitted fisheries dealers to assure that landings were reported accurately and timely as required by 50 C.F.R. § 648.7(a)(1). Plaintiff's Complaint at ¶¶ 66–69.

[10] The Secretary defends himself on this count by arguing that NMFS did not collect the information it was supposed to because of its negotiations with North Carolina. As stated above, *see supra* note 3, NMFS and North Carolina never reached a final agreement. The federal government also argues that “plaintiffs' suggestion that NMFS has the responsibility or ability to monitor every landing in every state and to monitor which purchasers are not adequately reporting landings is untenable.” Defendant's Brief in Support of Summary Judgment at 26. Yet, given that it is the federal government's responsibility to determine the quota from year to year, and it has decided that overages for any given year will be subtracted from the succeeding year's quota, that is exactly what the federal government must do. Not only must the government make these determinations, but it must do so in a reasonable amount of time so that states have at least a remote chance of making adjustments to their own fishery management schemes which will enable them to comply with the quota set by the federal government.

While the Court cannot go so far as Plaintiffs' request and order the government to publish the adjusted quotas by January 1 of each year, an order better left to Congress, the Court can and does ORDER the Secretary to publish the final adjusted quota within a reasonable period of time to enable the fisherman to utilize the quota appropriately.

Count Ten

In their final claim, Plaintiffs allege that Defendant violated the APA and Magnuson–Stevens Act because the Defendant used the 1995 harvest numbers in determining the 1997 quota and then reduced the 1997 quota by the 1995 overage. ¶¶ 71–72.¹⁴

In essence, Plaintiffs argues that all the fish that have been caught, including overages, are considered in the stock assessment. The stock assessment is then used in determining the quota. The overages are then subtracted from the quota once it is determined even though these numbers were already considered in determining the stock assessment. Therefore, according to Plaintiffs, there is a “double counting.”

[11] Plaintiffs are correct that the amount of summer flounder overfished are included in calculating the stock assessment.¹⁵ While this may, in fact, be a kind of *658 “double counting,” it violates neither the Magnuson–Stevens Act nor the Administrative Procedure Act. The subtraction of

overages called for in 50 C.F.R. § 648.100(d)(2) is a form of punishment meant to act as a deterrent to prevent overfishing in the future. Without this deterrent, fisherman could overfish every year with no consequences, and NMFS would have no means whatsoever to ensure compliance with the quotas. While another means of punishment may have been chosen, subtraction of overages is the most practical method which has been adopted for this purpose.

If Plaintiffs had wanted to challenge this method, they should have done so with 30 days of promulgation or publication of the regulation. See 16 U.S.C. § 1855(f). Having failed to do so, Plaintiffs must abide by the regulation until such time as they convince the Secretary or Congress to change it. Accordingly, the Court GRANTS Defendant's motion for summary judgment on Count Ten.

III. Conclusion

In conclusion, the Court notes that the NMFS's actions in this case are troublesome. The federal government indicates in one instance that the 1997 quota was arrived at separately and expertly. In another, the government indicates that, because the 1997 quota was the same as the 1996 quota, there is no need to conduct any analysis to determine whether the

quota has any significant economic impact. Finally, the most substantial problem in this case could have been avoided had the NMFS acted in a timely manner in adjusting the 1996 quota the first place.

Accordingly, the Court REMANDS the quota to the Secretary of Commerce and ORDERS the Secretary to conduct the requisite level of analysis to determine whether a certification of no significant impact is appropriate under § 605(b) of the Regulatory Flexibility Act and an economic analysis sufficient to comply with National Standard 8 of the Magnuson–Stevens Act. Furthermore, the Court ORDERS the Secretary to fix each year's fishing quota including adjustments, within a reasonable period of time.

The Court DISMISSES Counts Three and Five WITH PREJUDICE; and the Court GRANTS Defendant's motion for summary judgment on Counts Two, Four, Seven, Eight and Ten.

IT IS SO ORDERED.

All Citations

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Footnotes

- 1 The Summer Flounder Monitoring Committee consists of representatives from the Atlantic States Marine Fisheries Commission, the New England Fisheries Management Council, the Mid–Atlantic Fishery Management Council, and the National Marine Fisheries Service.
- 2 The Court bases this figure on how the 1997 quota was determined. See Minutes of the Mid–Atlantic Fishery Management Council Meeting, September 17–19, 1997, at 6, 9, 58, A.R. at 307, 310, 359. The figure for under-reporting varies from 20% to 50%. *Id.* Thus, 30% is an approximation.
- 3 The federal government notes in its response that, because North Carolina maintained a trip-ticket system and collected records of all landings of summer flounder in the state, NMFS approached North Carolina in March 1996 to negotiate an agreement whereby data could be shared thus decreasing the burden on dealers in North Carolina. Federal Defendant's Response at 13–14. (The federal government does not explain why it did not collect these reports in 1995.) The negotiations were suspended in December 1996 when North Carolina informed NMFS that the information was confidential under North Carolina law and could not be shared. *Id.* at 14. A negotiation is not an agreement, therefore, NMFS was not relieved of its responsibility to obtain information in a timely fashion until an agreement was reached.
- 4 North Carolina had previously had its 1996 quota reduced by 5,773 pounds which it voluntarily transferred to Virginia. 61 Fed.Reg. 10286 (1996).

5 Throughout the rest of this opinion, Plaintiffs and Intervenor–Plaintiffs will be referred to collectively as “Plaintiffs” as these parties adopted each others motions, memorandums in support and responses and divided the issues between them for oral argument.

6  Section 605(b) of the Regulatory Flexibility Act states:

Sections 603 and 604 of this title [requiring initial and final regulatory flexibility analyses] shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification.

7 Ever since Keynes proposed his theories of tax and spending, the government has undertaken to regulate all types of activity while supposedly considering economic effects. The court notes that the Secretary’s reasoning provides an interesting new economic theory—regulations which merely adopt the past have no economic effect on the future. The Secretary must believe the economy never changes. This theory must have Keynes in perpetual motion, and the court cautions anyone from treading too close to his grave lest that person be drawn into the ground by the funnel effect created.


8 Ironically, one of the very changes in condition that led to what appears to the court to be a significant impact is the central issue of this lawsuit—the fact that North Carolina is being forced to pay back 1995 overages, calculations of which were not finalized until December of 1996, when it was far too late to manage the fishery to avoid this outcome. While the overages do have to be subtracted under the existing law, the effect of NMFS’s timing in adjusting the 1996 quota was devastating on North Carolina fisherman.

The federal government knew when it made its proposal that the fisherman would be landing substantially less fish because of 1995 and 1996 overages: “I propose holding the harvest level at the level recommended by the Council, however. These measures, and the deduction of 1995 and 1996 overages, will reduce the actual 1997 landings substantially, more in line with the FMP objectives.” Memo from Dr. Andrew Rosenberg, Regional Administrator to Rolland Schmitt, Assistant Administrator for Fisheries A.R. at 629. “Many states have exceeded their 1996 quotas and the 1997 quota will be decreased at least 14% as a result” *Id.*, A.R. at 631.

The government also noted, directly after stating that there would be no significant economic impact because the quota had remained the same from 1996 to 1997, that “[t]hese measures may impact the fishing industry negatively for the short term, but will prove beneficial in the future.” 61 Fed.Reg. 66648 (1996).

9 NMFS’s own guidelines outline the criteria to be used in making this determination:

After reviewing the criteria for significant economic impact on a substantial number of small entities ..., the Council and the Regional Director may initially conclude that a regulatory flexibility analysis is unnecessary.

 Section 605(b) of the RFA allows certification at the time of the proposed or final rule that it will not, if promulgated, have a significant economic impact on a substantial number of small entities. An explanation of the certification of non-significance should be contained in the proposed rule. The certification is a legally conclusive determination that the regulatory flexibility analysis is unnecessary....

A certification should contain the following elements as appropriate made by the “agency head” or one to whom the “agency head” has formally delegated authority for the RFA

i. A statement that the regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities.

ii. A “succinct statement” explaining how the conclusion in 1 above was reached. The statement should include the following elements.

— It should make clear the reasoning for the determination, especially for important regulations.

— It should include the criteria used to determine that the rule will not have a “significant impact” on small entities.

NMFS's *Guidelines on Regulatory Analysis of Fishery Management Actions* ("*Guidelines* ") at 14, Administrative Record ("A.R.") at 61–62.

NMFS's *Guidelines* define a substantial number of small entities as follows:

In general, a "substantial number" of small entities is more than 20 percent of those entities This percentage is calculated on the number of small entities affected by the regulations out of the total universe of small entities in a particular industry or segment of that industry. If the effects of the rule fall primarily on a distinct segment, or portion thereof, of the industry (user group, gear type, geographical area, etc.), that segment would be considered the universe for the purposes of this criterion. The 20 percent criterion represents a general guide because there may be instances when the intent of the RFA would imply the need for a regulatory flexibility analysis even though less than 20 percent of the small entities in the industry are affected.

Guidelines at 13, A.R. at 60. It should be noted that North Carolina is allotted just under 27.5% of the quota suggesting that North Carolina fisherman constitute at least 20% of the small entities affected by the quota. Furthermore, because of the timing of the final 1996 quota adjustment for North Carolina, the effect of the 1997 quota fell heavily on one geographic segment of the industry, North Carolina. Therefore, under NMFS's *Guidelines*, North Carolina could be considered a "universe" for the purposes of this guideline.

NMFS outlines five criteria which, if met, would mean that there would be a significant economic impact on small entities:

1. The regulations are likely to result in a reduction in annual gross revenues by more than 5 percent.
2. Annual compliance costs (annualized capital, operating, reporting, etc.) increase total costs of production for small entities by more than [sic] 5 percent.
3. Compliance costs as a percent of sales for small entities are at least 10 percent higher than compliance costs as a percent of sales for large entities.
4. Capital costs of compliance represent a significant portion of capital available to small entities, considering internal cash flow and external financing capabilities.
5. The requirements of the regulation are likely to result in a number of the small entities affected being forced to cease business operations. This number is not precisely defined by SBA, but a "rule of thumb" to trigger this criterion would be 2 percent of the small entities affected.

Guidelines at 14, A.R. at 61. Clearly, both criterion (1) and criterion (5) appear to be implicated in this case. During oral argument, counsel for the Defendant noted the federal government's objection to the Court's taking of evidence that was outside the Administrative Record. The Court considered this evidence not to substitute its findings for the Secretary's but to determine whether there was any evidence of such an impact as the record was completely devoid of such evidence or of any showing that NMFS had tried to obtain it.

10 The Court also notes another differentiation in the treatment of North Carolina: North Carolina was the only state to have its 1996 quota adjusted in *December, 1996* long after it was feasible for the state to adopt a plan to account for the overage during the 1996 fishing season.

11 The Court also notes another differentiation in the treatment of North Carolina: North Carolina was the only state to have its 1996 quota adjusted in *December, 1996* long after it was feasible for the state to adopt a plan to account for the overage during the 1996 fishing season.

12 The Governor and Senator from North Carolina after inquiries and meetings had one understanding of what would be deducted from the 1997 quota while the Secretary and his representatives had another. Each side left the same meeting with a different view as to whether the 1995 overage was to be deducted from the 1997 quota. The position of the agency was that only the 1996 overage would be deducted from the 1997 quota. The North Carolina representatives believed the 1995 quota would not be deducted from the 1997 quota. However, later the agency's position was clarified when the 1996 quota was adjusted on December 10, 1996 for the 1995 overage, and then the entire 1996 overage was then deducted from the 1997 quota. Thus, according to the agency, the 1995 overage was not deducted from the 1997 quota. While the agency's action was legally correct, it is not a desirable way to do business.

13 The Court takes this opportunity to reiterate its determination below that the Secretary and NMFS *must* find a way to determine overages and adjust quotas in a reasonable amount of time so that states are able to respond to the information in such a way so as to avoid the devastating effect that this late determination has had on North Carolina.

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- 14 Plaintiff explains the application of the 1995 overage to 1997's quota as follows:
The [Mid-Atlantic Fishery Management Council committee responsible for calculating proposed summer flounder fishery quotas, [sic] uses the state's information data base for the last available year to calculate the next year's proposed quota. Since the 1996 fishing year was ongoing when quota calculation started in June, 1996, the 1995 landings were used in the calculation of the 1997 quota.
Plaintiff's Complaint at ¶ 71.
- 15 The Summer Flounder Monitoring Committee will annually review the best available data including, but not limited to, commercial and recreational *catch/landing statistics*, *current estimates of fishing mortality*, *stock status*, the most recent estimates of recruitment, VPA results, target mortality levels, beneficial impacts of size/mesh regulations, as well as the level of *noncompliance by fishermen or States* and recommend to the Council Committee and ASMFC Interstate Fisher Management Program (ISFMP) Policy Board commercial (annual quota, minimum fish size, and minimum mesh size) and recreational (possession and size limits and seasonal closures) measures designed to assure that the target mortality level on summer flounder is not exceeded
Measures to Attain Management Measures § 9.1.2.2, A.R. at 7 (emphasis added).

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