Stimulating Smarter Regulation: Summaries of Public Suggestions for Reform of Regulations and Guidance Documents

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I. SUGGESTIONS FROM THE PUBLIC FOR REFORM OF REGULATIONS

1. Child Nutrition Program Regulations

Regulating Agency: USDA/FNS

Citation: Federal Register--Tuesday, June 13, 1995

Authority: National School Lunch Act, Section 2, 42 USC 1751. Meal Requirements for Child Nutrition Programs

Description of What Existing Regulation Does: Existing regulation sets forth requirements for school breakfasts and school lunches. Guidelines were designed so that meals given through the program would provide a sufficient proportion of the Recommended Daily Allowance of calories and nutrients.

Commenter Description of Issue(s): Commenter feels that the minimum calorie level required in the regulations helps to contribute to childhood obesity and type 2 diabetes. Commenter states that recent research has shown that energy expenditure needs of children were overestimated by 25 percent.

Small Business Impact: No.

Commenter Proposed Solution(s): No solutions presented, though it can be inferred that the commenter would like to rescind the minimum calorie requirements.

Estimate of Economic Impacts: None provided.

Commenter(s): Joanne S. Hurley, Gila River Indian Community, Sacaton AZ. (148).
2. Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems

Regulating Agency: USDA/Food Safety and Inspection Service

Citation: 9 CFR 417.1, 417.2(a)(1), 417.3(b)(3), 417.6(e), 500.6, 500.4, 500.3, and 500.7


Description of What Existing Regulation Does: The current rule requires plants to implement science-based process control systems as a means of preventing food safety hazards, sets certain food safety performance standards, and establishes testing programs to ensure those standards are met. It also contains procedures for taking enforcement actions in meat and poultry plants, including the refusal to grant, the suspension, and the withdrawal of inspection.

Commenter Description of Issue(s):

- FSIS has deviated from HACCP principles as articulated by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), mandating critical control points and enforcing unwarranted withholding and suspension of inspections services at numerous plants. (47)
- Several regulatory provisions related to the suspensions, withholding actions, and withdrawal of establishment’s grant of inspection are outside the scope of FSIS’ statutory authority. (47)
- The regulation may be unlawful because USDA did not comply with PL 103-304, the Congressional Review Act, and U.S.C. 28.535 (b). (56)
- The rule imposes very large costs and has been especially hard on small businesses. (56)

Small Business Impact: Yes.

Commenter Proposed Solution(s):

- FSIS should amend the rule to account for other programs, such as SSOPs and GMPs when assessing the adequacy of HACCP systems and to reflect the definition and interpretation of a food safety hazard adopted by NACMCF. (47)
- FSIS should amend the regulatory language on product shipment to give consideration to situations where products leave an establishment, but remain under the control of the establishment, and to limit the determination of inadequacy in HACCP plans to actual shipment of product. (47)
- FSIS should amend the rule to eliminate provisions that are beyond the scope of their statutory authority. Specifically: 500.6 (a)-(f) and (h); 500.4 (d) and (e); 500.3 (a)(1)-(2); and 500.7 (a)(1)-(4).
- FSIS should amend the rule by redesignating 500.7(a)(5) as subsection (a) and amending it to read as follows: “(a) the FSIS Administrator may refuse to grant Federal inspection because an applicant is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA of section 18(1) of the PPIA”
- The state sanitation and inspection system should handle meat and poultry processing plants as an extension of the sanitation programs for restaurants, grocery stores and Custom Meat Processing plants. (56)

Estimate of Economic Impacts: Increase in efficiency and reduction in costs.

Commenter(s): American Meat Institute (47); James F. Boland (56).
3. Animal Identification and Traceback

Regulating Agency: USDA/Grain Inspection Packers and Stockyard Administration; USDA/Food Safety and Inspection Service

Citation: 9 CFR 201.49, 201.86, 201.94 and 201.95; 9 CFR 310.2

Authority: Packers and Stockyards Act and Federal Meat Inspection Act

Description of What Existing Regulation Does: Current regulations require detailed information to maintain carcass identification and/or allow for traceback through purchase and sale, including slaughter.

Commenter Description of Issue(s):

• The animal identification and traceback systems are overly prescriptive, outdated and fail to embrace technological and operational advances.
• The regulations increase food safety risks because of unnecessary handling of contaminated animal hides and identification tags.
• The regulations do not discriminate between meaningful identification and meaningless identification.

Small Business Impact: Yes.

Commenter Proposed Solution(s):

• FSIS and GIPSA should establish a flexible regulatory policy that identifies the information needed to meet the requirements of the Packers and Stockyards Act and the Federal Meat Inspection Act without prescribing how those needs are met.
• The regulatory policy should ensure that all carcasses are identified by a carcass ID number that, in turn, is linked to an incoming animal. Carcasses, viscera, and other parts of the animal destined for food or medicines are linked through completion of post-mortem inspection.
• Regulations should focus on tags that have consistent standardized meanings.

Estimate of Economic Impacts: None provided.

Commenter(s): American Meat Institute (47).
4. Post Mortem Inspection: Extent and Time of Post Mortem Inspection - Staffing Standards

Regulating Agency: USDA/Food Safety and Inspection Service

Citation: 9 CFR 310.1

Authority: Federal Meat Inspection Act and Poultry Products Inspection Act

Description of What Existing Regulation Does: The current rule establishes maximum rates for slaughter based on the number of inspectors available and the type of inspection required and requires each establishment to pay for USDA inspectors when inspectors are required to work outside establishments’ schedule of operations.

Commenter Description of Issue(s):

• The regulatory limits on the slaughter rate do not allow establishments to take advantage of new technologies and improved operations, which prevent establishments from improving efficiencies and capitalizing on investments. (47)
• The regulatory responsibilities of the establishment and USDA are the same regardless of whether work is performed during the schedule of operations or outside it. (161)
• The payment for overtime and holiday pay for inspectors imposes a financial burden on establishments. (161)

Small Business Impact: Yes.

Commenter Proposed Solution(s):

• FSIS should rewrite the staffing requirements such that they are formula based, or otherwise open ended to accommodate technological advances in operational efficiencies, or FSIS should separate staffing from line speeds. (47)
• FSIS should base staffing on establishment historical performance relative to compliance with regulatory requirements. (47)
• Establishments should not have to pay inspectors for overtime or holidays. (161)

Estimate of Economic Impacts: None provided.

Commenter(s): American Meat Institute (47); Matt Flanagan (160).
5. **Zero Tolerance for *Listeria monocytogenes* and Performance Standards**

**Regulating Agency:** USDA/Food Safety and Inspection Service; HHS/Food and Drug Administration

**Citation:** 21 CFR 109.3 and 67 Federal Register 15,013

**Authority:** Food, Drug, and Cosmetic Act, Federal Meat Inspection Act and Poultry Products Inspection Act

**Description of What Existing Regulation Does:** FDA’s current rule and a similar FSIS policy consider ready to eat (RTE) foods adulterated if any *L. monocytogenes* is detected. An FSIS proposed rule would require establishments that produce RTE meat and poultry products to test food contact surface for *Listeria* spp. to verify that they are controlling the presence of *L. monocytogenes* within their processing environments. Establishments that develop and implement HACCP controls for *L. monocytogenes* would be exempt from these requirements.

**Commenter Description of Issue(s):**

- CDC has indicated that the disease caused by *Listeria monocytogenes* has the highest rate of hospitalizations among foodborne pathogens and the second highest fatality rate. (81) (77)
- There is scientific agreement that low levels of *Listeria monocytogenes* are not uncommon in the food supply and that such low levels are routinely consumed without apparent harm. (47)
- Eradication of *Listeria Monocytogenes* in the food processing environment is not practical given the widespread ubiquitous nature of the organism and in light of currently available technologies. (47)
- Major trading partners have established flexible regulatory limits relative to *Listeria monocytogenes* that focus limited regulatory resources on foods presenting a realistic risk of listeriosis. (47)
- FSIS currently relies on a random sampling program to detect *Listeria monocytogenes*. There is no requirement that producers detect contamination by testing their own finished product. (81)
- FSIS’ proposed rule requires a level of testing that lacks a scientific basis and encourages companies currently conducting large sampling programs to decrease testing. (47)
- FSIS’ proposed rule misuses the concept of the HACCP system, fails to demonstrate how the regulation will have a significant impact on consumer health, and underestimates the impact. (47)
- FSIS’ proposed rule underestimates the benefits from death and illness reduction and the cost savings to business due to fewer recalls and litigation, reduced consumer demand resulting from adverse publicity, and disrupted schedules because of employee illness due to handling of contaminated products. (81)

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):**

- FDA and FSIS should adopt a new regulatory approach to ensure that trade in foods is not needlessly restricted in a manner that does not yield a corresponding public health benefit. (47)
- FSIS should finalize the proposed rule with no change. (81) (77)
- OMB should work with FSIS to develop a rule that will enhance food safety without conflicting with HACCP principles and without imposing substantial and unnecessary costs on the industry. Both voluntary environmental testing and product testing should be encouraged. (47)

**Estimate of Economic Impacts:** The regulatory impact analysis for the proposed rule contained estimates of the economic impact. As described above, commenters found fault with these estimates.

**Commenter(s):** American Meat Institute (47); OMB Watch (77); Center for Science in the Public Interest (81).
6. **Salmonella Performance Standards**

**Regulating Agency:** USDA/Food Safety and Inspection Service

**Citation:** 9 CFR 310.25(b) and 381.94(b)

**Authority:** Federal Meat Inspection Act and Poultry Products Inspection Act

**Description of What Existing Regulation Does:** The current rule establishes a national pathogen reduction performance standard for *Salmonella* on meat and poultry. Establishments that test positive for *Salmonella* at a rate exceeding the applicable performance standard must take corrective actions. Failure by the establishment to take corrective actions or failure to meet the standard on the third consecutive series of tests, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan and will cause FSIS to suspend inspection services.

**Commenter Description of Issue(s):**
- The scientific validity of the performance standards are questionable. (47)
- The Fifth Circuit ruled that FSIS did not have the statutory authority to close a plant because the *Salmonella* performance standard does not measure plant sanitation. (47)
- The Court decision removes an enforcement tool that allowed USDA to close down plants with excessive *Salmonella*. (77) (70)

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):**
- USDA should amend the performance standards utilizing a microbiological organism or organisms that accurately and adequately measure plant process control and sanitation. (47)
- The administration should support legislation that would restore USDA’s enforcement authority and also would provide clear authority for USDA to set pathogen reduction standards for other hazards in the meat supply. (77)
- USDA should promulgate a rule requiring prominent public dissemination of the names of all plants that repeatedly fail *Salmonella* tests. (77)
- USDA should promulgate regulations requiring suppliers of meat to intermediate “grinding” plants to certify that their products are relatively free from pathogens. (70)
- USDA should devote additional resources to conducting intensive inspections of plants and reassessing all HACCP programs. (70)

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Meat Institute (47); OMB Watch (77); Center for Progressive Regulation (70)
7. **National Organic Program**

**Regulating Agency:** USDA/Agriculture Marketing Service

**Citation:** 7 CFR 205

**Authority:** Organic Foods Production Act

**Description of What Existing Regulation Does:** The current rule contains national standards governing the labeling of agricultural products to be marketed as “organic”. It also contains certification requirements for farms and handling operations that want to label their product “organic” and a program accredits state officials and private entities to act as certifying agents.

**Commenter Description of Issue(s):**

- The rule imposes a uniform, highly technical standard on an issue and an industry which are incapable of precise definition. (186)
- The rule prohibits USDA-accredited certifiers from requiring practices that are greater, lesser, or in any way different from USDA’s uniform standards. This restrict variability and flexibility, jeopardizes competitive forces that foster innovation and improvement, and directly harms consumer choice (186)
- The rule’s prohibition on the use of the term “organic” by non-accredited entities may be unconstitutional. (78)

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):**

- USDA should revise the rule to allow private parties to define the term “organic” more flexibly. (186) (78)
- USDA could revise the rule to carry a disclaimer: “This package does not comply with USDA standards for organic labeling.” (186)
- USDA could revise the rule to allow certification to different standards and revise labeling requirements accordingly. (186)
- USDA could revise the rule to allow certifying agents to enforce a more stringent standard and label their products accordingly. (186)

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Competitive Enterprise Institute (186); Heritage Foundation (78)
8. Nutrition Labeling of Ground or Chopped Meat and Poultry Products

Regulating Agency: USDA/Food Safety and Inspection Service

Citation: 9 CFR 317 and 381; 66 Federal Register 4,969

Authority: Federal Meat Inspection Act and Poultry Products Inspection Act

Description of What Existing Regulation Does: Current regulations do not require nutrition labeling on single ingredient raw meat and poultry products. USDA proposed a rule in January 2001 that would require nutrition labeling for major cuts of single ingredient raw meat and poultry products. The rule would require retailers to provide nutrition information through product labels for ground meat and poultry products.

Commenter Description of Issue(s):

• The absence of labeling requirements for fresh meat and poultry is a major gap in the Federal government’s nutrition labeling regulations.
• Consumers should be provided greater nutrition information about specific types of fresh meat and poultry because they are major sources of fat, saturated fat, and calories in the American diet.

Small Business Impact: Yes.

Commenter Proposed Solution(s):

• USDA should finalize the proposed rule.

Estimate of Economic Impacts: None provided.

Commenter(s): Center for Science in the Public Interest (75).
9. **Plant Pest Regulations**

**Regulating Agency:** USDA/Animal and Plant Health Inspection Service

**Citation:** 7 CFR 330; 66 Federal Register 51340

**Authority:** Plant Protection Act

**Description of What Existing Regulation Does:** The current regulations govern the importation and interstate movement of plant pests. The current regulations allow for the shipment of nine species of butterflies across state lines with a permit. USDA published a proposed rule in October 2001 that would revise these regulations by adding risk-based criteria for determining the plant pest status of organisms, establishing a notification process that could be used as an alternative to the current permitting system and providing for the environmental release of organisms for the biological control of weeds.

**Commenter Description of Issue(s):**

- The proposed rule would prevent all species of butterflies, except for Vanessas, from being shipped out of state.
- USDA did not consider the impact of the regulation on the small businesses in the butterfly farming industry.

**Small Business Impact:** Yes.

**Commenter Proposed Solution:** None provided

**Estimate of Economic Impacts:** None provided

**Commenter(s):** Fluttering B Butterfly Ranch (125).
10. **Badge as Identification of Inspectors**

**Regulating Agency:** USDA/Food Safety Inspection Service

**Citation:** 9 CFR 306.3

**Authority:** Federal Meat Inspection Act

**Description of What Existing Regulation Does:** The current rule requires each inspector to be furnished with a numbered official badge. The badge entitles the inspectors to admittance at all regular entrances and to all parts of meat and poultry establishments and premises to which they are assigned.

**Commenter Description of Issue(s):**

- The badge denotes power or control under the law that is usually reserved for law enforcement personnel.
- Inspectors feel empowered because of their badge and abuse their authority to the detriment of the industry.

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):** None provided.

**Estimate of Economic Impacts:** None provided

**Commenter(s):** Matt Flanagan (161).
11. Mad Cow Disease

Regulating Agency: USDA/Food Safety Inspection Service; HHS/Food and Drug Administration

Citation: N/A

Authority: Meat Products Inspection Act

Description of What Regulation Would Do: The Food and Drug Administration and the Food Safety Inspection Service are proposing rules related to the control of BSE (commonly referred to as “mad cow disease”). Some of the ideas now being presented are rules put into place in other countries, which have BSE.

Commenter Description of Issue(s): The U.S. does not have BSE. Far different requirements are needed to keep a certain disease out of a country as compared to eradicating a disease already present in a country.

Small Business Impact: None Indicated

Commenter Proposed Solution(s):

• Both agencies need to use a scientific basis in recommending rules designed for one purpose and used for another purpose.
• The structure of the particular industries involved in each country needs to be taken into account.

Estimate of Economic Impacts: None provided.

Commenter(s): American Farm Bureau (24).
12. Phytosanitary Certificates for Seeds

Regulating Agency: USDA/Animal and Plant Health Inspection Service

Citation: 7 CFR 319.37; 66 FR 38137

Authority: Plant Protection Act

Description of What Existing Regulation Does: The current regulation requires that nursery stock, plants, roots, bulbs, seeds, or other plant products, for or capable of propagation offered for importation into the United States, other than certain greenhouse-grown plants from Canada, be accompanied by a phytosanitary certificate of inspection. In a policy statement APHIS published in the Federal Register on July 23, 2001 (66 FR 38137), APHIS announced its intent to enforce these provisions. Up to that time, APHIS had not consistently and routinely enforced the phytosanitary certificate requirements although the requirement had been in the regulations for a long time.

Commenter Description of Issue(s): Requiring small nurseries and specialty mail order growers to furnish phytosanitary certificates with each shipment will stop the seed selling of small businesses as well as put all the world-wide seed exchanges out of operation.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Stop the implementation of these regulations.

Estimate of Economic Impacts: None provided.

Commenter(s): Cathy Craig (115).
13. **Swine Production Contract Library**

   **Regulating Agency:** USDA/Agricultural Marketing Service

   **Citation:** None provided.

   **Authority:** Livestock Mandatory Reporting Act

   **Description of What Existing Regulation Does:** The Act required that USDA start a library of swine production contracts.

   **Commenter Description of Issue(s):**
   
   • The agency has not begun implementation of this library

   **Small Business Impact:** Yes

   **Commenter Proposed Solution(s):** None provided

   **Estimate of Economic Impacts:** None provided

   **Commenter(s):** American Farm Bureau Federation (24).
14. National Forests Land Use: Special Uses

Regulating Agency: USDA/National Forest Service

Citation: CFR Title 36 Part 251B

Authority: Forest and Rangeland Renewable Resource Planning Act 16 USC 1600, National Environmental Policy Act Title 42 Chapter 55 Section 4321, Endangered Species Act Title 16 Chapter 35 Section 1531.

Description of What Existing Regulation Does: Existing regulation delegates authority to the responsible official to determine terms and conditions and duration of special use permits in the National Forests, with special consideration given to protecting other users, minimizing damage to the environment, including scenic and esthetic values and fish and wildlife habitat. Existing regulation does not allow the National Forest Service to charge permittees the cost of the NEPA analysis.

Commenter Description of Issue(s):

• Special use permit duration is for 5 years. The permit duration is too short and imposes unacceptable burden on applicants.
• NEPA requirements are too burdensome for small businesses, which may shut down as a result of expensive studies required under NEPA.
• Wilderness Study Area (WSA) designation should be lifted to allow multiple uses to continue.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Support of HR 2386 “Outfitter Act of 2001”. This Act would limit National Forest official's discretion to determine length of permits, and would set a ten year duration except for extraordinary circumstances where conditions are expected to change sooner than ten years that would affect the permit's conditions.

Estimate of Economic Impacts: For this commenter, the NEPA analysis cost $47,000.

Commenter(s): Jon Shick and Dr. Lud Kroner High Mountain Heli-Skiing, Inc. (167).
15. **Roadless Area Conservation**

**Regulating Agency:** USDA Forest Service

**Citation:** 36 CFR §294

**Authority:** 16 USC §12601-1614

**Description of What Proposed Regulation Would Do:** Prohibit road building and reconstruction, and timber harvesting in almost 60 million acres of National Forest lands.

**Commenter Description of Issue(s):** By not quantifying marketable benefits, OMB understated the benefits of the Roadless Rule. The agency has failed to consider alternatives to the total ban on roads that would have achieved similar environmental benefits at less cost.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- OMB should report costs and benefits separately, not use cost-benefit analysis as decision criteria in environmental decision making, correct the bias of underreporting benefits, and compare past estimates of costs to actual costs.
- Forest Service should defend the legal challenges filed against the rule and implement the rule as issued in 2001.
- The Forest Service should consider alternatives to a total ban on road construction, such as building temporary roads.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Natural Resource Defense Council (80); OMB Watch (77); Mercatus Center (73); Center for Progressive Regulation (70).
16. **Low Cost Timber Sales and Grazing Fees**

**Regulating Agency:** USDA/Forest Service, Department of Interior/Bureau of Land Management

**Citation:** 43 CFR 4130.8-1 (grazing fees); 36 CFR Part 223 (timber sales)

**Authority:** Taylor Grazing Act, 43 USC 315b (grazing fees); 16 USC 472a(a) (timber sales).

**Description of What Existing Regulation Does:** Determines fees imposed on ranchers that use range and bidding process for timber sales to companies that harvest timber on National Forests.

**Commenter Description of Issue(s):**

- Low cost timber sales conducted by the Forest Service amount to government subsidies for a few industries that operate in direct competition with other corporations. Similarly, grazing fees for cattle on Federal lands are depressed to the point that they amount to a subsidy for ranchers.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- The Forest Service and BLM should reform these programs by raising the rates charged to ranchers and timber companies to at least the level of market rates.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Center for Progressive Regulations (70)
17. Annual Capital Expenditures Survey

Regulating Agency: Department of Commerce/Bureau of the Census

Citation: N/A

Authority: Title 13, U.S. Code. Sections 182, 224, 225.

Description of Information Collection: The Annual Capital Expenditures Survey (ACES) is part of a comprehensive program designed to provide detailed and timely information on capital investment in new and used structures and equipment by nonfarm businesses. The survey is based on a sample of approximately 44,000 companies with employees and approximately 15,000 companies without employees. Beginning with the 1999 ACES, for companies with employees, capital expenditures data are published for 132 industries comprised primarily of three-digit and selected four-digit industries from the North American Industry Classification System (NAICS).

Commenter Description of Issues:

- The Federal government is already collecting this information on IRS tax forms.
- The Annual Capital Expenditure Survey is too long and burdensome.

Small Business Impact: For small businesses, only some of the ACES data are collected and keyed by the IRS. For businesses selected with certainty into the sample (>500 employees), the data collected are not the same as data reported to IRS.

Commenter Proposed Solution: Extract the data from the IRS tax forms.

Estimate of Economic Impacts: None provided.

Commenter: Villelli Enterprises, Inc. (197).
18. **Title IX and Collegiate Sports Participation**

**Regulating Agency:** Department of Education

**Citation:** 34 CFR Part 106

**Authority:** Title IX of the Education Amendments of 1972

**Description of Existing Regulation:** Education programs supported by Federal aid may not discriminate on the basis of sex. To demonstrate compliance with regard to sports, a school must demonstrate one of the following: 1) participation is proportional to enrollment 2) programs are expanding to meet the interests and abilities of the "underrepresented sex" 3) the interests of the "underrepresented sex" have been fully accommodated.

**Commenter Description of Issues:**

- Colleges are imposing gender quotas on sports programs.
- Adverse impact on male participation in sports
- Policy is discriminatory and contradicts the spirit of Title IX.
- Strict proportionality denies men opportunities, when more men than women are interested in participating in sports.

**Small Business Impact:** No.

**Commenter Proposed Solutions:**

- Eliminate Title IX regulations demanding proportional representation.
- Review the second and third tests of compliance.

**Estimate Economic Impacts:** None provided.

**Commenter:** Heritage Foundation (78).
19. **Title IX and Single-Sex Schools**

**Regulating Agency:** Department of Education

**Citation:** 34 CFR, Part 106.35 (b) and 34, CFR, Part 106.34

**Authority:** Title IX of the Education Amendments of 1972

**Description of Existing Regulation:** 34 CFR, Part 106.35 (b) states that a recipient of Federal funds that is a local educational agency shall not, on the basis of sex, exclude any person from admission to:

> “Any other school or educational unit operated by such recipient, unless such recipient otherwise makes available to such person, pursuant to the same policies and criteria of admission, courses, services, and facilities comparable to each course, service, and facility offered in or through such schools.”

Part 106.34 refers to students’ access to course offerings and describes the exceptions to the regulation, such as physical education activities that require bodily contact, sexual education classes, choir groupings, and a few others.

**Commenter Description of Issues:**

- Regulations make it difficult for school districts to open and operate single-sex schools. Only 11 such public schools exist in the country.
- Research suggests that single-sex schools and classes benefit girls and low income and minority boys. These benefits include higher scholastic achievement, character development, and reduced disciplinary problems.

**Small Business Impact:** No.

**Commenter Proposed Solutions:**

- Replace existing Title IX regulations with regulations offering greater flexibility to school districts.

**Estimated Economic Impacts:**

- Flexibility would give parents more options.
- Researchers would have the opportunity to take a closer look at the benefits of single-sex education.
- Higher scholastic achievement, character development, and reduced disciplinary problems for some students.

**Commenter:** The Heritage Foundation (78).
20. **Federal Family Education Loan Program**

**Regulating Agency:** Education/FSA

**Citation:** 34 CFR

**Authority:** Higher Education Act

**Description of What Existing Regulation Does:** This collection is associated with the regulatory requirements for the Federal Family Education Loan (FFEL) program, the Direct Loan program, and the PLUS loan program. These programs include approximately 3,600 lenders, 6,000 institutions of higher education, 36 guarantee agencies, and 37 million borrowers. The overall outstanding loan balance for these programs is $250 billion.

**Commenter Description of Issue(s):** The regulations impose over 10 million hours of burden under the PRA annually.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Congressman Douglas Ose, House of Representatives (108).


Citation: 66 CFR 3313


Description of What Existing Regulation Does: Establishes new minimum energy efficiency standards for new clothes washers.

Commenter Description of Issue(s):

- DOE's standards for clothes washers would take away consumer choice by eliminating the most popular (vertical-axis) washing machine models.
- The standards would force Americans to buy washing machines that DOE estimates will be significantly more expensive than machines today, with fewer of the attributes consumers seek.
- DOE claims that mandating washing machine specifications is necessary to save consumers money through lower operating costs over the life of the machine. Yet, manufacturers currently offer energy- and water-efficient washing machines that would meet the new standards (and, by DOE’s calculus, save consumers money), but only five percent of consumers choose to buy them. DOE bases its estimated operating savings on an assumption that a household will operate a washer 392 times a year, however, less than 15 percent of consumers who responded to a survey we commissioned operate their clothes washer that frequently.
- More than two-thirds of households surveyed wash 5 or fewer loads a week, which DOE’s data reveal would not be enough to recoup the higher purchase price of the mandated washing machines.

Small Business Impact: No

Commenter Proposed Solution: If, as DOE suggests, consumers pass up energy efficient washers because they are “misinformed” about operating costs, it should provide consumers with information to make a more informed decision. Cost is only one factor influencing consumer preferences for clothes washers, and eliminating the machines that 95 percent of consumers prefer will not make consumers better off.

Estimate of Economic Impacts: DOE’s economic analysis focuses purely on the cost savings, without considering the value consumers place on the convenience or other attributes that vertical axis machines offer over horizontal-axis machines. It estimates annual operating savings of $30 over the lifetime of a machine, but this is based on washing 392 loads per year, or 7.5 loads per week. Consumers who use the machine less frequently will achieve much lower benefits. According to our analysis, a household that washed 5 or fewer loads per week would lose money, as well as convenience, if DOE imposes the proposed mandate. Even if annual savings were as high as $50.55, households running fewer than 3.5 loads of laundry per week would lose money. Thus, the evidence collected by DOE suggests that the proposed standards will harm the vast majority of consumers without helping the remainder.

Commenter: Mercatus Center (73), Competitive Enterprise Institute (186).
22. Energy Conservation Standards for Central Air Conditioners and Heat Pumps


Citation: 66 Fed. Reg. 38822 (withdrawing previous regulation and proposing substitute); 66 Fed. Reg. 7170 (promulgating final regulation)


Description of What Existing Regulation Does: The rule establishes energy conservation standards B a minimum seasonal energy efficiency ratio (SEER) B for air conditioners and heat pumps. The current standard, in place since 1992, is a minimum 10 SEER. Energy consumption is inversely related to SEER. An SEER of 13 is 30 percent more energy efficient (uses 30 percent less energy) than the minimum allowed under the current rule.

Commenter Description of Issue(s):

• Higher energy requirements are feasible because there are central air conditioners and heat pumps in the market at all of the efficiency levels prescribed in the regulation.
• Making air conditioners more expensive would decrease the proportion of elderly able to afford them. Furthermore, the lengthy payback periods for the more efficient air conditioners and heat pumps preferred by DOE discriminate against elderly consumers who possess limited life expectancies.
• According to DOE, mandating a 30 percent gain would have eliminated the need for 39 new electric power plants over the next 30 years, whereas the 20 percent gain will offset the need for 27 new plants.

Small Business Impact: No.

Commenter Proposed Solution(s):

• DOE should reverse its decision and implement the original rule promulgated in January of 2001.
• DOE should not go forward with any new standards. Since DOE believes that consumers pass up energy efficient appliances because they are “misinformed” about operating costs, the Department should seriously consider constructing a permanent program that can correct this deficiency. Preserving the market option of less expensive air conditioners and heat pumps that meet the existing (1992) standards will clearly benefit those consumers who would lose under the proposed standards.

Estimate of Economic Impacts:

• DOE found that approximately 61 percent of all consumers purchasing a new typical air conditioner would either save money or would be negligibly impacted as a result of the regulation, and that, in the case of a new typical heat pump, 94 percent of all consumers either would save money or would be negligibly impacted. At the same time, the regulation would have saved approximately 4.2 quads of energy over 25 years (2006 through 2030), which is the equivalent to all the energy consumed by nearly 26 million American households in a single year, producing a net benefit to the nation's consumers of $1 billion over the same period.
The proposed standards will make consumers worse off. DOE’s analysis focuses purely on the cost savings to the average consumer, without adequately considering either different usage patterns, or the value consumers place on reliability, performance (especially dehumidification), or esthetics. Thus, the standards would require consumers in northern states to purchase high-cost air conditioners, and residents of southern states to purchase high-cost heat pumps, even though they would not likely recoup those up-front costs in lower energy bills over the life of the unit. DOE’s static comparison of up-front costs to operating costs also ignores the fact that once the initial investment is made, lower operating costs will encourage more usage of the unit, possibly leading to increased energy use (less conservation).

Commenter(s): Center for Progressive Regulation (70); Mercatus Center (73); OMB Watch (77).
23. **Special Treatment: Hospitals that incur indirect costs for graduate medical education programs & Direct graduate medical education payments**

**Regulating Agency:** HHS/CMS

**Citation:** 42 CFR Section 412.105 & 42 CFR 413.86

**Authority:** 42 U.S.C. Section 1395ww

**Description of What Existing Regulation Does:** These provisions regulate the provision of Medicare funding to teaching hospitals for both direct and indirect physician training expenses.

**Commenter Description of Issue:** Commenter believes that these provisions are unduly narrow, restricting community teaching hospitals from responding to their communities and the changing healthcare environment.

**Small Business Impact:** Uncertain.

**Commenter Proposed Solution:** Commenter believes that the regulations should be amended to increase flexibility and provide additional exceptions to the resident limit as follows:

- Affiliation criteria should be relaxed to remove geographical restrictions, allow for agreements to be executed throughout the year, and permit all teaching hospitals that establish new teaching programs to voluntarily affiliate with other hospitals to share resident rotations.
- The criteria for counting residents should be modified to allow hospitals to count a resident training in one medical specialty as a prerequisite to another specialty based on the initial residency period of the medical specialty the resident plans to pursue.
- The regulations should be amended to allow hospitals that accept residents displaced by closure of one hospital/graduate medical education program to permanently adjust their resident limits by the number of residents it accepted for training.
- Regulations should be clarified to ensure that hospitals may receive Medicare payment for residents training in nonhospital settings when supervisory activities are provided on a volunteer basis and all other payment criteria are met.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Community Hospital Medical Education Alliance (31).
24. Medicare Secondary Payer Provision

Regulating Agency: HHS/CMS

Citation: 42 CFR 411.25, 489.2, and 489.20

Authority: 42 USC 1395y(b)

Description of What Existing Rule Does: This information collection requirement requires patients to complete a 25-question Medicare Secondary Payer (MSP) instrument when receiving services. The MSP is intended to identify other insurance coverage that a beneficiary might have. Patients are required to complete the form every 30 days for recurring therapy and every 60 days for cases where the provider has no direct contact with the patient. For example, when a hospital receives a specimen from the patient's doctor.

Commenter Description of Issue: Commenter is concerned about the burden on providers of completing the MSP instrument. Although the agency recently reduced the requirement that patients complete the MSP every time they come to the hospital for recurring services such as chemotherapy or blood work, the commenter believes that the burden of this collection remains too high.

Small Business Impact: None provided.

Commenter Proposed Solution: The commenter believes that completion of the MSP should not be required more often than every 90 days for recurring services. Further, hospitals should not be responsible for completing the form when they have no contact with the patient and are merely being used as a lab – just as independent labs performing the same services are not responsible for securing this information.

Estimate of Economic Impacts: None provided.

Commenter: American Hospital Association (50).
25. **Physician Certification Statement for Non-Emergency Ambulance Services**

*Regulating Agency:* HHS/CMS

*Citation:* 42 CFR 410.40(d)(3)

*Authority:* 42 U.S.C. 1395x(s)(7)

**Description of What Existing Regulation Does:** This regulation requires, as a precondition of coverage, ambulance suppliers to obtain a physician certification statement for most non-emergency trips within 48 hours of the transport.

**Commenter Description of Issue(s):** Ambulance suppliers have found the expense and delays in payment that result from this requirement to be overly burdensome. Although the regulations allow for ambulance suppliers to demonstrate that they have made good faith efforts to obtain the certification within the required timeframe, this process is unduly burdensome. Further, CMS' paperwork analysis understated the cost of compliance.

*Small Business Impact:* Not provided.

**Commenter Proposed Solution:** This requirement should be eliminated.

**Estimate of Economic Impacts:** The commenter estimates that ambulance suppliers will spend approximately one hour of staff time complying with this requirement for each of the 4.5 million non-emergency transports per year, for a total cost of over $45 million per year.

**Commenter(s):** American Ambulance Association (34).
26. **The 75 percent Rule**

**Regulating Agency:** HHS/CMS

**Citation:** 42 CFR 412.23(b)(2)

**Authority:** 42 U.S.C. Section 1395ww(d)

**Description of What Existing Regulation Does:** The 75 percent rule exempts rehabilitation hospitals and units from the DRG reimbursement system, stipulating that in a 12 month cost report year a minimum of 75 percent of the patients discharged must have one of ten clinical conditions. If a unit discharged patients with had a diagnostic ratio of 75/25, the unit has been deemed to be primarily engaged in provision of rehabilitation services.

**Commenter Description of Issue(s):** Medical advances have rendered the 75 percent requirement outdated and no longer reflective of current rehabilitative medical practice. The commenter believes that there are an increasing number of medical conditions outside of the recognized rehabilitation categories (e.g., cardiac pain, and disabling pulmonary conditions) for which patients would benefit from rehabilitation services. Further, the commenter states that some patients with conditions not included in the list of ten are currently being denied rehabilitation services so that facilities can maintain the 75/25 ratio.

**Small Business Impact:** Uncertain.

**Commenter Proposed Solution:** The 75 percent requirement should be eliminated, or modified to increase the number of conditions on the approved list from ten to twenty.

**Estimate of Economic Impacts:** The commenter does not provide an estimate of economic impact, but states that the elimination of the 75 percent requirement will result in more appropriate care for patients.

**Commenter(s):** RehabCare Group (54).
27. The Converted Bed Rule

Regulating Agency: HHS/CMS

Citation: 42 CFR 412.30(c)

Authority: 42 U.S.C. Section 1395ww(d)

Description of What Existing Regulation Does: The referenced regulations address Medicare policies and procedures for the payment of rehabilitation services. Hospitals opening or expanding a rehabilitation unit using converted beds must wait 12 months to establish compliance with the 75/25 rule and begin receiving Medicare reimbursement.

Commenter Description of Issue(s): Rehabilitation units created or expanded using new, rather than converted beds may begin receiving Medicare reimbursement immediately, leading to an inequity between new rehabilitation beds and converted beds. The commenter states that this results in fewer rehab beds, which reduces patients' access to intensive rehabilitation services.

Small Business Impact: Uncertain.

Commenter Proposed Solution: The converted bed rule should be eliminated.

Estimate of Economic Impacts: No economic impact information provided; however, the commenter believes that if the converted bed rule were eliminated patients would receive more appropriate care.

Commenter(s): RehabCare Group (54).
28. The Exemption Date Rule

Regulating Agency: HHS/CMS

Citation: 42 CFR 412.25(c)

Authority: 42 U.S.C. Section 1395ww(d)

Description of What Existing Regulation Does: This regulatory provision governs when Medicare recognizes a rehabilitation hospital or unit and begins providing reimbursement for rehabilitation services provided to Medicare beneficiaries. The exemption date rule requires that rehabilitation hospital units only be approved for receipt of Medicare payments at the hospital's annual cost reporting date.

Commenter Description of Issue(s): Historically the exemption date rule was required to ensure that rehabilitation costs were accurately captured within cost reports because inpatient rehabilitation facilities were reimbursed under a cost based system. However, now that Medicare pays for rehabilitation services via a prospective payment system, such units could open or expand mid year and still receive appropriate reimbursements.

Small Business Impact: Uncertain.

Commenter Proposed Solution: Eliminate the exemption date rule.

Estimate of Economic Impacts: No economic estimates were provided; however, the commenter believes that patients would have increased access to appropriate rehabilitation services.

Commenter(s): RehabCare Group (54).
29. **The Medical Director Rule**

Regulating Agency: HHS/CMS

Citation: 42 CFR 412.29(f)(1)

Authority: 42 U.S.C. Section 1395ww(d)

**Description of What Existing Regulation Does:** This regulatory provision requires that all rehabilitation units, regardless of size, have medical directors that provide a minimum of twenty hours of service per week.

**Commenter Description of Issue(s):** The commenter believes that requiring that all rehabilitation units, regardless of size, have a medical director that provides twenty hours of service per week is a one-size-fits-all approach that fails to recognize that the medical director resources needed to meet patient and administrative needs can and should vary based on size.

**Small Business Impact:** Uncertain

**Commenter Proposed Solution:** The commenter recommends that the regulatory provision be revised to include the following minimum staffing requirements:

<table>
<thead>
<tr>
<th>Beds</th>
<th>Medical Director Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 and under</td>
<td>10 hours</td>
</tr>
<tr>
<td>10 – 15</td>
<td>12 hours</td>
</tr>
<tr>
<td>15 – 20</td>
<td>16 hours</td>
</tr>
<tr>
<td>20 or more</td>
<td>20 hours</td>
</tr>
</tbody>
</table>

**Estimate of Economic Impacts:** No specific estimates of economic impact were provided; however, the commenter believes that, if implemented, the suggested revisions to the minimum staffing requirements will lead to reduced costs for providers and the Medicare program.

**Commenter(s):** RehabCare Group (54).
30. Minimum Staffing Standards for Nursing Homes

Regulating Agency: HHS/CMS

Citation: 42 CFR 483.30

Authority: Social Security Act, as amended

Description of What Regulatory Prompt Would Do: The commenter's proposed regulatory provision would provide minimum staffing standards for Medicare/Medicaid-funded nursing homes.

Commenter Description of Issue(s): Commenter states that HHS reports indicate that over 90 percent of nursing homes are understaffed, leading to overworked employees and a lack of adequate care for residents.

Small Business Impact: Uncertain

Commenter Proposed Solution: Specifically, the commenter recommends adopting the standards proposed by the Citizen's Coalition for Nursing Home Reform, which call for all nursing home residents to receive at least 4.13 hours of direct nursing care each day.

Estimate of Economic Impacts: No estimate of the economic impact was provided; however, the commenter believes that the cost of hiring more employees to adequately staff nursing homes would be offset by the increase in service to the residents, and the reduction in workplace injuries of overworked employees.

Commenter(s): OMB Watch (77).
31. One-Hour Restraint Rule

Regulating Agency: HHS/CMS

Citation: 42 CFR Part 482

Authority: 42 U.S.C. 1395bb; 1395hh; 1302; Social Security Act

Description of What Existing Regulation Does: This interim final rule contains standards for the use of patient restraint and seclusion in hospitals. The one-hour provision referenced by the commenter requires that a physician examine, in-person, any patient for which restraint or seclusion is ordered within one hour of the issuance of that order.

Commenter Description of Issue(s): The one-hour restriction is particularly burdensome for small and rural hospitals because it requires treating physicians to make a face-to-face assessment of the patient within one hour of initiating restraint or seclusion. The commenter states that the agency did not adequately analyze the impact of the one-hour provision or possible alternatives.

Small Business Impact: The commenter believes that this provision disproportionately affects small businesses, and adoption of their proposed solution would alleviate the burden placed on small and rural hospitals.

Commenter Proposed Solution: The commenter recommends that the agency meet with affected industry groups and professional associations to devise a patient standard that would balance the need for both quality patient care and adequate provider resources. After obtaining sufficient input, the regulation could be re-issued with a more appropriate standard.

Estimate of Economic Impacts: None provided.

Commenter(s): Small Business Administration, Office of Advocacy (97), American Hospital Association (50).
32. **Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units under the Physician Fee Schedule for Calendar Year 2002**

**Regulating Agency:** HHS/CMS

**Citation:** 42 CFR Part 45

**Authority:** 42 U.S.C. Section 1848(c) (Social Security Act)

**Description of What Existing Regulation Does:** This regulation adjusts the fee schedule for services provided primarily by physicians; however, various non-physician groups such as portable x-ray and EKG providers are also included.

**Commenter Description of Issue(s):** The commenter believes that the regulation adopts a one-size-fits-all approach that affects small providers disproportionately. Further, the commenter believes that the agency failed to assess adequately the true operating costs of the portable x-ray and EKG provider industry in its consideration of the regulatory flexibility analysis, which could result in severe economic hardship for portable x-ray and EKG providers.

**Small Business Impact:** The commenter believes that this regulation has a disproportionate effect on small providers.

**Commenter Proposed Solution:** The commenter recommends changes to the methodology for updating physician fees by replacing the sustainable growth rate system with a system that tracks practice costs more accurately.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Small Business Administration, Office of Advocacy (97).
33. **Certificates of Medical Necessity**

**Regulating Agency:** HHS/CMS  
**Citation:** None provided.  
**Authority:** 42 U.S.C. Section 1395m(j)(2)

**Description of What Existing Regulation Does:** Under Medicare regulations, physicians must supply certificates of medical necessity for items of durable medical equipment, short-term nursing home rehabilitation, home health nursing services, and pharmaceutical items such as diabetic supplies.

**Commenter Description of Issue(s):** The commenter believes that the requirement to accompany prescriptions with certificates of medical necessity is unnecessary and duplicative, and that the prescription alone should be adequate to certify the medical need for items like monitors, syringes, test strips, etc.

**Small Business Impact:** The commenter states that the vast majority of physicians are considered to be small businesses and are disproportionately impacted by this requirement.

**Commenter Proposed Solution:** Modify the Medicare regulations to eliminate certificates of medical necessity where a prescription would be adequate.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Small Business Administration, Office of Advocacy (97).
34. Medicare Program Prospective Payment System for Hospital Outpatient Services Final Rule

Regulating Agency: HHS/CMS

Citation: 42 CFR Section 489.24

Authority: Emergency Medical Treatment and Labor Act

Description of What Existing Regulation Does: Provisions of this regulation address compliance with the Emergency Treatment and Labor Act, which is intended to ensure that patients needing emergency services receive access to those services.

Commenter Description of Issue: The commenter is concerned that CMS regulations have extended beyond the intent of the EMTALA statute. Hospitals and physicians face overcrowded emergency departments, a lack of access to critical emergency care, and significant compliance costs associated with EMTALA that provide little added value to patient care.

Small Business Impact: None provided.

Commenter Proposed Solution: The commenters believe that CMS needs to revise the regulations to provide a more narrow interpretation that does not exceed the intent of the statute. Medicare carriers should also interpret and enforce EMTALA more uniformly, reducing confusion with compliance. EMTALA should not apply to inpatients because once the patient is admitted, there are other standards that ensure access to appropriate care. To avoid conflicting application of policies, local medical review policies should exclude services provided in the emergency room to comply with EMTALA obligations.

Estimate of Economic Impacts: None provided.

Commenter: American Osteopathic Association (39), American Hospital Association (50).
35. Medicare and Medicaid Programs Use of the OASIS for Home Health Agencies and Supporting Regulations

Regulating Agency: HHS/CMS

Citation: None provided.

Authority: None provided.

Description of What Existing Regulation Does: This reporting requirement and supporting regulations require that Home Health Agencies report Medicare and Medicaid patient data to CMS using a standard core assessment data set. The patient data are used for case mix adjustment in the prospective payment system for Medicare reimbursement, as well as for quality assurance efforts.

Commenter Description of Issue(s): The commenter is concerned about the paperwork burden associated with implementation of these regulatory and information collection requirements.

Small Business Impact: Uncertain.

Commenter Proposed Solution: None provided.

Estimate of Economic Impacts: No economic impact information was provided; however, the annual information collection burden on the public of complying with these requirements is over 10 million hours per year.

Commenter(s): American Hospital Association (50); U.S. Representative Doug Ose (108).
36. Regulations Implementing Clinical Laboratory Improvement Act

Regulating Agency: HHS/CMS

Citation: 42 CFR 493

Authority: Clinical Laboratory Improvement Act of 1988

Description of What Existing Regulation Does: Pursuant to CLIA, these regulations set forth requirements that must be met by every laboratory testing human specimens for diagnostic purposes. The regulations include extensive recordkeeping and quality control requirements and are intended to improve the accuracy of laboratory testing.

Commenter Description of Issue:

• The CLIA requirements are too burdensome and costly. An unintended consequence of these regulations is that patients fail to have lab tests done because they are required to physically go to another location to receive them. Physicians should be able to conduct lab tests in their offices.
• The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: None provided.

Commenter Proposed Solution:

• The commenter believes that CMS should review laboratory tests to determine if any can be moved to a more administratively simple test category.
• OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: None provided.

Commenter: American Osteopathic Association (39); U. S. Representative Doug Ose (108).
37. **Health Insurance Portability and Accountability Act Claims Processing Standards**

**Regulating Agency:** HHS/CMS

**Citation:** 45 CFR 160

**Authority:** Health Insurance Portability and Accountability Act of 1996

**Description of What Existing Rule Does:** The HIPAA final regulation on electronic formats and code sets establishes national standards for electronic submission of claims. The regulation clearly states that health plans are not permitted to require additional data elements nor standard data elements in a format different from that specified in the standards. Health plans also may not refuse to accept standard transactions.

**Commenter Description of Issue:** One of the major administrative costs facing hospitals and one of their greatest sources of frustration is frequent delays in the processing and payment of claims. Although Medicare regulations and many state laws have been implemented to try to ensure the prompt payment of claims, these prompt pay rules are often violated. Hospitals' confidence in, and continued support for, administrative simplification is being eroded by agency statements indicating that providers should not expect to see faster or smoother processing and payment as a result of HIPAA standardization. Currently, health plans are somewhat arbitrary with respect to the processing of a claim, leaving providers facing payment delays and engaging in wasteful resubmission and reconciliation.

**Small Business Impact:** None provided.

**Commenter Proposed Solution:** The prompt would promote the realization of administrative simplification through the HIPAA regulations and specifically clarify that health plans must accept a HIPAA-compliant claim as a "clean claim" for the purposes of contractual provisions with other covered entities under HIPAA, and for state and Federal prompt pay requirements. Additional guidance is necessary to address some of the ambiguities in claims that concern electronic formats and code sets.

**Estimate of Economic Impacts:** None provided.

**Commenter:** American Hospital Association (50).
38. **Standard of Chemical Quality—Arsenic**

Regulating Agency: HHS/Food and Drug Administration

Citation: 21 CFR165.110(b)(4)


Description of What Existing Regulation Does: EPA revised the National Primary Drinking Water Regulation for arsenic from 50 ppb to 10 ppb in 2001. The current FDA standard for bottled water remains at 50 ppb.

Commenter Description of Issue(s):

- Under 21 USC 349, FDA is required to review any change to EPA drinking water contaminant regulations and either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register their reasons for not making such amendments.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

- FDA should promulgate a 10 ppb standard for arsenic in bottled water.
- FDA should also maintain the same annual monitoring frequency and the process for compliance that are currently in place.

Estimate of Economic Impacts: Because the industry association has lowered its Model Code to which members must adhere to 10 ppb, the commenter estimates that there will be minimal economic impact. Information was not provided on the impact on the 20 percent of the bottled water industry that does not belong to IBWA.

Commenter(s): International Bottled Water Association (4).
39. Standard of Chemical Quality—Uranium

Regulating Agency: HHS/Food and Drug Administration

Citation: 21 CFR165.110(b)(5)(i)


Description of What Proposed Regulation Would Do: EPA promulgated a National Primary Drinking Water Regulation in 2000 setting the maximum contaminant level at 30 ug/L. FDA currently has no bottled water standard for uranium.

Commenter Description of Issue(s):

• Under 21 USC 349, FDA is required to review any change to EPA drinking water contaminant regulations and either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register their reasons for not making such amendments.
• If no uranium standard is adopted, bottled water producers will be subject to EPA requirements for monitoring and compliance testing for uranium while being subject to FDA requirements for all other radionuclides.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

• FDA should promulgate a 30 ug/L standard for uranium in bottled water.
• FDA should maintain the current frequency for making compliance determinations.

Estimate of Economic Impacts: Not provided.

Commenter(s): International Bottled Water Association (4).
40. **Standard of Microbiological Quality—Total Coliform**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** 21 CFR 165.110(b)

**Authority:** 21 U.S.C. 349 21 U.S.C. 342 and 343

**Description of What Proposed Regulation Would Do:** FDA proposed a total coliform standard for bottled water in 1993. The rule would have prohibited the presence of any coliform bacteria in water. The rulemaking has not been completed.

**Commenter Description of Issue(s):**

- The FDA rule did not recognize that coliform testing often produces positive test results for both pathogenic and non-pathogenic coliform.
- A sample that tests positive for coliform should be subject to a second test for E coli.
- This requirement is in line with EPA requirements for public water systems, and the WHO drinking water guidelines.

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):**

- FDA should finalize its regulation with a confirmatory test of no E coli.

**Estimate of Economic Impacts:** Not provided.

**Commenter(s):** International Bottled Water Association (4).
41. **Labeling Genetically Modified Foods**

Regulating Agency: HHS/Food and Drug Administration

Citation: 66 Fed Reg 4830

Authority: 21 U.S.C. 321(n), 343 (a)(1), 343(i)

Description of What Regulatory Prompt Would Do: Require all manufacturers to label genetically modified foods as such. FDA has issued draft guidelines for labeling genetically modified foods. The guidelines give examples of how food that is or is not bioengineered could be labeled and not be misleading.

Commenter Description of Issue(s):

• The FDA guidance discourages companies from informing consumers that food is or is not genetically modified.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

• FDA should promulgate binding regulations requiring all manufacturers to label genetically modified foods as such.

Estimate of Economic Impacts: Not quantified, costs classified as “modest.”

Commenter(s): Center for Progressive Regulation (70)
42. **Hormones in the Food Supply**

Regulating Agency: HHS/Food and Drug Administration

Citation: N/A

Authority: 21 U.S.C. 343(i)(2)

**Description of What Proposed Regulation Would Do:** Require that meat taken from cattle given bovine growth hormone, estrogen, or other hormones be labeled to that effect.

**Commenter Description of Issue(s):**

- FDA does not currently require that meat taken from cattle given bovine growth hormone, estrogen, or other hormones be labeled to that effect.

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):**

- FDA should promulgate regulations requiring that meat taken from cattle given bovine growth hormone, estrogen, or other hormones be labeled to that effect.

**Estimate of Economic Impacts:** Not quantified, costs classified as “relatively small compared to benefits to consumers.”

**Commenter(s):** Center for Progressive Regulation (70).
43. **Antibiotics in the Food Supply**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** N/A

**Authority:** 21 U.S.C. 351

**Description of What Proposed Regulation Would Do:** Regulate the use of antibiotics in cattle, chickens, pigs, and hogs that would prevent the further erosion of such drugs in humans.

**Commenter Description of Issue(s):**

- Antibiotics in animal feed contribute to antibiotic resistance in humans. Increased resistance will eventually result in antibiotics becoming ineffective in combating disease.
- The WHO, CDC and other health organizations have supported a ban on the sub-therapeutic use of antibiotics.

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):**

- FDA should promulgate binding regulations regulating the use of antibiotics in cattle, chickens, pigs, and hogs that would prevent the further erosion of such drugs in humans.

**Estimate of Economic Impacts:** Not quantified, costs classified as "modest."

**Commenter(s):** Center for Progressive Regulation (70).
44. Food Identity Standards

Regulating Agency: HHS/Food and Drug Administration

Citation: 21 CFR secs 130-169

Authority: Food, Drug, and Cosmetic Act

Description of What Existing Regulation Does: This series of standards covers the content required in order to label food a particular way. They cover everything from cherry pies and sherbert to canned mushrooms.

Commenter Description of Issue(s):

• Meant to protect consumers, the regulations actually hurt them by limiting choice and variation.
• The standard creates a disincentive for manufacturers to make healthier products.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

• FDA should undertake a thorough review of these identity standards and rescind those not found to be necessary

Estimate of Economic Impacts: None provided.

Commenter(s): Heritage Foundation (78).
45. **Medical Drug and Device Regulations**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** 21 CFR sec 200; 21 CFR Ch. I subchapter H

**Authority:** Food, Drug, and Cosmetic Act, Medical Device Amendments of 1976.

**Description of What Existing Regulation Does:** The statute requires that new medical drugs and devices be shown to be safe and effective in order to be approved by the agency.

**Commenter Description of Issue(s):**

- In practice, FDA often requires that new therapies be more effective than existing therapies in order to be approved.
- On occasion FDA has denied approval to proposed therapies that hold substantial promise and pose no new risks due to disputes over whether these therapies were more effective than already available therapies.

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):**

- Individual doctors and hospitals should be able to make their own determination of whether to use these new therapies (those for which there is minimal or no added risk).

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Competitive Enterprise Institute (186).
46. Premarket Notice for Bioengineered Foods

Regulating Agency: HHS/Food and Drug Administration

Citation: 66 FR 4706 (NPRM)

Authority: Food, Drug, and Cosmetic Act

Description of What Proposed Regulation Would Do: This proposed rule would require plant breeders to submit data and other information to FDA prior to commercializing new bioengineered plant varieties.

Commenter Description of Issue(s):

• The requirements in the NPRM are not scientifically justified as bioengineered plants have not shown greater risks than other plants.
• The rule would add needlessly to the costs of bioengineering techniques.
• It could also keep potentially beneficial products off of the market and raise the costs of those products that do make it to market.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

• FDA should either not require premarket notification or substantially revise the proposed rule so that regulatory oversight is focused on identifiable high-risk products and that it not single out only bioengineered products for heightened scrutiny.

Estimate of Economic Impacts: None provided.

Commenter(s): Competitive Enterprise Institute (186).
47. **Labeling of Carmine**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** N/A

**Authority:** Food, Drug, and Cosmetic Act

**Description of What Proposed Regulation Would Do:** Commenter petitioned agency to either require labeling of carmine/cochineal extract or to ban its use.

**Commenter Description of Issue(s):**

- Recent medical research has demonstrated that cochineal extract and carmine can cause severe allergic reactions including, hives sneezing, rhinitis, and life-threatening anaphylactic reactions.

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):**

- Cochineal extract and carmine should be listed by name and origin on ingredient lists of foods, drugs, and cosmetics.
- FDA should conduct scientific reviews or require studies to assess the safety of cochineal extract and carmine and determine whether approval should be revoked.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Center for Science in the Public Interest (76).
48. **Labeling of Sorbitol**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** 21 CFR 184.1835(e)

**Authority:** Food, Drug, and Cosmetic Act

**Description of What Existing Regulation Does:** The current regulation states, “The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 50 grams of sorbitol shall bear the statement: ‘Excess consumption may have a laxative effect.’”

**Commenter Description of Issue(s):**

- Clinical studies show that sorbitol can cause gastrointestinal effects at doses far lower than 50 grams per day.
- Consumption of sorbitol is widespread

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):**

- All products containing one or more grams of sorbitol per serving should bear the required label notice.
- The sorbitol label notice should be prominent and conspicuous.
- The statement should indicate that sorbitol is the ingredient that may induce gastrointestinal problems, describe the symptoms that may result and state that children should not consume sorbitol containing products.
- Products containing mannitol and other diarrhea inducing sugar-alcohols should be subject to the same labeling requirements as those proposed in this petition.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Center for Science in the Public Interest (76).
49. Labeling of Caffeine Content

Regulating Agency: HHS/Food and Drug Administration

Citation: N/A

Authority: Food, Drug, and Cosmetic Act

Description of What Existing/Proposed Regulation Does: While caffeine must be listed as an ingredient, there is no requirement to list the amount of caffeine.

Commenter Description of Issue(s):

• There is widespread confusion about the amount of caffeine in food products.
• Caffeine consumption is widespread.
• Caffeine has significant effects on pregnant women including effects on fertility, fetal growth, miscarriage, and birth defects.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

• FDA should require disclosure of the caffeine content of foods and beverages.
• FDA should conduct a thorough review of the health effects of caffeine to determine what additional regulatory and educational actions should be taken to protect the public from the adverse effects of caffeine.

Estimate of Economic Impacts: Not quantified but commenter asserts that any costs would be offset in whole or in part by the savings gained from possible health benefits.

Commenter(s): Center for Science in the Public Interest (76).
50. **Labeling of Food Allergens**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** N/A

**Authority:** Food, Drug, and Cosmetic Act

**Description of What Regulatory Prompt Would Do:** Provide adequate notice and protection to individuals with food allergies through the imposition of labeling requirements for food allergens. FDA has concluded that the undeclared presence of food allergens is a serious public health issue. No regulation requiring labeling currently exists.

**Commenter Description of Issue(s):**

- Each year, about 30,000 people receive emergency room treatment due to eating allergenic foods and an estimated 150 people die from anaphylactic shock caused by a food allergy.
- Approximately four million Americans including up to six percent of children suffer from food allergies.
- The amount of an allergenic food needed to cause a severe reaction is minimal.

**Small Business Impact:** Not addressed.

**Commenter Proposed Solution(s):** FDA should amend its regulations to provide adequate notice and protection to individuals with food allergies through the imposition of labeling requirements for food allergens, and the establishment of Good Manufacturing Practices aimed at preventing the inadvertent introduction of such allergens into non-allergenic foods.

**Estimate of Economic Impacts:** Not addressed.

**Commenter(s):** Center for Science in the Public Interest (76).
51. **Investigational New Drug (IND) Regulations**

**Regulating Agency:** HHS/Food and Drug Administration

**Citation:** 21 CFR 312

**Authority:** Federal Food Drug and Cosmetics Act.

**Description of What Existing Regulation Does:** This collection is associated with FDA regulatory requirements for submission of a new drug application. An IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population. The IND application must contain information in three broad areas, animal pharmacology and toxicology, manufacturer information and clinical protocols.

**Commenter Description of Issue(s):**

- The PRA burden associated with this rule is over 10 million hours.

**Small Business Impact:** None provided.

**Commenter Proposed Solution(s):** OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

**Estimate of Economic Impacts:** The total burden is 17 million hours. The provisions of the regulations with the highest burden are the application itself (3 million hours), making amendments to the protocol (4 million hours), and recordkeeping of individual case histories (4 million hours).

**Commenter(s):** Rep. Doug Ose (108).
52. Pediatric Rule

Regulating Agency: HHS/Food and Drug Administration

Citation: 21 CFR 201, 212, 34, and 601


Description of Regulation: This regulation gave FDA the authority to require drug companies to perform testing on children for new drugs.

Commenter Description of Issue(s):
• The FDA requirement applies even for drugs that will only be marketed to adults.
• By making drugs found safe for adults unavailable, this will increase the health risks of Americans overall.

Commenter Proposed Solution(s):
• Rescind the rule.

Estimate of Economic Impacts: The FDA estimate is $80 million/year.

Commenter(s): The Heritage Foundation (78).
53. Standards for Individually Identifiable Health Information

Regulating Agency: HHS/Office of Civil Rights

Citation: 45 CFR Parts 160 and 164

Authority: Health Insurance Portability and Accountability Act of 1996

Description of Regulation: This regulation, initially issued in 2000 put in place a large number of requirements to protect the privacy of individual medical records.

Commenter Description of Issue(s):
• Given the limited benefits and high costs the rule may damage the long term health of Americans. (Mercatus)
• A business associate agreement should not be required between covered entities. (AOA)
• Definitions should be modified as they pertain to accrediting organizations so they are not covered by the “business associate” provisions. (AOA)

Commenter Proposed Solution(s):
• “A more constructive approach may rest in clearly delineating ownership rights and then clearly protecting those rights.” (Mercatus)
• “Reduce the administrative costs as much as possible. Include private sector accrediting groups in the definition of a health oversight agency and eliminate the requirement that physicians be the enforcer of the regulation.” (AOA)

Estimate of Economic Impacts: Present value costs of $16.1 billion. (Mercatus)

Commenter(s): American Osteopathic Association (39); The Mercatus Center (73); Center for Regulatory Effectiveness (83).
54. Protection of Human Subjects

Regulating Agency: Department of Health and Human Services/OS/OHRP

Citation: 56 CFR 28003

Authority: 45 U.S.C. 46

Description of What Existing Regulation Does. The regulation sets forth specific requirements for federally supported research involving human subjects.

Commenter Description of Issue(s):

• The regulations governing the use of human participants in research have expanded rapidly over the past decade and evolved into a complex matrix of overlapping requirements. In addition, the situation has been exacerbated by the introduction of mandatory privacy review of research outlined in HIPAA. The HHS OIG, the National Bioethics Advisory Committee and the Institute of Medicine have all characterized the system as over-burdened and in need of reform.
• A thorough review is needed to ensure that the regulations emphasize the protection of participants in the context of the type of research and level of risk and that overly burdensome provisions do not inhibit critical biomedical, epidemiological and health sciences research.

Small Business Impact: The complex requirements may prove especially burdensome for small private labs and biotechnology companies.

Commenter Proposed Solution(s): Propose a thorough review of the regulations governing human subject research as a whole to ensure consistency and minimize burden. Also suggests that requirements should be proportional to the level of risk for participants.

Estimate of Economic Impacts: None provided.

Commenter(s): Council on Government Relations (145)
55. Predatory Lending

Regulating Agency: HUD

Citation: None provided.

Authority: None provided.

Description of What Existing Regulation Does: The existing rules have been implemented in order to protect consumers from predatory lending practices by unscrupulous brokers offering services at higher cost or higher interest rates than what a borrower can qualify for. It also protects borrowers from high-pressure tactics from brokers.

Commenter Description of Issue(s): Commenter feels that the brokerage industry is highly overregulated, and that the requirements make the process more difficult for borrowers instead of protecting those borrowers.

• Most brokers are legitimate businesses that do not engage in predatory tactics
• Very few complaints of predatory lending among brokered loans
• 50+ disclosures needed for mortgages

Small Business Impact: No. Most brokers are small businesses, but the rules are in place to protect consumers from predatory lending practices, which come from both big and small brokerage firms.

Commenter Proposed Solution(s): Rescind rules on brokers, and simplify or eliminate paperwork burden.

Estimate of Economic Impacts: None provided.

Commenter(s): Mike Schnezler, Presidential Mortgage Corporation/South Carolina Mortgage Broker’s Association (143).
56. **Insured 10-Year Protection Plans**

*Regulating Agency:* HUD/FHA

*Citation:* 24 CFR 203.200-203.209

*Authority:* None provided.

*Description of What Existing Regulation Does:* The rules contain requirements for warranty coverage definition for FHA home loans.

*Commenter Description of Issue(s):* The commenter asserts that HUD has accepted warranty coverage definitions that deviate from the definition in the rule since 1994, creating an unfair advantage to some providers.

*Small Business Impact:* No. The commenter asserts that all providers of Insured Ten-Year Protection Plans are small businesses; there is no differential impact based on size.

*Commenter Proposed Solution(s):* The commenter recommends the adoption of the “uniform warranty” developed by the National Association of Home Builders (NAHB) Home Buyer Warranty Task Force. This would streamline the requirements for home warranties for FHA properties and allow uniform coverage for all FHA buyers.

*Estimate of Economic Impacts:* None provided.

*Commenter(s):* W.E. (Em) Fluhr, Ph.D., P.E., Chief Executive Officer, 2-10 Home Buyers Warranty (124).
57. Digital Aircraft Radios

Regulating Agency: DOI/Office of Aircraft Services and USDA/FS

Citation: None provided.

Authority: None provided.

Description of What Existing Regulation Does: As an outgrowth of Project SAFECOM, the wireless public safety interoperable communications initiative of e-government and in compliance with EIA/TIA-102 Standards (EIA/TIA refers to the Electronic Industries Association and the Telecommunications Industry Association; together they formalized these accepted standards), DOI, through the Office of the Chief Information Officer, has mandated that all FM radios in use by DOI be narrow band digital by January 1, 2005. The Office of Aircraft Services (OAS) is responsible for contracting aircraft for use by the various bureaus in the Department. The current price of a narrow band digital radio is in the $13,000 range, and may well be expected to drop substantially over the next few years as competition intensifies among radio manufacturers.

Commenter Description of Issue(s): After a major upgrade three years ago to radios that use split frequencies, this change requires an expensive upgrade of radio equipment for all providers of aircraft services. The upgrade may bring about incompatibilities with state and local governments if they are unable to afford the upgrades.

Small Business Impact: Yes. Small businesses are least able to afford large capital expenditures, particularly if required all at once. The increased time for upgrades and the need for greater interoperability appear to justify the requirement.

Commenter Proposed Solution(s): The upgrade is unnecessary.

Estimate of Economic Impacts: For this commenter, this requirement imposes an expenditure of $53,000.

Commenter(s): Mark Gibson, Timberland Logging (141).
58. **Conservation Use in Grazing**

**Regulating Agency:** DOI/Bureau of Land Management

**Citation:** 43 CFR Part 4130

**Authority:** 43 U.S.C. Chapter 35

**Description of What Existing Regulation Does:** The rule allows a person to bid and obtain a grazing permit for a tract of Federal land for the sole purpose of preventing grazing. This tactic was used in the West by environmental groups concerned about degraded Federal lands and demonstrated that their willingness to pay to prevent grazing.

**Commenter Description of Issue(s):** The current rule improperly allows holders of permits to graze livestock to choose not to graze livestock. This “conservation use” of permits was struck down by the Tenth Circuit Court of Appeals in *Public Lands Council, et al. V. Babbitt*, 167 F.3d 1287 (1999).

**Small Business Impact:** No.

**Commenter Proposed Solution:** The rule is illegal and must be removed

**Estimate of Economic Impacts:** None provided. However, “conservation use” allows environmentalists to bid up the price of grazing permits, harming ranchers.

**Commenter(s):** Richard Newpher, American Farm Bureau Federation (24).
59. **Surface Management of Mining Claims**

**Regulating Agency:** DOI/Bureau of Land Management

**Citation:** 66 FR 54863

**Authority:** Federal Land Policy and Management Act, 43 U.S.C. 1732(b), 1733, 1740; General Mining Law, 30 U.S.C. 22

**Description of What Existing Regulation Does (or What Regulatory Prompt Would Do):** The definition of “unnecessary and undue degradation” was amended on October 30, 2001 to reflect Administration policy. The previous definition included a “substantial irreparable harm” provision which the Administration believes might have exceeded BLM’s authority. Also, other mechanisms exist to allow BLM to protect the resources covered by the SIH standard.

**Commenter Description of Issue(s):** In 2000, the Clinton Administration amended the BLM’s surface management rules prohibiting activities that result in unnecessary and undue degradation of the public lands. The stated purpose of the amendments was to make it clear that operators must not cause substantial irreparable harm to surface resources that cannot effectively be mitigated, even if customary and prudent practices would lead to that result. In 2001, the BLM repealed the 2000 amendments, thereby restoring the pre-2000 regulations, which the BLM had previously characterized as too subjective and vague. The BLM explained that it should not have adopted this “truly significant provision” without affording better opportunity to comment. The 2001 amendments also repealed performance standards installed by the 2000 amendments. At the same time as it adopted the 2001 amendments, the BLM solicited further comment on its most recent changes.

**Small Business Impact:** Yes

**Commenter Proposed Solution(s):** Restore the 2000 definition of “unnecessary and undue degradation” and the 2000 performance standards repealed in 2001 to ensure that the integrity of surface resources on the public lands is protected against damage caused by mining activities, regardless of whether customary and prudent practices would have caused that damage.

**Commenter Estimate of Economic Impacts:** The BLM estimated that the costs of the 2000 regulations would have ranged between $106 million and $649 million. The proposed solution would generate benefits in the form of increased protection of natural resources found on public lands on which mining operations occur, including the avoidance of both land and water pollution on those public lands. Like the roadless area policy, the former BLM rule was not a “regulation” in the traditional sense; it was an attempt by the Federal government to impose on users of public lands B free some of the true costs of doing business. This is another efficiency-promoting rule OIRA should support enthusiastically.

**Commenter(s):** Center for Progressive Regulation (70).
60. **Endangered Species Act**

Regulating Agency: DOI/Fish and Wildlife Service (FWS) and DOC/National Oceanic and Atmospheric Administration/National Marine Fisheries Service (NMFS)

Citation: 50 CFR Part 17

Authority: 16 USC 1531 et. seq.

Description of What Existing Regulation Does: The rules seek to protect the biological diversity of the United States and promote the recovery of threatened and endangered species through the designation of critical habitats and development of recovery plans. In addition, lawsuits are playing a greater and greater role in setting agency priorities.

Commenter Description of Issue(s):

• More than 75 percent of all endangered and threatened species listed under the ESA inhabit private property. For more than 34 percent of all listed species, private property is their only habitat. If the ESA is to succeed, the cooperation of private landowners is critical.

• The law is not working, precisely because the cooperation of private landowners has not been solicited. Instead, Federal agencies have administered the law through coercive regulation of private landowners. As a result, the law has not achieved its purpose of recovering species.

• Involving landowners early in the process and providing incentives rather than heavy-handed regulation will increase the willingness of landowners to manage species on their lands instead of the opposite result. Command-and-control tactics that have marked administration of the ESA from the beginning make landowners wary of the presence of listed species on their property because of the increase restrictions on the use of their property that result.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Require independent scientific peer review for most ESA decisions.

• Provide that landowners applying for a Federal permit or license or receiving technical assistance or finding from a Federal agency be given the opportunity to participate and have their input considered in consultations required by section 7 of the ESA.

• Require that affected landowners, local communities and the general public be given an opportunity to provide comments and have their comments considered on all draft recovery plans and draft biological opinions under the ESA.

• Develop a consistent framework for the FWS and NMFS for implementation of the ESA, especially in areas where their jurisdictions overlap.

• Require notification to persons holding Federal permits or licenses who are affected by a citizen suit under the ESA.

• Provide a thorough economic analysis of all proposed critical habitat designations, with opportunity for affected parties to participate and have their input considered from the early stages of the analysis.

• Foster incentives through regulations to implement the Landowners Incentive Program and the Private Grant Program.

Estimate of Economic Impacts: None provided.
Commenter(s): Richard Newpher, American Farm Bureau Federation (24); George Parris (191).
61.  **Endangered Species Act Delisting**

**Regulating Agency:** DOI/Fish and Wildlife Service (FWS)

**Citation:** 50 CFR Part 17

**Authority:** 16 USC 1531 et. seq.

**Description of What Existing Regulation Does:** The ESA provides that listed species are to be removed from the list when they have recovered. Recovery is normally determined by recovery goals established by recovery teams through recovery plans.

**Commenter Description of Issue(s):** Grizzly bears in the Yellowstone Park area, gray wolves in the Great Lakes region, and bald eagles – three very highly visible species – have clearly and admittedly met all of the recovery goals set forth in their respective recovery plans, yet de-listing has not moved forward.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** OIRA should issue a "prompt" letter to FWS to begin de-listing these species at once.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Richard Newpher, American Farm Bureau Federation (24).
62. National Landscape Conservation System

Regulating Agency: DOI/Bureau of Land Management

Citation: N/A.

Authority: Antiquities Act (16 USC 431 et seq)

Description of What Regulatory Prompt Would Do: BLM would issue rules establishing a framework under which BLM would develop management plans for Presidential-designated National Monuments.

Commenter Description of Issue(s): The designation of 15 new national monuments in the final days of the previous administration caused significant controversy in the Western states where they were created. The designation also created considerable uncertainty in people within the monument areas and the surrounding communities with respect to what a designation meant for the continued use and enjoyment of their private property. DOI has recently announced that it will begin the process of developing management plans for these monuments, yet there is no framework for developing such plans.

Small Business Impact: No.

Commenter Proposed Solution(s):

• A regulatory framework for this program is essential to ensure compliance with the Antiquities Act, to provide consistent application throughout the system, and to provide area residents and communities with some expectations as to how management of monuments will be achieved. We suggest that such regulations specify:
  • Private property will not be included in the monument or regulated by a management plan.
  • All existing rights, such as water rights, grazing rights, and access rights, will be respected and unaffected by the management plan.
  • A process for significant public input into development of management plans.
  • A process for revision or amendment of management plans.
  • A statement whether BLM will seek to purchase privately owned property or interests in privately owned property in the administration of the monuments.

Estimate of Economic Impacts: None provided.

Commenter(s): Richard Newpher, American Farm Bureau Federation (24).
63. Possessory Interest Assets

Regulating Agency: DOI/National Park Service

Citation: 36 CFR Part 51

Authority: NPS Concessions Management Improvement Act of 1998 (16 U.S.C. 5951 et seq.)

Description of What Existing Regulation Does: Under the 1965 Concessions Policy Act, a NPS concessioner that constructed real property improvements on park area lands under the terms of a concession contract obtained a compensable interest in the improvements in the form of a "possessory interest." The NPS Concessions Management Improvement Act repealed the Concessions Policy Act of 1965 and reformed the possessory interest provisions of the 1965 Act through the leasehold surrender interest concept. The leasehold surrender interest provisions are intended to "reflect the real value of the improvements and should not result in undue compensation to a concessioner upon expiration of a concession contract."

Commenter Description of Issue(s): Depreciation of possessory interests harms small businesses by discouraging capital improvements to park concessions. Small businesses will only invest in their concession operations if they are ensured a return on the improvement if they should lose the concession. The Commenter also cites a currently pending suit against NPS.

Small Business Impact: No. Although the commenter believes that this rule harms small business, the purpose was to ensure competition in NPS concessions. If depreciation were not required, the incumbent would always have a significant advantage because it would not have to reimburse himself for the concession assets.

Commenter Proposed Solution(s): Aside from a clarification on the meaning of "book value", the commenter has filed suit to modify the terms of its contract.

Estimate of Economic Impacts: None provided.

Commenter(s): Edward and Carol Wimberly, Lake Roosevelt Vacations, Inc. (123).
64. **Snowmobiles in Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr. Parkway**

**Regulating Agency:** DOI/National Park Service

**Citation:** 36 CFR Part 7

**Authority:** 16 U.S.C. Chapter 1

**Description of What Existing Regulation Does (or What Regulatory Prompt Would Do):** There is no uniform policy for the use of snowmobiles in National Parks, so NPS must issue park specific regulations as problems are identified. At the end of the previous Administration, NPS proposed and issued regulations to ban snowmobiles from Yellowstone National Park by the 2002-2003 winter season. After a statutorily-imposed delay of one year, NPS has published a proposed rule that would delay implementation of the ban an additional year. This was to allow the Park Service sufficient time to consider new information provided on snowmobile technology that could reduce emissions and noise.

**Commenter Description of Issue(s):**

- Tens of thousands of snowmobiles speed through Yellowstone and Grand Teton National parks each year, emitting huge amounts of air pollution. In just one winter, snowmobiles in Yellowstone released the equivalent of 68 years of automobile pollution, according to the Natural Resources Defense Council. The DOI announced on June 29, 2001, that it would reconsider a rule (completed at the end of the Clinton administration) that would phase out snowmobile use in Yellowstone and Grand Teton National Parks by 2004. The decision came out of a settlement agreement reached between Interior and the International Snowmobile Association and others, which had brought suit to stop the ban in Federal District Court in Wyoming. As a result of the June 29 agreement, the National Park Service released a Supplemental Environmental Impact Statement (SEIS) on March 29, 2002, even though this research has already been done, and will issue a final rule on the proposed ban by November 15, 2002, a month before the official snowmobiling season begins and the first phaseouts under the Clinton rule were due to begin. (77)
- The NPS erroneously certified that there would be no significant impact on a substantial number of small entities. The NPS did not adequately consider alternatives such as the use of new four-stroke snowmobile technology that was quieter and less polluting. (97)

**Small Business Impact:** Yes. One commenter guesses that small businesses will see a 78 percent drop in profits based on NPS’s original analysis. (97)

**Commenter Proposed Solution(s):**

- NPS should allow the existing final rule to take effect. (77)
- NPS should withdraw certification made in the existing final rule and amend it in light of new information in the SEIS. NPS should then either recertify based on fact or prepare a final regulatory flexibility analysis and release it for comment. (97)

**Estimate of Economic Impacts:** One commenter cites an NPS estimate of lost revenue to 74 snowmobile rental firms of $3.9 million.

**Commenter(s):** OMB Watch (77), SBA Office of Advocacy (97).
65. **Snowmobiles in the Rocky Mountain National Park**

**Regulating Agency:** DOI/National Park Service

**Citation:** 36 CFR Part 7

**Authority:** 16 U.S.C. Chapter 1

**Description of What Existing Regulation Does:** There is no uniform policy for the use of snowmobiles in National Parks, so NPS must issue park specific regulations as problems are identified.

**Commenter Description of Issue(s):** The National Park Service (NPS) proposes to close Rocky Mountain National Park to snowmobiles except for a 2-mile stretch of the North Supply Access Trail. Currently, 18 linear miles of snowmobile trails exist within the 414 square miles in the Park. The NPS justifies this proposal with Executive Orders 11644 and 11989, which state that recreational snowmobile use should be disallowed within a national park if it causes adverse impacts on park resources. However, the NPS does not present any data on adverse impacts to justify the prohibition. Instead, the proposal seems driven by a conflict between use by snowmobiles and non-motorized recreationists. The park was created in 1915 “for the benefit and enjoyment of the people of the United States” with regulations being primarily aimed at the “freest use of said park for recreation purposes by the public and for the preservation of the natural conditions and scenic beauties”(38 Stat. 798). (Emphasis added.) EO 11644 also requires agencies to minimize conflicts among competing users of public lands. Eliminating one type of use from the park seems to violate these requirements.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- The NPS should conduct a better benefit-cost analysis that takes into account all of the park’s constituents, not just the non-motorized users. In addition, the NPS might consider requesting authority from Congress to charge differential fees based on the type of use so that there could be a market test of the value of “noisy” and “natural quiet” days in the park. At the very least, the Park should experiment with ways of reducing conflicts between users instead of simply claiming one set of users is superior to another set.
- The Environmental Assessment (EA) conducted to examine potential adverse impacts did not discover any data to justify the NPS preferred alternative. Some preliminary data on soil and sediment contamination from snowmobile use have been gathered but are insufficient to determine any effects. The EA did not identify any impacts on endangered, threatened, or rare species. It did raise concerns about potential effects on bighorn sheep, elk, moose or deer. It noted, however, that the current trails are not in areas where there is winter forage for these species. Air quality issues are a significant concern with snowmobiles because fuel-inefficient, two-stroke engines power them. There are no data, however, that show that using snowmobiles on the 18 miles of trail within the 414 square mile park has any adverse effect on air quality in the park.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Mercatus Center (73).
66. Wild and Scenic Rivers—Water Resources Projects

Regulating Agency: DOI/Bureau of Land Management

Citation: Proposed 43 CFR Part 39

Authority: Wild and Scenic Rivers Act (16 U.S.C. 1278)

Description of What Proposed Regulation Would Do: This rule would establish uniform standards and procedures by which agencies within the Department that administer rivers in the National Wild and Scenic Rivers System will consider consenting to construction of water resources projects affecting components of the System or rivers authorized by Congress for study as potential additions. This rule affects Federal agencies that construct or assist in the construction of water resources projects. Section 7 of the Wild and Scenic Rivers Act prohibits all Federal agencies from providing assistance for any water resource project that would have an adverse effect on the values for which such rivers have been or may be designated.

Commenter Description of Issue(s): A year and a half after the USDOT/FHWA Record of Decision, in December 27, 1996, the NPS issued a Section 7(a) determination indicating that the proposed project would adversely impact the scenic and recreational values protected by the Wild and Scenic Rivers Act. The project stopped after $14 million was spent by the States of Minnesota and Wisconsin in reliance on the NEPA Record of Decision and after endangered species were moved, property acquired, buildings razed, utilities moved, and families and businesses relocated in reliance on these analyses and independent Federal approvals to proceed. The approximately $160 million bridge project across the St. Croix River of part of the National Highway System remains at an impasse due to the conflict between the historic interests – keep the old historic bridge – and the river interests – one bridge in, old bridge out.

Small Business Impact: Yes

Commenter Proposed Solution(s): Make sure States can rely on a Record of Decision under NEPA and resolve the conflicting historic and river goals by allowing the USDOT to make the final decision. USDOI/National Park Service has yet to promulgate any implementing rules that resolve the historic and river interest conflicting goals.

Estimate of Economic Impacts: $100s of Millions. It is also the obvious bypass/alternative route if the critical I-94 Bridge connecting Minneapolis/ St. Paul, MN and Wisconsin is damaged or destroyed.

Commenter(s): Jim Thiel, General Counsel, Wisconsin Department of Transportation (90).
67. **Cooperative Conservation Initiative**

**Regulating Agency:** DOI

**Citation:** None provided.

**Authority:** None provided.

**Description of What Existing Regulation Does (or What Regulatory Prompt Would Do):** The President proposed the Cooperative Conservation Initiative in the FY 2003 Budget:

Partnerships achieve more conservation for the same investment. An excellent example of this approach is the Cooperative Conservation Initiative (CCI). To leverage funds and promote conservation, the CCI allocates $100 million in matching funds for natural resource conservation projects. Projects can range from working with The Nature Conservancy to remove invasive species from Channel Islands National Park, to working with local communities to reclaim abandoned mine sites on public lands. Half of these funds would be allocated through cost-shared programs between non-Federal partners and DOI’s NPS, FWS, and BLM. The other half would be distributed to states as part of the LWCF state grant program. However, as with other LWCF programs, all of the funds have a common goal: to get more conservation results by working in concert with the people who know the land.

**Commenter Description of Issue(s):** Regulations should be put in place immediately so that benefits of the program can be maximized.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** Issue regulations immediately.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Richard Newpher, American Farm Bureau Federation (24).
68. Hemp Food Products

Regulating Agency: DOJ/Drug Enforcement Administration

Citation: 66 FR 51530 (Interpretative Rule), 66 FR 51535 (Proposed Rule), 66 FR 51539 (Interim Rule); 21 CFR Part 1308

Authority: 21 U.S.C. 811, 812, 817 (b); Controlled Substances Act

Description of What Existing/Proposed Regulation Does: The interpretative rule read the Controlled Substances Act (CSA) and DEA regulations to declare any product containing any amount of Tetrahydrocannabinols (THC) to be a schedule I controlled substance. The proposed rule, issued simultaneously, revised the wording of DEA regulations to make clear that the listing of THC in schedule I refers to both natural and synthetic THC. The interim rule, also issued simultaneously, exempted industrial-use products (i.e., soap) as long as the products are not used or intended for human consumption.

Commenter Description of Issue(s):

- DEA did not analyze the impacts on the hemp foods industry and ignored their substantive and administrative rights.
- By labeling one of the rules as an “interpretation,” DEA was able to bypass notice and comment rulemaking and the requirements of the RFA.
- DEA did not consider establishing guidelines to allow products that did not leave detectable traces of THC in the bloodstream.

Small Business Impact: Yes

Commenter Proposed Solution: Rescind regulations.

Estimate of Economic Impacts: The hemp food industry would be eliminated. According to industry data, sales of hemp food products reached about $5 million annually.

Commenter(s): Small Business Administration, Office of Advocacy (97).
69. **List of Terrorist Organizations**

**Regulating Agency:** DOJ/Federal Bureau of Investigation

**Citation:** N/A

**Authority:** 28 CFR Sec. 0.85

**Description of What Proposed Regulation Would Do:** Emphasis would be placed on adding domestic organizations that support terrorist activities to other existing lists of terrorist organizations.

**Commenter Description of Issue(s):**

- Since the agriculture sector is extremely vulnerable to terrorist activity, it is critical to have such organizations listed.

**Small Business Impact:** No

**Commenter Proposed Solution(s):** Expand the list of terrorist organizations to include domestic organizations.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Farm Bureau Federation (24).
70. **Driver's Privacy Protection Act**

**Regulating Agency:** Department of Justice, Immigration and Naturalization Service

**Citation:** N/A

**Authority:** 18 USC 2721-2725

**Description of What Regulatory Prompt Would Do:** The rule would tighten up 13 exceptions, removing towing and impounding authorities and private investigators.

**Commenter Description of Issue(s):**

- There is no consistent interpretation across the country of the Driver's Privacy Protection Act, which is intended to protect the personal privacy and information of individuals who have motor vehicle records.
- The Act restricted an individual from obtaining another person's record with personal information on it, however, it allows motor vehicle crash record personal data to be retrieved. Interpretation of the Act varies from State to State. DOJ has not issued any guidance on this.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Tighten up the 13 exceptions, removing towing and impounding authorities and private investigators.
- Require DOJ to provide guidance to the states.

**Estimate of Economic Impacts:** Wisconsin experienced an additional $200,000 in staff time to implement and answer questions from local DMVs.

**Commenter(s):** Wisconsin Department of Transportation (90).
71. **Electronic Storage of I-9 Forms**

**Regulating Agency:** Department of Justice, Immigration and Naturalization Service

**Citation:** 8 C.F.R. 274a.2

**Authority:** 8 U.S.C. 1324a

**Description of What Existing Regulation Does:** This section states the requirements and procedures persons or entities must comply with when hiring, or when recruiting or referring for a fee, or when continuing to employ individuals in the United States.

**Commenter Description of Issue(s):** INS does not permit the electronic storage of Employment Eligibility Verification I-9 forms. Current INS regulations provide that these forms must be kept in the original hard copy or on microfilm or microfiche. This is extremely burdensome on employers.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** Allow the option for electronic storage of INS I-9 forms.

**Estimate of Economic Impacts:** None given.

**Commenter(s):** Equal Employment Advisory Council (2)
72. **Admission Period for B-1/B-2 Visitors**

**Regulating Agency:** Department of Justice, Immigration and Naturalization Service

**Citation:** Proposed Rule, 67 Fed. Reg. 18065 (April 2002), 8 C.F.R. Parts 214, 235 and 248

**Authority:** 8 USC Sections 1101 et seq.

**Description of What Proposed Regulation Would Do:** This proposed rule eliminates the minimum admission period of B-2 visitors for pleasure, reduces the maximum admission period of B-1 and B-2 visitors from 1 year to 6 months, and establishes greater control over a B visitor's ability to extend status or to change status to that of a nonimmigrant student.

**Commenter Description of Issue(s):**

- The uncertainty of whether a longer than 30-day period of stay will be granted will deter some travelers from venturing to the U.S.
- This rule will limit the plans of travelers to the 30 day period, resulting in potentially millions of dollars in lost revenue.
- This rule will negatively impact the adult children and parents of temporary workers in the U.S., who have been historically permitted to use the B-2 category to accompany a temporary worker to the U.S.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- The final rule should clarify the circumstances under which individuals may be admitted for longer than 30 days and provide an opportunity to appeal the admission decisions to the immigration inspectors.
- The final rule should also recognize the circumstances of other categories of long-term visitors including family members of temporary workers.

**Estimate of Economic Impacts:** One estimate from the Department of Commerce is that visitors who stay longer than 30 days spend an average of $4 billion annually in the U.S.

**Commenter(s):** U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak, and Stewart (33); Gill Studios (61); Brent Bedford (65).
73.  **Forms I-140 and I-485**

**Regulating Agency:** Department of Justice, Immigration and Naturalization Service

**Citation:** 8 CFR 204, 8 CFR 245

**Authority:** 8 U.S.C. Section 1101, 1103, 1153, 1154, 1182, 1186a, 1255, 1641

**Description of Existing Regulation:** Current regulations establish procedures for application of an immigrant to enter the U.S. as an employee and how an individual applies for an adjustment of status to that of a permanent resident.

**Commenter Description of Issues:** Presently, when an employer files the I-140, Immigrant Petition for Alien Worker, a separate filing must be made for the I-485, Application to Register for Permanent Residence or Adjust Status. INS has discussed “concurrent” filing but currently does not allow for this. Separate filings create additional work and delays for the government and employer.

**Small Business Impact:** No.

**Commenter Proposed Solutions:** Promulgate regulations that allow for joint filing of these forms.

**Estimated Economic Impacts:** Joint filing would streamline the process, by not requiring review of duplicative information. Joint filing would also eliminate the need to file for advance parole, work authorization and other documents necessary to maintain foreign national’s status simply because of the lag time between adjudication of the I-140 and the I-485.

**Commenters:** American Council on International Personnel (183)
74. I-9 Employment Verification

Regulating Agency: Department of Justice, Immigration and Naturalization Service

Citation: Proposed Rule, Reduction in the Number of Acceptable Documents and other changes to Employment Verification Requirements, 63 Fed. Reg. 5287 (February 2, 1998) (RIN 1115-AE94)

Authority: 8 U.S.C. Section 1324a

Description of Proposed Regulation: The proposed rule reduces the number of documents acceptable for I-9 purposes. This proposed rule simplifies the process of applying for an I-9 work employment verification.

Commenter Description of Issues: I-9 forms are confusing and the documentation required is extensive and complicated.

Small Business Impact: No.

Commenter Proposed Solutions: Issue an interim rule that reduces the number of documents available for I-9 purposes. The instructions on the I-9 must be updated to reflect the new requirements and the changes in available documentation for verification purposes.

Estimated Economic Impacts: The I-9 form currently is estimated to have approximately 13,020,000 burden hours. ACIP believes that this is underestimated. Clarification of what documentation is needed will save employers money by easing compliance. A new I-9 and updated instructions will allow employers more easily and quickly train employees of requirements.

75. Birth and Adoption Unemployment Compensation

Regulating Agency: Department of Labor

Citation: 20 CFR, Part 604

Authority: 42 U.S.C. 503 (a)(2) and (5) and 1302(a); 26 U.S.C. 3304(a)(1) and (4) and 3306(h); Secretary's Order No. 4-75 (40 FR 18515); and Secretary's Order No.14-75 (November 12, 1975).

Description of Existing Regulation: Allows the States to develop and experiment with innovative methods for paying unemployment compensation to parents on approved leave or who leave their employers to be with their newborns or newly-adopted children. The purpose of the regulation is to allow the Department of Labor to test whether its interpretation of the Federal “able and available” requirements promotes a continued connection to the workforce in parents who receive this type of paid leave.

Commenter Description of Issues:

- Diverting UI trust funds is contrary to Congress's intent under the Federal Unemployment Tax Act and the Family and Medical Leave Act.
- Workers who take leave are not “unemployed.”
- Jeopardizes unemployment funds for those who need it.
- Adverse economic consequences possible, if payroll taxes must be increased to finance unemployment benefits.
- Several states have already needed Federal loans to pay unemployment benefits.
- Puts the Federal government's budget at risk, since it guarantees state benefits.
- Employers should not be required to subsidize the personal choices of their employees via the UI system, when those choices are unrelated to employers' decisions.
- Using UI trust funds for purposes not authorized by FUTA or SSA is irresponsible and unlawful.
- Regulation is contrary to numerous individual state and Federal unemployment statutes.
- There are other viable alternatives.
- Regulation singles out one type of leave at the exclusion of other types of leave.
- Approach will ultimately conflict with and discourage many tailored benefits the private sector is willing to offer.
- Small businesses, exempt from FMLA, would be financially responsible for supplementing paid voluntary leave through taxes for workers who are not their employees.
- Rule needs to be rescinded before any state enacts a "Baby UI" statute, since the judicial system will need years to resolve the issue.

Small Business Impact: Yes.

Commenter Proposed Solutions:

- Rescind the BAA-UC regulation.
- In place of regulation, allow employees to make penalty-free, tax-free withdrawals (up to 12 weeks of wages) from personal saving accounts (IRA, 401(k), 403 (b), Keogh, etc).
- Provide tax credit or other incentives to employers who increase contributions to employees' personal savings accounts or who set-up special funds to compensate employees on leave for the birth or adoption of a child.

Estimated Economic Impacts:
• Half of state UI trust funds do not have or are close to not having sufficient reserves.
• Small businesses or those with slim profit margins may not be able to pay the taxes required to keep UI trusts solvent, without raising prices and cutting staff.
• Will depend on how many states choose to permit unemployment funds for employee birth and adoption leave.
• Puts the Federal government's budget at risk, since it guarantees state benefits.

Commenters: Texas Association of Business (11); Food Marketing Institute (13); Michigan Health and Hospital Association (17); FMLA Technical Corrections Coalition (25); LPA (27); Printing Industries of America (29); National Federation of Independent Business (30); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); Howell Instruments (57); Gill Studios (61); Adolph's Coffee Service (64); Bedford, Brent (65); Coors of Longview (66); Mac Vicar, Neil (147); Oxfeld, Eric (155); California Association of Hospitals and Health Systems (202).
76. Family and Medical Leave Act (FMLA) Regulations

Regulating Agency: Department of Labor, Employment Standards Administration

Regulation: Seven FMLA Regulations (see below)

Authority: Family and Medical Leave Act of 1993

1. Serious Health Condition

Citation: 29 CFR Part 825.114

Description of Existing Regulation: Established general standards to determine what a “serious health condition” entails and discusses when FMLA leave may be taken in the case of an employee having a serious health condition.

Commenter Description of Issues:

- Definition is overly broad. It allows employees to take leave for “minor illnesses” such as cold, flu, & headaches. Vague conditions, such as depression, stress, and back pain are covered. These conditions were not intended to be included by Congress and allow employee to abuse leave.
- Employers lack guidance on what is a serious health condition. Guidance letters have been inconsistent.
- Chronic conditions- employees with asthma can easily abuse or those with absentee problems.
- Employees find it easy to obtain certification from a physician for a chronic condition.
- Leads to resentment from colleagues, due to covering for absent employees.
- Misused to extend vacation time.
- Results in unnecessary litigation.
- Increases administrative burden.
- Reduces employers’ incentive to provide more progressive policies, including paid-leave.
- Increased absenteeism in companies where paid family medical leave was provided prior to enactment of FMLA.

Small Business Impact: No.

Commenter Proposed Solutions:

- Rescind wage and hour opinion letter.
- Restore meaning of the word “serious.” Have clear criteria or examples of what conditions qualify.
- Reaffirm that incapacity for three days and continuing treatment by a health care provider do not convert a minor illness into a “serious health condition.”
- Regulations must specifically state that FMLA leave may not be taken for short-term illnesses or other impairments for which treatment and recovery are brief.
- Statement on medical certification form should emphasize the above comment.
- Institute a rulemaking to determine whether current regulation is consistent with statute.
- Short term solution: Rescind DOL’s current opinion letters #86, #87 and replace them with an opinion stating that minor illnesses are not covered by the FLMA, similar to that expressed in Opinion Letter #57.

Estimated Economic Impacts: Many commented that administrative burden and costs would be reduced by modifying the "serious health condition" provision.
Commenters: We received over 1,000 identically worded e-mails on this rule. In addition, we received comments from the National Association of Manufacturers (7); TFMLA Technical Corrections Coalition (25); Society for Human Resource Management (26); National Federation of Independent Business (30); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); Washington Business Group on Health (40); Howell Instruments (57); CNF, Inc. (59); Gill Studios (61); Excel Energy (63); Adolph's Coffee Service (64); Bedford, Brent (65); Coors of Longview (66); Commonwealth of Virginia (87); LPA (102); SBC Communications (190); Wegmans Food Markets (55); Equal Employment Advisory Council (2); Laurie Gronlund (162); and Mary Curtin (169).

2. Request for Leave and Notice

Citation: 29 CFR Part 208 & Part 302 (d)

Description of Existing Regulation: An employee is not required to expressly refer to the FMLA for leave to qualify as FMLA leave. Employer must follow-up with employee to determine if leave qualifies under FMLA, after employee requests time off and provides a reason. Employer has two days after request to determine if leave qualifies under FMLA.

Small Business Impact: No.

Commenter Description of Issues:

• Employee should bear more of the responsibility for requesting/designating leave FMLA. The time required for employer to make a determination is excessive. When an employee calls in sick, a supervisor is often unaware that the mention of illness triggers obligations to determine FMLA coverage.
• Mistakenly ignoring or misreading FMLA regulation can put employers in court or out of business. Individual supervisors are personally liable under FMLA.
• Supervisors are uncomfortable investigating employees' medical/personal circumstances.
• Two day notice requirement is too burdensome, since designation of FMLA may be tied to the process for payroll records, completed on a weekly or biweekly basis.
• Two day notice, post-leave, is burdensome and allows for misuse by employees.

Commenter Proposed Solutions:

• Amend 29 CFR 825.208 & 825.302 (c), so that employees must request FMLA leave in order for it to be designated as FMLA leave.
• Permit employers to require employee provide at least 5 days advance notice, unless it's a serious health emergency that physically prevents employee from giving notice

Estimate of Economic Impacts:

• Reduced cost to employers, since less time will be spent investigating whether an employee's leave qualifies under FMLA.
• Eliminates personal liability for employers' supervisors.
• Reduced administrative costs.
• Lower productivity losses, with fewer employees misusing FMLA leave.
• Higher morale, with fewer employees misusing FMLA leave.
• Less time spent trying to manage unexpected absences.

Commenters: TFMLA Technical Corrections Coalition (25); Society for Human Resource Management (26); Ogletree, Deakins, Nash, Smoak & Stewart (33); CNF, Inc. (59); Gill Studios (61); Bedford, Brent (65); LPA (102); SBC Communications (190); U.S. Chamber of Commerce (32).

3. Intermittent Leave

Citation: 29 CFR Part 825.203 (d)

Description of Existing Regulation: Employer may limit leave increments to the shortest period of time that the employer's payroll system uses to account for absences or use of leave, provided it is one hour or less.

Commenter Description of Issues:
• Employees who are frequently and unpredictably absent play havoc on productivity and scheduling for an entire department.
• Employees can misuse to justify tardiness and early departures.
• An employer can have regular tardiness and never run out of FMLA leave.
• For the health care industry, intermittent leave is particularly difficult, with the need to avoid harming patients or other valued employees.
• It's administratively difficult to track intermittent leave in small increments.
• It's administratively difficult esp. with respect to "white collar" employees exempt from the FLSA overtime requirements.
• The threshold for mandatory FMLA compliance based on business size creates a disincentive for small businesses to expand.
• An employee requesting 10 min. of leave every week to attend a contact lens problem generates a significant amount of paperwork.
• It's costly.
• It's administratively more difficult to process payroll records.
• Regulations prohibit an employer from requesting for recertification a second or third medical opinion.

Commenter Proposed Solutions:
• Allow employer to require use of leave in up to half day increments.
• If a health care provider fails to specify duration and frequency, allow employers to authorize leave for an initial period of 30-90 days, with recertification required upon expiration of the initial leave period (7).
• Allow employers to request that employees provide proof of treatment received if they are off work on intermittent leave for periodic treatments (7).
• Relax regulations that prohibit employers from contacting health care providers (7).
• Rescind DOL opinion letter FMLA-101 (January 15, 1999) to amend 29 CFR Parts 825.302 & 825.303, by requiring employees provide at least one week of notice except in cases of emergency. For emergencies, employees must provide notice on the day of absence, unless they can show it was impossible to do so.
• Allow second or third medical opinions on recertification.
• Require advance notice w/ limited exceptions and with sufficient details explaining reasons for leave.

Estimate of Economic Impacts:
• Less paperwork/ record-keeping.
• Increased productivity.
• Less misuse by employees.
• The employer's administrative burden is disproportionate to the attainment of any real benefit to the employee.
• The value of absences consisting of portions of a day, to an otherwise legitimate beneficiary of FMLA leave, is marginal at best, given the time to commute to work and prepare for work.

Commenters: We received over 1,000 identically worded e-mails on this rule. In addition, we received comments from the Equal Employment Advisory Council (2); National Association of Manufacturers (7); Valley Employers Association (10); TFMLA Technical Corrections Coalition (25); Society for Human Resource Management (26); National Federation of Independent Business (30); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); Washington Business Group on Health (40); Wegmans Food Markets (55); Howell Instruments (57); CNF, Inc. (59); Gill Studios (61); Excel Energy (63); Bedford, Brent (65); Coors of Longview (66); Curto, Samantha (165); Townley, Angela (166); Gartzke, Nicole (168); Ashby, Denise (171); Dudley, Brad (164); LPA (102); and SBC Communications (190).

4. Perfect Attendance Awards

Citation: 29 CFR Part 825.215 (c)(2) and 29 CFR 825.220

Description of Existing Regulation: Taking leave cannot result in the loss of any employment benefit accrued prior to the date of leave. The DOL has interpreted this to include perfect attendance awards.

Commenter Description of Issues:
• Detrimental for employee moral, when employees who have been absent for months receive recognition alongside their colleagues who have not been absent.
• Employers have eliminated attendance awards, since they have become meaningless.
• Congress intended the protection of health insurance, sick leave, annual leave, etc. not attendance awards.
• Policy significantly increases recordkeeping for employers, since they must count employee absences due to FMLA in several different ways.

Small Business Impact: None.

Commenter Proposed Solutions: Clarify the statute so that employers may record FMLA leaves as absences for purposes of perfect attendance awards only.

Economic Impact: No comments

Commenters: TFMLA Technical Corrections Coalition (25); Society for Human Resource Management (26); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); CNF, Inc. (59); Exel Energy (63); Bedford, Brent (65); LPA (102).

5. Inability to Work

Citation: 29 CFR Part 825.115

Description of Existing Regulation: An employee may take FMLA leave when he or she is unable to perform the essential functions of his or her job, within the meaning of the ADA (42 USC 12101 et seq.), and the regulations at 29 CFR Sec. 1630.2(n).

Commenter Description of Issues: The Department of Labor's interpretation of the regulation is too broad, since an employee who cannot perform one essential function may take leave.

Small Business Impact: No.
Commenter Proposed Solutions:

• Amend the statute to limit an employee’s use of FMLA leave to situations where a serious health condition prevents the employee from performing the majority of essential job functions.
• Permit employers to provide “light duty” or other alternative work for employees unable to perform their regular jobs.

Economic Impact: Allowing employees to be put on “light duty” rather than leave will reduce costs associated with employee absences.

Commenters: TFMLA Technical Corrections Coalition (25); Society for Human Resource Management (26); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); CNF, Inc. (59); Gill Studios (61); Bedford, Brent (65).

6. Substitution of Paid Leave

Citation: 29 CFR Part 825.207

Description of Existing Regulation: FMLA permits an eligible employee to substitute paid leave for FMLA leave in some circumstances. An employer is not required to allow substitution of paid sick or medical leave for unpaid FMLA leave where the employer's uniform policy would not normally allow such paid leave. If an employee does not choose to substitute accrued paid leave, the employer may require that the employee use accrued paid leave.

Commenter Description of Issues:

• Most FMLA leave has become paid leave.
• Regulations prohibit employers from disciplining employees’ absences, even though employers pay for those absences under their short-term disability programs (when an employee or employer elects to substitute paid leave).
• Employers can't monitor employee absences for employees that qualify for FMLA
• Companies that had generous leave programs prior to FMLA find it unaffordable and difficult to administer their programs.

Small Business Impact: No.

Commenter Proposed Solutions:

• Amend statute to require employee to choose between paid leave and FMLA leave.
• Amend Section 102 (d) (2) of the Family Medical Leave Act with specific language provided, essentially requiring employee to choose between paid and unpaid leave, notwithstanding subparagraphs (A) and (B) of the Family Medical Leave Act.

Economic Impact: A change in policy would provide an incentive for employers to continue their generous sick leave policies.

Commenter: TFMLA Technical Corrections Coalition (25).

7. Temporary Agency Workers

Citation: 29 CFR Part 825.104; 825.106(d); Opinion Letter FMLA 37

Description of Existing Regulation: The FLMA defines a “covered employee” as having worked a minimum of 12 months and performed a minimum of 1250 hours of service for his/her employer during the previous 12 month
period. These regulations direct that temporary agency workers shall be counted toward the 50 employee threshold for employer coverage.

Commenter Description of Issues:

- The regulations do not specifically address whether time worked performing services for a covered employer by a temporary agency worker, who is subsequently hired by the employer, must be counted toward the hours worked and minimum service requirements for FMLA eligibility.
- DOL Opinion Letter FMLA 37 interprets these regulations to require that an employee's time worked for a temporary agency be counted toward both the 1250 work hour and 12 months of service thresholds.
- This Opinion letter interpretation, neither dictated by statute nor regulations, creates burden on employers, who cannot verify the time records of temporary employees.
- This also imposes a cost burden on employers by expanding the definition of “covered employee” beyond the original intent of the FMLA.

Small Business Impact: No.

Commenter Proposed Solutions:

- Rescind DOL Opinion Letter FMLA-37 and any similar letters or guidance.
- Revise current regulations 29 CFR 825.106 and/or 104 so that they explicitly exclude time worked for a temporary agency from the 1250 hours/12 months of service thresholds for FMLA leave eligibility.

Economic Impact:

- Reduction of administrative burden by more narrowly defining “covered employee”.
- Reduction of cost burden by limiting FMLA leaves to those employees who actually meet eligibility requirements with their current employer.

Commenters: CNF, Inc. (59).
77. **Medical Certification**

**Regulating Agency:** Department of Labor, Employment Standards Administration

**Citation:** 29 CFR Part 825.307 & 825.308

**Description of Existing Regulation:** Prohibits employer from contacting the health care provider of the employee directly to verify information without the employee's permission, including to clarify information.

**Commenter Description of Issues:**

- Costly, since if the form is incomplete, then the employer must spend extra time verifying.
- “Does the fact that a healthcare provider checked ‘yes’ to ‘serious health condition’ override the Act’s language and above all its intent?”
- Restrictions on contacting physician for leave & fitness to return to duty are burdensome.
- Forcing employers not to delay the return of an employee to work can create unnecessary risk to patients and co-workers.
- Doctors may fill out forms at employee’s behest due to fear of malpractice suites.
- Employees allowed to get non-serious medical conditions certified encourages other employees to do the same, and this drives up medical costs.

**Small Business Impact:** No

**Commenter Proposed Solutions:**

- Employer should have the right to question healthcare provider's rationale with regard to method of treatment and prognosis without having to seek a second opinion.
- Allow employers to verify info the same way other employee absences for illness are verified, while protecting employee privacy.
- Amend regulation so that employers may directly contact health care providers to authenticate or clarify medical certification.
- Require medical certification for each absence.
- Medical certification form should reinforce that short-term illnesses do not qualify employee for FMLA leave.
- Revise 29 CFR Parts 825.307 and 825.308 regulations to allow an employer to seek simple clarification and/or verification of an FMLA certification directly from health care providers.

**Estimate of Economic Impacts:**

- Employers and health care providers will be able to communicate so that health care providers understand an employee’s job.
- Employers will be able to more easily determine if leave qualifies as FMLA.
- A change will reduce related FMLA costs, since only those who qualify for FMLA will get it.

**Commenters:** TFMLA Technical Corrections Coalition (25); Society for Human Resource Management (26); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); Wegmans Food Markets (55); CNF, Inc. (59); Excel Energy (63); Bedford, Brent (65); LPA (102); SBC Communications (190).
78.  Computer Professional Exemption under the Fair Labor Standards Act (FLSA)

Regulating Agency: Department of Labor, Employment Standards Administration

Citation: 29 CFR 541.3(a)(4)

Authority: 29 USC Section 213(a)(17)

Description of What Regulatory Prompt Would Do: Clarify what “other similarly skilled workers” are in the context of which worker categories are considered exempt workers under the FLSA for individuals in computer-related occupations.

Commenter Description of Issue(s):

• Significant changes have occurred in computer professional occupations and the information technology industry and the proper interpretation of the exemption of “other similarly skilled workers” has become difficult for compliance oriented employers.
• Regulatory clarification has not been provided by DOL after the 1996 amendments that added computer systems analysts, computer programmers, software engineers, and “other similarly skilled workers” in the exemption category.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Clarify what “other similarly skilled workers” are in the context of which worker categories are considered exempt workers under the Fair Labor Standards Act.

Estimate of Economic Impacts: None provided.

Commenter(s): National Association of Computer Consultant Businesses (9).
79. **White Collar Exemption**

**Regulating Agency:** Department of Labor

**Citation:** 29 CFR Part 541

**Authority:** Fair Labor Standards Act of 1938, as amended (29 USC 201, et seq.)

**Description of Existing Regulation:** Under the Act, employees working in a “bona fide executive, administrative, or professional capacity” are exempt from the overtime wage requirements. DOL defines exempt employees as those who meet each of three tests. These tests are: 1) the employee must be paid a salary, not an hourly wage 2) the amount of the salary must be commensurate with professional or managerial status 3) the employee's job responsibilities/duties must indicate professional or managerial status.

**Commenter Description of Issues:**

- Administrative exception language is difficult to interpret to apply the standard.
- Minimum salary language is outdated.
- Regulations not well designed for use in the public sector.
- The regulatory duties test leads to inconsistent results in classifications of similarly situated employees.
- Duties test involves difficult and subjective determinations. As a result, the duties test is a source of contention in DOL audits.
- The definition of a “white collar” employee is inconsistent with the modern notion of this term, resulting in confusion and litigation.
- Restrictions prevent employers from offering employees more flexible work schedules.
- Restrictions prevent employers from using essential disciplinary tools, such as one-day suspensions without pay.
- Many highly skilled employees have been classified as “nonexempt,” even though this classification is inconsistent with the intent of the statute.
- The computer professionals exemption, added in 1992, is outdated because of technological progress.
- Litigation trends demonstrate how the plaintiffs' bar has targeted employers under the outmoded regulations. In 2001, FLSA class actions outpaced employment discrimination class actions.
- Highly-skilled employees who refer to written procedures or practices are generally considered not to exercise discretion and therefore classified as nonexempt, leading to absurd results.
- Many highly skilled employees who perform non-manual work do not have a formal degree, and therefore cannot be exempt.
- Jobs not included in the computer professionals exemption, such as database and network administrators, are in danger of being considered nonexempt.
- Nearly obsolete terms, such as “computer keypunch operators” are frequently mentioned in the regulations.
- Small businesses do not have adequate staff to interpret the regulations.
- In small businesses, the line between employee and manager is frequently blurred.

**Small Business Impact:** No.

**Commenter Proposed Solutions:**

- Expand the explanation of administrative exception including examples particularly as it relates to “the performance of office or nonmanual work directly related to management policies.”
- Update minimum salary language.
- Secretary of Labor needs to work with both private and public sector representatives to reach solutions that meet the needs of twenty-first century workplaces.
• Amend regulation so criteria reflect the modern workplace, including programmers and other technical personnel in the workplace today.
• Change the salary basis test to permit employers to deduct pay for partial day absences.
• Grant employers more flexibility to use suspensions without pay as a disciplinary measure.
• Eliminate the administrative-production dichotomy under the administrative exemption.
• Clarify or eliminate the Regulatory Definition of Discretion.
• Redefine the definition of a professional to recognize skills instead of degrees.
• Modify the computer professionals definition consistent with current technology.
• Simplify the current hybrid wage test and the responsibility test. Changes should reflect the modern workplace, and the geographic and economic factors that differentiate businesses.

Estimated Economic Impacts:

• Cost of administrative difficulties, attributable to ambiguities in the regulation's language.
• Changes should reduce litigation associated with misclassifications and loss of exemptions because of violations of the salary basis test.
• Changes will allow the Wage and Hour Division to focus its enforcement funds on the worst offenders.

Commenters: LPA (27); National Federation of Independent Business (30); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nah, Smoak & Stewart (33); CNF, Inc (59); Gill Studios (61); Excel Energy (63); Bedford, Brent (65); City of Richardson, TX (86); IPMA (154); Laurie Gronlund (163); Harold Fujita (173); National Association of Computer Consultant Businesses (150); Jaffus Hardrick (153); National Association of Computer Consultant Businesses (15).
80. **FLSA Administrative Exemption**

**Regulating Agency:** Department of Labor, Employment Standards Administration

**Citation:** 29 C.F.R. Part 541; Administrative Exemption: Part 541, Subpart B sections 541.201 through 541.208

**Authority:** 29 U.S.C. 201 et seq.

**Description of What Existing Regulation Does:** These regulations discuss the types of administrative employees, types of work, and categories of duties.

**Commenter Description of Issue(s):**

- The administrative exemption language is hard to interpret and use in the application of the standards.
- The minimum salary language is outdated.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Expand the explanation of administrative exception, including examples particularly as it relates to the "performance of office or non-manual work directly related to management policies."
- Update the minimum salary language.

**Estimate of Economic Impacts:** None given.

**Commenter(s):** Wisconsin Department of Transportation (90).
81. Permanent Labor Certification

Regulating Agency: Department of Labor, Employment Standards Administration

Citation: Proposed Rule, 67 Fed. Reg. 30466 (May 6, 2002), RIN 1205-AA66, amending 20 C.F.R. Parts 655 and 656

Authority: 8 USC Sections 1101 et seq.

Description of Proposed Regulation: The Department of Labor is proposing to amend its regulations governing the filing and processing of labor certification applications for the permanent employment of aliens in the United States to implement a new system for filing and processing such applications. The proposed rule would also amend the regulations governing the employer's wage obligation under the H-1B program.

Commenter Description of Issue(s):

• The proposed rule does not address the underlying assumption and concepts of individual recruitment as a labor market test, the issues of prevailing wage determinations, and ignores the real-world recruitment practices of the business community.
• The proposed rule reimposes outmoded processes of testing the labor market, does not take full advantage of technology, and ignores individual business needs.
• The proposed rule discourages companies from training and promoting their best employees in that it does not allow for experience gained with an employer.
• Penalty provisions do not target “willful” or “intentional” violations of law nor allow for corrective measures for those employers who attempt good faith compliance.
• Current prevailing wage laws make it impossible to get the lowest possible bid and abide with the law. Subcontractors find themselves paying employees off the books and often at less than the prevailing wage.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Promulgate final regulations that use a broader approach to the issue of certifying the unavailability of U.S. workers for positions for which foreign nationals are sponsored, including integrating concepts such as those outlined in the Labor market Information Pilot Program, enacted but never implemented by DOL.
• The Department could improve the current proposed rule also be incorporating practices it accepts in the current Reduction in Recruitment program that has been operating successfully for several years, and recognizing legitimate employer recruitment efforts as a baseline.
• DOL should explore avenues that would present efficiencies of scale such as pre-certifying established U.S. sponsors or multiple openings.

Estimate of Economic Impacts: None given.

Commenter(s): U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak, and Stewart (33); American Council on International Personnel (183); Brent Bedford (65); Paul Savage (175).
82. Service Contract Act/Wage Determination Process/Wage Surveys

Regulating Agency: Department of Labor, Employment Standards Administration

Citation: 40 C.F.R. Part 60-2

Authority: 41 U.S.C. Sections 351 et seq.

Description of What Existing Regulation Does: The current regulations establish procedures regarding pay and benefits for service employees performing government contract work and laborers and mechanics employed by contractors and subcontractors engaged in Federal construction projects. The current regulations require that prevailing wages and benefits be afforded to these individuals.

Commenter Description of Issue(s):

• The current method of determining prevailing wage is insufficient.
• There is a lack of good survey data since approximately 1996 and there are systemic flaws in the wage determination process.
• The process has prevented service contractors from paying their employees a market-based wage, while government employees and members of the military received regular cost of living adjustments.
• There are substantial inaccuracies in wage reports relied upon by DOL in determining prevailing wages.
• Pressure from Congress and GAO in the late 1990s forced DOL to undertake significant changes to the entire wage determination process. Those changes included comprehensive surveys, redesigned contractor wage reporting forms, verifications of information reported to DOL, improved technology.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Reform the regulatory definition of “in the locality” (29 CFR Parts 4 et seq.) so that wage determinations directly reflect wages in the nearby area, instead of excessively broad areas.
• Reform the regulations setting the wage calculation process once the Bureau of Labor Statistics conducts the surveys.
• Reform the directory of occupations (index of jobs for which prevailing wages are maintained) to reflect current jobs.
• In the absence of regular wage determinations, the SCA should be amended to provide for regular wage increases based on the cost-of-living adjustment provided to Federal employees.
• DOL should have enough information on the measures implemented in the late 1990s to issue proposed amendments to the Federal regulations governing its prevailing wage determinations. DOL should do so.


Commenter(s): LPA (27); U.S. Chamber of Commerce (32); Brent Bedford (65); Olgetree, Deakins, Nash, Smoak, and Stewart (33); Paul Savage (175).
83. **Davis Bacon Act/Service Contract Act – Inclusion of Pension and Benefit Plans**

**Regulating Agency:** Department of Labor, Employment Standards Administration

**Citation:** 40 C.F.R. Part 60-2

**Authority:** 40 U.S.C. Sections 276a et seq. and 41 U.S.C. Sections 351 et seq.

**Description of What Existing Regulation Does:** The current regulations establish procedures regarding pay and benefits for service employees performing government contract work and laborers and mechanics employed by contractors and subcontractors engaged in Federal construction projects. The current regulations require that prevailing wages and benefits be afforded to these individuals.

**Commenter Description of Issue(s):**

- The treatment of self-insured/self-funded employee pension and benefit plans under the current regulations is inappropriate and unnecessary because it disallows applicable credit toward the fringe benefits requirements of relevant Prevailing Wage Determinations.
- The Davis-Bacon Act and Service Contract Act are outdated in that they apply to all contracts over $2,000 – this is too low and covers almost all contracts.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Review and revise regulations regarding the treatment of self-insured/self-funded employee pension and benefit plans to permit the crediting of employee benefits paid by self-insured company programs to be applied toward prevailing wage determinations.
- Raise the threshold amount for Davis-Bacon and Service Contract Act applicability from $2,000 to $75,000.
- When self-funded/self-insured plans meet financial obligations of the employer and are actuarially sound, the contractor maintaining such plans should not be placed at a competitive disadvantage merely because the plans are not part of a collective bargaining agreement.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Council for Employment Law Equity (3).
84. Service Contract Act – Wage Increases and Benefit Improvements during the Term of the Government Contract

Regulating Agency: Department of Labor, Employment Standards Administration

Citation: 29 CFR Parts 4.53-4.56

Authority: 41 U.S.C. Sections 351-358

Description of Existing Regulation: Under the Service Contract Act, every Federal service contract or subcontract greater than $2500 requires wages and fringe benefits to be “prevailing.” An alternative to the “prevailing wage” determinations, wages and benefits may be established by a collective bargaining agreement.

Commenter Description of Issues: Federal regulations have expanded the practice of setting “prevailing wages” and benefits in accordance with the terms of a particular collective bargaining agreement by establishing disparate standards for nonunion employers, who want to grant wage increases and benefit improvements over the period of a government contract.

Small Business Impact: No.

Commenter Proposed Solutions: SCA regulations should be revised to equalize treatment of union and nonunion contractors with respect to implementation of wage and benefit improvements to service employees during the term of the Federal service contract.

Estimated Economic Impacts: Changes will:

• Remove the current bias against nonunion contractors.
• Allow proper and timely adjustment of wages and benefits without discrimination based on collective bargaining status.
• Reduce costs of Federal service contracts for the government and taxpayers by eliminating the incentive for artificially higher collectively bargained wages and benefits.
• Help to better ensure more accurate “prevailing” rates on Federal service contracts.

85.  **Fair Labor Standards Act (FLSA) & Medical Leave**

**Regulating Agency:** Department of Labor, Employment Standards Administration

**Citation:** 29 CFR 785.1

**Authority:** 29 USC 206(a) and 207(a)

**Description of What Existing Regulation Does:** The FLSA establishes minimum wage, overtime pay, recordkeeping, and child labor standards affecting full-time and part-time workers in the private sector and in Federal, State, and local governments. Employees are paid for all hours worked in a work week/pay period.

**Commenter Description of Issue(s):** Currently under DOL's regulations and FLSA, employees are supposed to "make up time" for hours taken for a doctor's appointment, in the same workweek. This is confusing to many employees who think in terms of a pay period.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** Allow for "make up time" to occur within a pay period and not within the same workweek.

**Estimate of Economic Impacts:** None given.

**Commenter(s):** Jennifer Young (194).
86. **Across the Board Penalties**

**Regulating Agency:** Department of Labor, Employment Standards Administration

**Citation:** 29 CFR Part 825

**Authority:** Family Medical Leave Act 1993

**Description of What Regulatory Prompt Would Do:** The regulatory prompt would request that DOL address the penalty provisions in current regulations that go beyond Congressional intent and have been challenged in court. It should also eliminate erroneous rules struck down by the Supreme Court (i.e. permitting employees to claim more than 12 workweeks of FMLA leave per year even if they have not be harmed by the employer’s late designation of FMLA leave).

**Commenter Description of Issue(s):**
- The Supreme Court struck down a portion of existing DOL regulations in the first FMLA case before the Supreme Court (Ragsdale v. Wolverine Worldwide, Inc.). The Court decided that permitting employees to claim more than 12 workweeks of FMLA leave per year even if they have not be harmed by the employer’s late designation of FMLA leave, as allowed by regulations (29 CFR Section 825.700a).
- Although the Court focused on one particular DOL regulation, there are a number of other DOL regulations that impose “across the board” penalties that will not meet the Court’s standard, in light of the rationale the Court used in Ragsdale.
- There are DOL regulations that include penalty provisions are now in question because they may not withstand judicial scrutiny.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** The regulatory prompt would request that DOL address the penalty provisions in current regulations that go beyond Congressional intent and have been challenged in court. It should also eliminate erroneous rules struck down by the Supreme Court (i.e. permitting employees to claim more than 12 workweeks of FMLA leave per year even if they have not be harmed by the employer’s late designation of FMLA leave).

**Estimate of Economic Impacts:** None given.

**Commenter(s):** FMLA Technical Corrections Coalition (25).
87. **H-1B LCA**

**Regulating Agency:** Department of Labor/Employment and Training Administration

**Citation:** 20 C.F.R Parts 655 and 656, Proposed Rule, 67 Fed. Reg 30466 (May 6, 2002) RN 1205-AA66, amending 20 CFR Parts 655

**Authority:** 8U.S.C. Section 1101 et seq.

**Description of What Existing Regulation Does:** Sets out the procedures to secure information sufficient to make factual determinations of: (i) Whether U.S. workers are available to perform temporary employment in the United States, for which an employer desires to employ nonimmigrant foreign workers, and (ii) whether the employment of aliens for such temporary work will adversely affect the wages or working conditions of similarly employed U.S. workers.

**Commenter Description of Issue(s):** The current regulations:

- Impose significant logistical and practical burdens on employers.
- Do not represent a streamlined process.
- Are problematic with regards to the treatment of traveling employees, increased paperwork requirements, wage and benefit issues, ignorance and interference with normal business practices and legal commercial transactions.
- Violated the APA and PRA in the manner in which they were promulgated.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Create new regulations which better address these concerns.
- Promulgate final regulations that use a broader approach to the issue of certifying the unavailability of U.S. workers for positions for which foreign nationals are sponsored, including integrating concepts such as those outlined in the Labor Market Information Pilot Program enacted in the Immigration Act of 1990, but never implemented by DOL.
- Incorporate practices it accepts in the current Reduction in Recruitment program and recognizing legitimate employer recruitment efforts as a baseline.

**Estimate of Economic Impacts:** None given.

**Commenter(s):** Brent Bedford (65); U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoah & Stewart (33); American Council on International Personnel (183).
88. Explosives

Regulating Agency: Department of Labor/MSHA

Citation: 30 CFR 56.6000

Authority: 30 U.S.C. 811

Description of What Existing Regulation Does. The regulation requires certain safety precautions to protect miners who work with or around explosives. 30 CFR 56.6000 defines the terms relating to the MSHA regulations for use of explosives in mines, including “blasting agent,” “explosive,” and “detonator.”

Commenter Description of Issue(s): The definitions of terms used in the regulation are outdated and inconsistent with DOT regulations. The current DOT requirements are superior to the 1989 MSHA requirements. MSHA has acknowledged this and administratively voided violations based on obsolete terms. However, administrative burden could be avoided if MSHA updated the regulations to reflect current DOT standards.

Small Business Impact: This issue does not uniformly impact the entire mining industry. Individual mines who are charged under obsolete MSHA rules incur undue burdens to appeal the violation to MSHA. This administrative burden may be of particular concern to small mines.

Commenter Proposed Solution(s): Propose that MSHA update the regulation to incorporate by reference the appropriate, most recent version of 49 CFR.

Estimate of Economic Impacts: None provided.

Commenter(s): Institute of Makers of Explosives (184).
89. **Affirmative Action and EO Survey**

**Regulating Agency:** Department of Labor, Office of Federal Contract Compliance Programs (OFCCP)

**Citation:** 41 C.F.R. Part 60-2

**Authority:** Executive Order 11246

**Description of What Existing Regulation Does:** The current regulations establish the purpose and contents of affirmative action programs, methods to determine availability of jobs to minority groups and women, and set forth requirements for affirmative action programs.

**Commenter Description of Issue(s):**

- Affirmative action programs are required for each physical establishment, unless the contractor reaches agreement providing otherwise with OFCCP. Contractors are forced to create, maintain and report on many more AAPS than they had prior to the 2000 revisions of this requirement.
- The EO Survey is too burdensome and there are less burdensome ways to collect information that would ensure compliance.
- OFCCP recordkeeping and reporting burden amounts to 11 million hours.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Allow companies to report as they always have, by functional groupings. Also develop guidelines for functional affirmative action programs.
- Eliminate, or greatly simplify and shorten the EO survey.
- OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

**Estimate of Economic Impacts:** None given.

**Commenter(s):** U.S. Chamber of Commerce (32); Brent Bedford (65); CNF Inc. (59); Gill Studios (61); Olgetree
Deakins, Nash, Smoak, and Stewart (33); Congressman Doug Ose (108).
90. Explosives and Process Safety Management

Regulating Agency: Department of Labor/OSHA

Citation: 29 CFR 1910.109

Authority: 29 U.S.C. 653, 655

Description of What Existing Regulation Does: The regulation requires certain safety precautions to protect employees who work with or around explosives.

Commenter Description of Issue(s):

• The existing regulations are outdated and contain outdated references to DOT explosives classifications. OSHA requirements applicable to explosives are spread across several different standards.
• The OSHA regulations overlap/conflict with requirements in the jurisdiction of other Federal agencies, such as the DOT and the Bureau of Alcohol, Tobacco and Firearms.

Small Business Impact: None given.

Commenter Proposed Solution(s):

• The Institute of Makers of Explosives has drafted a proposed revised section 1910.109 that it intends to present to OSHA. The revised standard would address the problems discussed above.
• Suggest OSHA initiate rulemaking to replace the outdated 1910.109 with the IME revised 1910.109.

Estimate of Economic Impacts: None provided.

Commenter(s): Institute of Makers of Explosives (184).
91. Hexavalent Chromium

Regulating Agency: Department of Labor/OSHA

Citation: N/A

Authority: Occupational Safety and Health Act, 29 U.S.C.

Description of What Proposed Regulation Would Do: Implement a lower permissible exposure limit (PEL) for hexavalent chromium.

Commenter Description of Issue(s):

- Hexavalent chromium is used in chrome plating, stainless steel welding and the production of chromate pigments and dyes. Airborne hexavalent chromium is a carcinogen.
- OSHA estimates that approximately 1 million workers are exposed to hexavalent chromium, and every year hundreds of workers die prematurely of lung cancer because of that exposure. As many as 34 percent of workers could contract lung cancer if exposed for eight hours a day for 45 years at OSHA current exposure limit.

Small Business Impact: N/A

Commenter Proposed Solution(s): Propose OSHA implement the lower PEL that has been proven feasible.

Estimate of Economic Impacts: The regulation would save hundreds of lives.

Commenter(s): OMB Watch (77).
92. Hazard Communication

Regulating Agency: Department of Labor/OSHA

Citation: 29 CFR 1910.1200

Authority: Occupational Safety and Health Act, 29 U.S.C. 655

Description of What Existing Regulation Does. The regulations set forth specific requirements for employers to ensure that the hazards of all chemicals produced or imported are evaluated and that information concerning their hazards is transmitted to employers and employees so that appropriate protective measures can be instituted.

Commenter Description of Issue(s): The requirement that employers keep every material safety data sheet (MSDS) for every substance used in certain office settings is absurd. This information is readily available on the Internet and it should not be necessary to keep large binders of MSDSs.

Small Business Impact: The administrative burden of copying and filing MSDSs, as well as finding space to store large binders of MSDSs is more pronounced for small businesses and private health care practices.

Commenter Proposed Solution(s): None provided.

Estimate of Economic Impacts: None provided.

Commenter(s): Jack Irwin (130).
93. **Lead in Construction Standard**

Regulating Agency: Department of Labor/OSHA

Citation: 29 CFR 1926.62

Authority: Residential Lead-Based Paint Hazard Reduction Act, 42 U.S.C. 4853

**Description of What Existing Regulation Does.** The regulation sets forth requirements to reduce exposures to lead in the construction industry.

**Commenter Description of Issue(s):** In 1993 OSHA issued an Interim Final Lead in Construction Standard. This standard was promulgated without fully considering exposure data for specific residential construction and remodeling activities. The standard is problematic for two reasons. First, the Standard applies to residential structures where no lead-based paint exists. The Consumer Product Safety Commission banned the use of lead-based paint in homes in 1977, which means there has been no lead-based paint in homes or apartments built after 1978. Second, there was limited data available to support the applicability of a lead standard to the construction industry when the rule was issued.

**Small Business Impact:** Because the majority of businesses engaged in residential remodeling activities are small businesses, the impact of this regulation in this industry segment is substantial. This rule was promulgated prior to the passage of the Small Business Regulatory Enforcement Fairness Act, so small business impact were not identified.

**Commenter Proposed Solution(s):** Propose that OSHA:

- immediately issue a standard interpretation letter to exempt from compliance all residential remodeling activities that are performed on homes built after 1977;
- review this regulation to determine if it has become unnecessary; and
- reopen the rulemaking process to finalize a permanent Lead in Construction standard, seek stakeholder input and assess the economic impact on small employers.

**Estimate of Economic Impacts:** In the preamble to the Lead in Construction Standard, OSHA estimated the total annual recurring costs of the standard for residential remodeling activities would be $59,163,000.

**Commenter(s):** National Association of Home Builders (48).
94. Payment for Personal Protective Equipment

Regulating Agency: Department of Labor/OSHA

Citation: N/A

Authority: Occupational Safety and Health Act, 29 U.S.C.

Description of Proposed Regulation. Require employers to pay for all PPE (with an exception for safety shoes and maybe goggles, on the theory that they could be worn outside the workplace).

Commenter Description of Issue(s):

• Some OSHA rules explicitly require that employers pay for safety equipment that employees must wear and others do not. Over the years, OSHA enforced these rules by, in most cases, requiring the employer to pay when the employee was required to use PPE. The courts, however, struck down this interpretation and said employers only had to pay when the rule was explicit.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Propose OSHA promulgate a rule that would require employers to pay for all PPE (with an exception for safety shoes and maybe goggles, on the theory that they could be worn outside the workplace).

Estimate of Economic Impacts: None provided.

Commenter(s): OMB Watch (77).
95. Exposure to Silica

Regulating Agency: Department of Labor/OSHA

Citation: N/A

Authority: Occupational Safety and Health Act, 29 U.S.C.

Description of What Regulatory Prompt Would Do: Lower the permissible exposure limit (PEL) for respirable silica and promulgate a standard to protect workers affected by silica dust.

Commenter Description of Issue(s):

• Silicosis is a disease caused by inhaling silica dust, the most common mineral in the Earth’s surface. Cases of silicosis appear in rock drill operators working on surface mines and highways, construction workers who use sand in abrasive blasting and foundry workers who make sand castings. NIOSH has recommended exposure limits that are much lower than those currently existing.
• Silicosis is entirely preventable with the implementation of conventional public health methods including the use of less hazardous materials, dust suppression techniques, improved ventilation and respirator use. However, due to under-utilization of these techniques, silicosis remains a problem.

Small Business Impact: NA

Commenter Proposed Solution(s): Propose OSHA lower the PEL for respirable silica and promulgate a standard to protect workers affected by silica dust.

Estimate of Economic Impacts: A rule would save thousands of lives and prevent many years of respiratory illnesses.

Commenter(s): OMB Watch (77).
96. **Sling Standard**

**Regulating Agency:** Department of Labor/OSHA

**Citation:** 29 CFR 1910.184

**Authority:** 29 U.S.C. 655(b)(1)-(5)

**Description of What Existing Regulation Does:** The regulations set safety requirements in the use of slings to lift, hoist, and load heavy items.

**Commenter Description of Issue(s):**

- The current standard is out of date. It is nearly 30 years old and does not address current industry practices.
- The sling standard is also in conflict with the consensus standard B30.9, which was promulgated by the American Society of Mechanical Engineers and which represents the current safety practices of the industry.

**Small Business Impact:** The sling standard has a disproportionate impact on small firms.

**Commenter Proposed Solution(s):**

- Propose OSHA issue an updated standard that is more realistic and practical for sling operations today. The standard should be based on the ASME B30.9 standard.
- Propose OSHA issue a public enforcement notice citing the ASME B30.9 standard as the sole basis for OSHA citations regarding sling safety until the revised OSHA sling standard is implemented.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Small Business Administration, Office of Advocacy (97), Brent Bedford (65), Associated Wire Rope Fabricators (35), U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart, P.C. (33).
97. **Tuberculosis (TB) Standard**

**Regulating Agency:** Department of Labor/OSHA

**Citation:** N/A

**Authority:** Occupational Safety and Health Act, 29 U.S.C.

**Description of Proposed Regulation:** OSHA proposed a rule to protect workers in high risk occupations from tuberculosis in Oct. 1997. The agency has not yet issued a final rule.

**Commenter Description of Issue(s):** TB is a contagious airborne disease that is potentially lethal and tends to affect those with more vulnerable immune systems. The failure to promulgate a final rule means that workers are denied enforceable protections.

**Small Business Impact:** N/A

**Commenter Proposed Solution(s):** Propose OSHA promulgate a rule to protect workers from TB exposure.

**Estimate of Economic Impacts:** OSHA estimates that a workplace standard would help protect an estimated 5.3 million workers in more than 100,000 hospitals, nursing homes, hospices, correctional facilities, homeless shelters and other work settings with a significant risk of TB infection, and would save over 130 lives per year.

**Commenter(s):** OMB Watch (77).
98. **Walking/Working Surfaces**

**Regulating Agency:** Department of Labor/OSHA

**Citation:** 29 CFR 1910.24

**Authority:** Occupational Safety and Health Act, 29 U.S.C.

**Description of What Existing Regulation Does:** The Fixed Stair Standard defines the requirements for fixed ladders or stairs around machinery, tanks and other equipment and leading to or from floors, platforms or pits.

**Commenter Description of Issue(s):**

- The Standard requires the use of fixed ladders when, under certain circumstances, spiral stairways or ship stairs would be safer. It is very common to have a tight location in industry where there is insufficient space for stairs that meet the OSHA requirements. Employers are required to use rung ladders in those areas, which are less safe than spiral or ship stairs.

**Small Business Impact:** N/A

**Commenter Proposed Solution(s):**

- Propose OSHA revise the Walking/Working Surfaces regulations to permit the use of ship stairs and spiral stairs.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Copper & Brass Fabricators Council, Inc. (16).
99. Process Safety Management (PSM) of Highly Hazardous Chemicals

Regulating Agency: Department of Labor/OSHA

Citation: 29 C.F.R. 1910.119

Authority: 29 U.S.C. 653, 655 & 657

Description of What Existing Regulation Does: The standard applies to all facilities that operate a process involving more than a threshold amount of a highly hazardous chemical. The standard is intended to prevent or minimize the consequences of a catastrophic release of toxic, reactive, flammable or explosive chemicals. It places a number of requirements on such facilities including process hazard analysis, operating procedures, training, procedures for management of changes, incident investigations and several others.

Commenter Description of Issue(s):

• The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: No

Commenter Proposed Solution(s): OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: The total burden is 79 million hours. The two most burdensome provisions are the requirement for procedures for the management of change (50 million hours), and the requirements for a quality assurance program to ensure the continued mechanical integrity of equipment (10 million hours).

Commenter(s): Rep. Doug Ose (108).
100. Bloodborne Pathogens Standard

Regulating Agency: Department of Labor/OSHA

Citation: 29 C.F.R. 1030

Authority: Needlestick Safety and Prevention Act of 2000 (P.L. 106-430)

Description of What Existing Regulation Does: This collection is associated with the OSHA standard for protecting workers exposed to contaminated needlesticks (largely in the hospital setting). It sets a number of requirements for employers to protect such workers including employee training, maintenance of a needlestick injury log, and recording of vaccinations to such workers.

Commenter Description of Issue(s):

• The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: No

Commenter Proposed Solution(s): OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: The burden of this collection is 35,107,856 hours.

Commenter(s): Rep. Doug Ose (108).
101. Metalworking Fluids

Regulating Agency: Department of Labor / OSHA

Citation: N/A

Authority: Occupational Safety and Health Act, 29 U.S.C.

Description of What Regulatory Prompt Would Do: Protect workers from metalworking fluids.

Commenter Description of Issue(s):

Occupational exposure to metalworking fluids can have harmful health effects and according to OSHA have been associated with skin problems such as contact dermatitis and various respiratory diseases including bronchitis. A number of epidemiological studies have found evidence that exposure to metalworking fluids can cause substantially elevated risk of cancer of the pancreas, bladder, larynx, scrotum and rectum. OSHA issued guidance on metalworking fluids in November 2001, but this is not enforceable.

Small Business Impact: NA

Commenter Proposed Solution(s):

• Propose OSHA make the guidance mandatory by promulgating a rule protecting workers from metalworking fluids.

Estimate of Economic Impacts: None provided.

Commenter(s): OMB Watch (77).
102. Recordkeeping for Work-Related Injuries, Illnesses and Fatalities

Regulating Agency: Department of Labor/OSHA

Citation: 29 CFR 1904

Authority: 29 U.S.C. 655(b)(1)-(5); 29 U.S.C. 657(c)(1)-(3)

Description of What Existing Regulation Does: The regulations require employers to record and report work-related injuries, illnesses and fatalities.

Commenter Description of Issue(s): There are several problems with the regulations, which were communicated to OSHA when the rule was initially proposed. The definition of “work-relatedness” is ambiguous. The means by which employers would be able to accurately determine the cause of an employee’s injury, and whether is it recordable is also not clear. The proposed change to the hearing loss threshold is unreasonable and unrealistic and should not be implemented. Finally, the definition of musculoskeletal disorder (MSD) must account for the work-relatedness or lack thereof, of the disorder.

Small Business Impact: The recordkeeping requirements are particularly burdensome for small employers.

Commenter Proposed Solution(s):

• Propose rescinding the regulation and working with industry to devise a clear and enforceable regulation.
• Propose maintaining the current hearing loss thresholds, and definition of “material impairment.”
• Propose including in the definition of “musculoskeletal disorder” the likelihood that the injury may have been caused in whole or significant part by, and/or significantly exacerbated by, factors unrelated to the afflicted employee’s work-related activities. Accordingly, absent a significant and ascertainable degree of work-relatedness, the MSD should not be recorded as a workplace injury or illness.

Estimate of Economic Impacts: This rule impacts 1.4 million establishments, many of which are small.

Commenter(s): Small Business Administration, Office of Advocacy (97), Brent Bedford (65), Gill Studios, Inc. (61), Ogletree Deakins Attys at Law (33), U.S. Chamber of Commerce (32).
103. Ergonomics Standard

Regulating Agency: Department of Labor / OSHA

Citation: N/A

Authority: Occupational Safety and Health Act, 29 U.S.C. 655(b)

Description of What Existing Regulation Does: The ergonomics regulation would have set forth requirements for employers, designed to protect workers from musculoskeletal disorders in jobs that require heavy lifting or forceful repetitive motion.

Commenter Description of Issue(s): OSHA has replaced the ergonomics injury standard promulgated under the previous administration with voluntary guidelines. This voluntary plan will not effectively protect workers because it is not enforceable. The literature indicates that voluntary guidelines are not an adequate substitute for regulatory standards.

Small Business Impact: NA

Commenter Proposed Solution(s): Propose OSHA promulgate a rule protecting workers from ergonomic hazards and injuries.

Estimate of Economic Impacts: Conservative estimates indicate that 24 to 813 per 1000 general industry employees will suffer a musculoskeletal disorder over the life-time that they work, depending on the particular industry in which the worker is employed. Employers annually pay out, in direct workers’ compensation costs, between $15-$18 billion, for MSD-related claims. OSHA estimated that its regulation would result in at least a $9.1 billion benefit and a $3.9 billion cost in its first 10 years (using a discount rate of 7 percent).

According to the AFL-CIO, 1.8 million workers suffered from work-related musculoskeletal disorders per year. The National Academy of Sciences reported that, in 1999, nearly 1 million people took time away from work to recover from work-related musculoskeletal pain or impairment. Conservative estimates of the economic burden imposed, as measured by compensation costs, lost wages and lost productivity, are between $45 billion and $54 billion annually.

Commenter(s): Center for Progressive Regulation (70), Council on Government Relations (145), OMB Watch (77).
104. Claims Procedures

Regulating Agency: DOL/Pension and Welfare Benefits Administration

Citation: 29 CFR 2560

Authority: Employee Retirement Income Security Act (ERISA)

Description of What Existing Regulation Does: Regulation establishes minimum requirements for benefit claims procedures of group health plans. It applies to claims filed on or after the first day of the first plan year beginning on or after July 1, 2002.

Commenter Description of Issue(s): Regulation in many instances permits state laws to govern issues and prohibit arbitrary arbitration. Because of possible enactment of Patient's Bill of Rights legislation standards established in this regulation may change.

Small Business Impact: No.

Commenter Proposed Solution(s): Suspend the current effective dates pending resolution of Patient's Bill of Rights legislation and proceed with a new rulemaking.

Estimate of Economic Impacts: No quantified costs provided. Commenters state that making changes will help reduce costs related to claims procedures by ensuring that adjustments to the regulatory standards only happen once rather than twice.

Commenter(s): U.S. Chamber of Commerce (32); Ogletree, Deakins, Nash, Smoak & Stewart (33); CNF, Inc. (59); Brent Bedford (65).
105. **Flight Simulators**

**Regulating Agency:** Department of State/Office of Defense Controls

**Citation:** 22 CFR Part 120 through 130

**Authority:** Arms Export Control Act (22 U.S.C. 2778)

**Description of What Existing Regulation Does:** The State Department has the authority to control the export of items on the United States Munitions List (22 CFR 121). This list includes not only military hardware, software, electronics, and training equipment, but the technical data associated with these items as well.

**Commenter Description of Issue(s):**

- The commenter wants to export to the Brazilian Test Pilot School a training device based on that used by the U.S. Air Force Test Pilot School. The simulator should not fall within the Munitions List because it is a generic simulator, not appropriate for training a person to pilot, navigate, or fight and not including aerodynamic or operational information about any specific planes. He challenges the idea that the simulator is a “defense article.” State has responded that any aircraft simulator sold to a foreign military customer falls within the export laws.
- The commenter believes that this is a knee-jerk application of regulations serving no purpose and not contributing to national security. He also challenges the appeals processes as a grotesque perversion of the concept of due process because appeals are handled internally.

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):**

- OIRA should consider the issue of export requirements, specifically the adverse effect of the ITAR implementation upon small businesses in the aerospace sector.
- OIRA should press for regulatory reform to promote, not hinder, the exportation of products that should not, by common-sense standards, be subject to ITAR, but which currently and unfairly appear to be, due to sweeping inclusions in the wording of the regulations, such as the language used throughout the list, “including, but not limited to”.

**Estimate of Economic Impacts:** This small business must spend the time and effort necessary to comply with the regulations, including registering as an exporter and applying for a license, both of which require the payment of fees.

**Commenter(s):** Ralph Smith, High Plains Engineering (180).
106. Disadvantaged Business Enterprise Program - Excessive and Conflicting Paperwork

Regulating Agency: Department of Transportation

Citation: 49 CFR Part 26

Authority: P. L. 105-78 and 49 USC 47107 and 47113

Description of What Existing Regulation Does: DOT has separate DBE requirements for its major grant programs. FHWA has statewide annual goals, but FAA has required a separate annual goal for each airport (as well as for airport concessions). Furthermore, each agency has separate annual reporting forms that differ and do not comply with the regulation.

Commenter Description of Issue(s):

• Entirely too much paperwork and inconsistency between FHWA and FTA, and FAA's insistence on its own annual and separate goal setting justifications.
• Although there may be some justification for separate goals for concessions in each airport, there is no reason for separate goals for each airport, particularly when most air carrier airports in Wisconsin have only one or two federally funded contracts each year.

Small Business Impact: Program serves small businesses owned and controlled by socially and economically disadvantaged individuals.

Commenter Proposed Solution(s):

• A new uniform DBE achievement reporting form and OMB approval of the form.
• Amend regulation to clarify what firms are to be included in "Bidder's List" and eliminate/modify requirements for "gross receipts information."
• Eliminate actual payment requirements, the new trucking counting regulation and race/gender presumptions
• Amend or clarify provisions requiring all recipients in Wisconsin to "sign an agreement for a Unified Certification Program and "submit to Secretary for approval."

Estimate of Economic Impacts: Commenter states that there are no requirements in Federal statutes for imposing rigorous and contradictory race and gender conscious mechanisms on the States or their citizens.

Commenter(s): State of Wisconsin Department of Transportation (90).
107. General Definitions

Regulating Agency: DOT/Federal Aviation Administration

Citation: Title 14, CFR, Aeronautics & Space Subchapter A - Definitions, Part 1 - Definitions and Abbreviations, 1.1 General Definitions; 27 FR 4588

Authority: 49 U.S.C. 106(g), 40113, 44701

Description of What Existing Regulation Does: The rule defines the terms “major repair” to be 1) a repair that, if improperly done, might appreciably affect weight, balance, structural strength, performance, powerplant operation, flight characteristics, or other qualities affecting airworthiness; or 2) a repair that is not done according to accepted practices or cannot be done by elementary operations. The rule also defines the term “minor repair” to be “a repair other than a major repair.”

Commenter Description of Issue(s):

• The definitions are outdated.
• The rule is inconsistent with parallel European regulations.
• Current implementation of the rule is costly and penalizes maintenance facilities by discounting the quality of their work.

Small Business Impact: No

Commenter Proposed Solution(s):

• The definition of “major repair” and the “major repair” guidance material should be revised to focus on the repair design, not the repair embodiment.

Estimate of Economic Impacts: The rules cost operators manpower and money while providing very little improvement in safety. The cost of accomplishing the repair process is estimated to be one-quarter the resale value of an airplane.

Commenter(s): Boeing (62).
108. Design and Construction (General)

Regulating Agency: DOT/Federal Aviation Administration

Citation: 14 CFR 25.601; 19 FR 18289

Authority: 49 U.S.C. 106(g), 40113, 44701-44702, 44704

Description of What Existing Regulation Does: This rule requires that airplanes “may not have design features or details that experience has shown to be hazardous or unreliable. The suitability of each questionable design detail and part must be established by tests.”

Commenter Description of Issue(s):

- The rule is applied inconsistently, allowing FAA to implement policy without prior notice and comment.
- The rule has not undergone a cost/benefit analysis.

Small Business Impact: No

Commenter Proposed Solution: The rule should be deleted.

Estimate of Economic Impacts: The rule imposes significant costs in terms of manpower, testing, and physical changes to airplanes.

Commenter(s): Boeing (62).
109. Standards for Approval for High Altitude Operation of Subsonic Transport Airplanes

Regulating Agency: DOT/Federal Aviation Administration

Citation: 14 CFR 25.831, 25.841, Amendment 25-87; 61 FR 28965

Authority: 49 U.S.C. 106(g), 40113, 44701-44702, 44704

Description of What Existing Regulation Does: The portions of the rule addressed by commenters establish cabin ventilation and pressure requirements.

Commenter Description of Issue(s):

• The minimum amount of fresh air requirement is unattainable and does not increase safety.
• Compliance with the temperature and humidity provisions would be costly while not increasing safety.
• Rule requirements are prescriptive rather than performance-based, which limits design innovation.
• Pressurization provisions do not increase safety significantly.

Small Business Impact: No

Commenter Proposed Solution(s):

• The Aviation Rulemaking Advisory Committee (ARAC) should develop and propose new rules based on input from recognized subject matter experts.

Estimate of Economic Impacts: For manufacturers, the rule require significant hardware and software expenses. The costs inhibit development of new subsonic airplanes and derivatives of existing models competitive with the existing fleet. For aircraft, the rule decreases fuel economy and increases engine emissions.

Commenter(s): Boeing (62).
110. Seats, Berths, Safety Belts, and Harnesses

Regulating Agency: DOT/Federal Aviation Administration

Citation: 14 CFR 25.785; 61 FR 57945

Authority: 49 U.S.C. 106(g), 40113, 44701-44702, 44704

Description of What Existing Regulation Does: This amendment defines two new types of passenger emergency exits in transport category airplanes, provides more consistent standards with respect to the passenger seating allowed for each exit type and combination of exit types, and requires escape slides to be erected in less time.

Commenter Description of Issue(s): Several terms in the rule are vague and are interpreted inconsistently.

Small Business Impact: No

Commenter Proposed Solution(s):

• The terms "injury" and "injurious" should be more explicit as to the type and severity of injury to be avoided.
• The terms "occupant" and "person" should be clarified.
• The terms "firm" and "moderately rough air" should be quantified.

Estimate of Economic Impacts: More compliance discrepancies or incomplete certifications are attributed to this regulation than other seat-related regulations. This impact was not quantified.

Commenter(s): Boeing (62).
111. **Emergency Landing Dynamic Conditions**

**Regulating Agency:** DOT/Federal Aviation Administration

**Citation:** 14 CFR 25.562; 53 FR 17640

**Authority:** 49 U.S.C. 1344, 1354(a), 1355, 1421, 1423, 1424, 1428, 1429, 1430; 49 USC 106(g); and 49 CFR 1.47(a).

**Description of What Existing Regulation Does:** This rule revised the seat and restraint system requirements for transport category airplanes to ensure that seats meet crashworthiness performance standards.

**Commenter Description of Issue(s):**
- Rule has significantly increased costs to seat manufacturers and installers.
- A recent study of the benefits and costs of this rule suggest the benefits were overstated.

**Small Business Impact:** No

**Commenter Proposed Solution(s):**
- Instead of implementing the injury criteria, the rule should emphasize the structural capability of the seat under dynamic emergency landing conditions.
- The cost-benefit analysis should be re-analyzed.

**Estimate of Economic Impacts:** For Boeing, the rule imposes $5 million/year in costs. The costs to seat manufacturers, airframe modification companies, and other U.S. airframe manufacturers is likely in the tens of millions of dollars per year.

**Commenter(s):** Boeing (62).
112. Improved Flammability Standards for Thermal/Acoustic Insulation Materials used in Transport Category Airplanes

Regulating Agency: DOT/Federal Aviation Administration

Citation: 14 CFR 25.853; 14 CFR 91.613; 14 CFR 121.312; 14 CFR 125.113; 14 CFR 135.170

Authority: 49 U.S.C. Parts 25, 91, 121, 125, and 135

Description of What Existing Regulation Does: This rule governs flammability resistance and increase flame penetration resistance for insulation materials installed on commercial aircraft.

Commenter Description of Issue(s):

• The rule lacks an adequate cost/benefit analysis.
• The assumptions used in the supporting cost/benefit analysis are not supported by experience and overstate the benefits.
• The requirements are infeasible.

Small Business Impact: No

Commenter Proposed Solution(s):

• The enhanced flammability resistance standards should only be applied to new type designs.
• The burn-through resistance provision should be deleted because it is not cost/benefit effective.

Estimate of Economic Impacts:

• Revision to thousands of part numbers for current production, resulting in approximately 660,000 man hours of engineering labor ($93 million).
• Recurring expenditures for engineering labor for out-of-production blanket orders.
• Additional radiant panel testing and burn-through tests of multiple configurations: approximately $3 million per year.
• To meet the burn-through requirements, approximately 70 percent of blankets would have to be revised.
• To meet burn-through standard, required materials will likely be more expensive than current materials.

Commenter(s): Boeing (62).
113. Contract Requirements for Minor Federally Funded Transportation Projects

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR 810

Authority: 23 USC 133(b)(8) and (d)(2) as defined in 23 USC 101(a)(35).

Description of What Existing Regulation Does: The rules govern transportation enhancement activities, which are intended to improve the transportation experience in and through local communities.

Commenter Description of Issue(s):  
- Local enhancement projects have high administration costs and require extensive State oversight simply to inform local personnel of Federal contract requirements.
- Federal funding requirements are geared to large highway construction projects, not smaller non-highway projects. Most of the time, typical highway development rules don't fit these projects and even the reduced requirements for these projects are excessively burdensome and confusing.

Small Business Impact: No.

Commenter Proposed Solution(s): Implement a grant program for locals to administer what would significantly reduce costs and the amount of oversight. Possible solutions include:

- authorize USDOT/FHWA to approve alternative state or local processes/provisions if considered sufficiently similar to Federal requirements;
- substantially increase the $ amount required before all the Federal mandatory contract requirements apply; and/or
- simply exempt the transportation enhancements, congestion mitigation and air quality and similar programs from most of the standard Federal contract requirements as long as they don't exceed a certain $ amount.

Estimate of Economic Impacts: Would greatly reduce staff time and administrative costs. Compliance is already inconsistent due to lack of local familiarity with extensive Federal contract requirements for this type of work.

Commenter(s): State of Wisconsin Department of Transportation (90).
114. Historic Preservation Regulations

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR Part 771.135 [Section 4(f) (49 U.S.C. 303)]; and 36 CFR Part 800

Authority: 23 USC 138, 49 USC 303 [formerly 49 USC 1653(f), Section 4(f) of the Department of Transportation Act]; and 16 USC 470f (National Historic Preservation Act of 1966)

Description of What Existing Regulation Does: The regulation provides for the protection of historic places from transportation projects.

Commenter Description of Issue(s):

• Inconsistent and uncoordinated overlap between 4(f) requirements and the Section 106 process for historic properties.
• Section 106 and Section 4(f) overlap because they both protect properties listed on the National Register of Historic Places. Transportation agencies end up satisfying two sets of requirements—Section 106 & 4(f)—when a transportation project affects one of these historic properties, and this results in delays and duplicative analysis and reports. Non-transportation agencies only have to satisfy the requirements of Section 106.

Small Business Impact: No.

Commenter Proposed Solution(s): Legislatively eliminate historic properties from Section 4(f) or change Federal regulation, 23 CFR 771.135, to allow compliance with Section 106 to satisfy Section 4(f), for properties on the National Register of Historic Places.

Estimate of Economic Impacts: Costs are related to project delays. Most transportation designers will do anything to avoid a 4(f) designation, so delays are rare. What we do see is poor decisions, based on avoiding the historic resource, that result in the loss of other resources. In addition, there is no guaranteed long-term protection for a privately owned historic resource; and we often find that after meeting the requirements of both laws, minimizing harm and most likely avoiding the site, it is razed by the owner.

Commenter(s): State of Wisconsin Department of Transportation (90).
115. Outdoor Advertising Control

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR 750.707 (c), (d) and (e)

Authority: 23 USC 131

Description of What Existing Regulation Does: The rule governs the erection and maintenance of outdoor advertising signs, displays, and devices in areas adjacent to certain highways to protect the public investment in such highways, to promote the safety and recreational value of public travel, and to preserve natural beauty.

Commenter Description of Issue(s):

• Wisconsin enacted conforming legislation to the Federal Highway Beautification Act that created a class of nonconforming signs in 1972. Other nonconforming signs have come into existence over the years due to changes in highway designations, zoning and other changes.
• It has prohibited States and local units of government from requiring removal of nonconforming signs after a period of time. Federal law requires payment for removal of the signs regardless of how old or how long they have been nonconforming.
• The Federal law allows these nonconforming signs to continue to exist for the remainder of their normal structural life with reasonable maintenance, but not perpetually. However, it provides no mechanism for establishing that normal life expectancy. The legislative intent is that nonconforming signs disappear over time. It has not happened.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Amend 23 CFR 750.707 (c), (d) and (e) so that the regulation clearly spells out what is the “duration of its normal life” of a nonconforming sign “subject to customary maintenance.”
• The regulation should state that cumulative reasonable repair or maintenance of a sign cannot exceed 50 percent of the replacement costs of the same.
• The regulation should be amended to set a deadline for the continued existence of any nonconforming sign. When it loses its nonconforming status the sign should no longer lawful and must be removed at the sole expense of the sign owner.

Estimate of Economic Impacts: Commenter argues that the proposed solution would save expenditures of public funds to acquire nonconforming signs, would protect the funds needed and used for public investment in such highways, would promote the safety and recreational value of public travel, and would preserve natural beauty. They would also allow fair competition and not give a geographic monopoly to the owners of nonconforming signs that presently continue long beyond any normal expected structural life -- perhaps perpetually.

Commenter(s): State of Wisconsin Department of Transportation (90).
116. Highway Design

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR 625

Authority: 23 USC 109 – Infrastructure Program Administration Design Standards

Description of What Existing Regulation Does: Design standards for projects on the National Highway System (NHS) must be approved by FHWA. State highway departments develop design standards through a series of committees and task forces. FHWA contributes to the development of the design standards through membership on these working units, sponsoring and participating in research efforts, and many other initiatives. Following development of the design standards, FHWA issues regulations that adopt those it considers suitable for application on the NHS.

Commenter Description of Issue(s):

• One of the key deficiencies in geometric design and traffic engineering that has been recognized repeatedly over the years is the failure to produce design standards and practices that are carefully indexed to different types of theoretical "design drivers."
• A "design driver" is a set of driver variables, such as choices of perception-reaction time, driver height-of-eye in relation to sight distance, and motor control capabilities that are representative of segments of the driving population and that differ markedly from younger to older members of the driving population.
• Different types of roads present different safety risks depending on how well they are designed and built. Freeways and expressways using the highest level of design and carefully applied traffic engineering techniques tend to have low fatal crash rates.
• As one descends in what is called the functional classification of type of road (from freeways to arterial highways to collector roads and then to local streets), there is a clear trend of increasing fatal crash and fatality rates that has persisted for several decades.
• The configuration, or geometry, of a highway has two main parts: its alignment, that is, how the road is laid out linearly before the driver; and the width of its lanes, shoulders, and immediate roadside environment. Both of these basic components of highway design are crucial to operating safety and together they are referred to by highway designers as cross-section elements.
• Leaving the travel lanes and entering the off-road area is especially dangerous because many fixed object hazards are located near the edge of the travelway. Oftentimes, these fixed objects are also narrow, such as trees, light poles, signal supports or the leading ends of barriers, so that impacts involve tremendous crash forces concentrated in only a small part of the vehicle.
• The current generation of barriers and crash cushions, in particular, are designed primarily to respond to impacts by passenger vehicles. This means that much safety hardware on our roadides either fails to protect larger, heavier vehicles from the hazards that are being shielded or, in some cases, actually creates more dangerous crash conditions.

Small Business Impact: No.

Commenter Proposed Solution(s):

• FHWA should develop a uniform set of human factors criteria which specify "design drivers" governing highway geometric design and traffic engineering standards.
• FHWA should require the use of state-of-the-art engineering standards on the National Highway System and other Federal-aid Highways.
• FHWA should issue standards, not just guidelines, to regulate geometric design on highways constructed with Federal funding.
• FHWA should require improved safety and crash data collection in work zones.
FHWA needs to establish specific standards for barriers and impact attenuators that can reduce the severity of heavy vehicle roadside crashes and to require the use of these improved safety designs as a condition of receiving Federal assistance for highway reconstruction and rehabilitation.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
117. Traffic Operations (Intersection Safety and Traffic Control Devices)

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR Part 655

Authority: 23 U.S.C. 109(d) and 402(a)

Description of What Existing Regulation Does: The rules prescribe FHWA's policies and procedures to ensure basic uniformity of traffic control devices on all streets and highways. They include the Manual on Uniform Traffic Control Devices (MUTCD), which is the national standard for all traffic control devices installed on any street, highway, or bicycle trail open to public travel.

Commenter Description of Issue(s):

• Vehicle conflicts at intersections produce an overabundance of severe crashes with fatalities and serious injuries. Estimates by NHTSA and other organizations indicate that more than 40 percent of all fatalities occur in vehicle collisions at or near intersections.

• In crashes at intersections vehicle occupants are vulnerable to severe injury and death because the majority of the collisions involve side impacts into one of the vehicles.

• Pedestrians are particularly vulnerable when they cross a road because a driver failing to obey the direction of signs, markings, and signals can easily kill or seriously injure a pedestrian.

• One of the many problems inherent in current traffic engineering criteria detailing safe pedestrian crossing of highways and streets, is the inadequate time allotted by most traffic control signals for pedestrians, particularly older citizens and those with ambulatory disabilities to cross busy streets.

• Traffic control devices, such as signs, pavement markings and signals, are essential in promoting highway safety. They assist drivers in knowing exactly where they are on a roadway, especially at night and under adverse weather conditions, and they alert drivers about what to expect ahead.

• A crucial feature of both warning and guide signs is early detection and rapid comprehension of their messages so that drivers have enough time to make corrections in their driving or to make choices of destination. Consequently, signs need to be conspicuous and legible so that drivers can safely perform maneuvers consistent with the information supplied.

• It is well recognized that the current standard for one inch of letter height on signs for each 50 feet of viewing distance is inadequate for older drivers, particularly now that average travel speeds have increased since the repeal of the national speed limit. Research findings repeatedly indicate that legibility standards should probably be improved to at least one inch of letter height for each 40 feet of viewing distance.

Small Business Impact: No.

Commenter Proposed Solution(s):

• FHWA should emphasize the need for State and local governments to provide safer intersections for vehicles and pedestrians through better design, improved traffic control measures and, where warranted, rehabilitation or reconstruction of intersections.

• States should enact legislation that enables localities to install photo enforcement.

• FHWA and the States should revise the existing practices for traffic control devices to permit longer phasing for pedestrian signals to enable safer pedestrian crossing on high-volume roadways.

• FHWA should establish standards with minimum levels of brightness for traffic signs.

• FHWA should amend current standards to require one inch of letter height on signs for every 40 feet of viewing distance.
Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
118. Highway Work Zone Safety

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR Part 630

Authority: Section 1051 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA)

Description of What Existing Regulation Does: The rules govern FHWA's highway work zone safety program to improve work zone safety at highway construction sites by enhancing the quality and effectiveness of traffic control devices, safety appurtenances, traffic control plans, and bidding practices for traffic control devices and services.

Commenter Description of Issue(s):

• This area of highway design and operation deserves treatment in its own right because major reconstruction and resurfacing of U.S. roads and streets has continued to increase over the last 20 years as roads and bridges have reached the end of their useful lives.
• Providing drivers safe travel paths and guarding against crashes in highway work areas has become even more critical due to the increase in opportunities for severe crashes, occurring simply because of the nature of the work being pursued in the construction or maintenance zone.

Small Business Impact: No.

Commenter Proposed Solution(s):

• FHWA should evaluate and revise the standards for temporary traffic control in highway work zones, especially for driver decision sight distance, temporary alignment and cross-section design features contained in the Manual on Uniform Traffic Control Devices (MUTCD), in order to provide a safer operating environment for commercial vehicles on roads undergoing reconstruction and maintenance.
• FHWA should also revise the MUTCD sections on pedestrian and worker safety given the unnecessary pedestrian deaths and injuries that occur in highway and street work zones, as well as the very high fatality rate for construction workers.
• FHWA also needs to require the States to report work zone injury and fatal crash data with appropriate measures of exposure in order to determine whether specific traffic control practices and other safety countermeasures have measurable benefits.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93)
119. Commercial Vehicle Size and Weight

Regulating Agency: DOT/Federal Highway Administration (FHWA)

Citation: 23 CFR 657 and 658

Authority: 23 USC Section 127, Vehicle Weight Limitations -- Interstate System; 49 USC Section 31111, Length Limitations

Description of What Existing Regulation Does: The rules govern a program of vehicle size and weight enforcement on Federal-aid (FA) highways, including the required annual certification by the State. The plans describe the procedures, resources, and facilities that States devote to the enforcement of its vehicle size and weight laws. Each State plan must be accepted by the FHWA and will then serve as a basis by which the annual certification of enforcement will be judged for adequacy.

Commenter Description of Issue(s):

• The submission date for the vehicle size and weight enforcement plan is out of synchronization with the annual size and weight compliance certification date.
• The timing of FHWA's acceptance and return of comments on the certification and plan have not been predictable, nor received at a time to have a meaningful effect on the content of the next subsequent enforcement plan.
• There are firm indications that both the sizes and weights of large commercial vehicles have reached and even exceeded the operating safety and structural limits of our highways.
• Truck sizes and weights are subject to a confusing patchwork of other Federal and state limits and legal exemptions. These provisions have multiplied over the past quarter-century to the point where the nation's infrastructure is unable to accommodate today's big trucks.
• Numerous studies have consistently shown that increasing the gross, that is, the total or overall weight of large trucks, rapidly increases their chances of suffering a rollover crash.
• Similarly, extra-heavy, overweight trucks have significantly poorer braking which results in longer stopping distances than lighter trucks.
• Studies, such as those performed by the American Association of State Highway and Transportation Officials in the late 1980s, showed that even trailers 48 feet long could not negotiate a large percentage of the nation's freeway ramps because of offtracking. Offtracking consists of the different paths taken by the front steering tires and the wider path taken by the rear cargo tires of a large vehicle.
• Longer combination vehicles (LCVs) are even more dangerous because they are composed of two or even three trailing cargo units instead of just one.
• Overweight axles and excessive gross weights also radically increase both the severity and rate of damage to road pavement and to bridges.

Small Business Impact: No.

Commenter Proposed Solution(s):

• FHWA should prepare and deliver comments on annual size and weight certification by March 1 each year in order to include action based on comments in the enforcement plan that it submits around July to August.
• Consolidate submission of the enforcement plan and certification on the same date.
• Congress should extend the current Federal weight limit (80,000 pounds) and length limit (53 feet) to the entire National Highway System.
• Congress should continue the freeze on LCVs.
• Congress should not enact special interest exemptions that permit trucks to exceed current Federal gross and axle weight limits.
• States should not permit increased weight limits on state and local roads and streets.
Estimate of Economic Impacts: None provided.

Commenter(s): State of Wisconsin Department of Transportation (90); Public Citizen/Advocates for Highway and Auto Safety (93).
120. Transportation Planning and Environmental Review Procedures

Regulating Agency: DOT/Federal Highway Administration (FHWA) and Federal Transit Administration (FTA)

Citation: 23 CFR Parts 450 and 771

Authority: Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) and National Environmental Policy Act of 1969 (NEPA)

Description of What Existing Regulation Does: These rules govern the development of statewide and metropolitan transportation plans and ensure compliance with NEPA requirements concerning environmental impacts of transportation plans. DOT issued proposals in May 2000 to implement TEA-21 provisions for more effective coordination of the planning and NEPA processes. By integrating planning and project development, DOT hoped to make decisions on investment choices and trade-offs more rational and environmentally sound while reducing paperwork and regulatory burden.

Commenter Description of Issue(s):

• The May 2000 proposals would complicate, not streamline, DOT's existing procedures.
• Current Federal planning and environmental review procedures for highway and transit projects are costly and complex. Environmental streamlining should thus remain a top DOT priority.

Small Business Impact: No.

Commenter Proposed Solution(s):

• FHWA and FTA should formally withdraw the May 2000 proposed regulations and should close the rulemaking dockets for these regulations.
• FHWA and FTA should defer new rulemaking involving these issues (i.e., modifying or replacing 23 CFR Parts 450 and 771) until after the upcoming reauthorization of the Federal surface transportation program.

Estimate of Economic Impacts: None provided.

Commenter(s): American Association of State Highway and Transportation Officials (88).
121. Inspection, Repair, and Maintenance

Regulating Agency: DOT/Federal Motor Carrier Safety Administration (FMCSA)

Citation: 49 CFR 396

Authority: 49 U.S.C. 31133, 31136, and 31502; 49 CFR 1.48

Description of What Existing Regulation Does: Under this rule, FMCSA and State officials use information collected from motor carriers during compliance and enforcement activities to verify that they have established an inspection, repair, and maintenance program for their equipment. It is generally recognized that there is a relationship between inspection, repair, and maintenance practices for commercial motor vehicles (CMVs) and defect-related CMV accidents. CMVs are frequently operated in excess of 100,000 miles annually.

Commenter Description of Issue(s):

• The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: No

Commenter Proposed Solution(s): OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: The burden of this collection is 35,107,856 hours.

Commenter(s): Rep. Doug Ose (108).
122.  Background Checks for Truckers Hauling Hazardous Materials

Regulating Agency: DOT/Federal Motor Carrier Safety Administration (FMCSA)

Citation: N/A

Authority: USA Patriot Act, Section 1012

Description of What Regulation Would Do: The Patriot Act prohibits States from issuing licenses to operate motor vehicles that transport hazardous materials unless DOT has determined that the operator does not pose a security risk. DOJ will be providing certain information to DOT as part of DOT’s risk assessment.

Commenter Description of Issue(s):

• This requirement would impose a heavy and unnecessary burden on small trucking companies.
• Some of the truckload shipments that would be considered hazardous materials under this requirement include consumer products such as air fresheners aerosols.

Small Business Impact: Yes

Commenter Proposed Solution(s): None provided.

Estimate of Economic Impacts: The delays in hiring and assigning drivers caused by the background check requirement could put small operations out of business.

Commenter(s): Alan Parsons (109).
123. Commercial Vehicle Cross-Border Safety

Regulating Agency: DOT/Federal Motor Carrier Safety Administration (FMCSA)

Citation: 49 CFR Parts 350, 365, 368, 385, 387, 393

Authority: Transportation and Related Agencies Appropriations Act, 2002

Description of What Existing Regulation Does: The rules establish requirements for cross-border operations by Mexican motor carriers after the U.S.-Mexican border is opened pursuant to the North American Free Trade Agreement.

Commenter Description of Issue(s):

• The impending opening of the U.S. borders to Mexican trucks and truck drivers, under the North American Free Trade Agreement (NAFTA), has the potential to exacerbate the truck safety problems encountered on U.S. roads and streets if certain safety precautions are not met.
• The NAFTA agreement failed to link the schedule for the opening of the border to the development of a truck safety program in Mexico that would bring its program up to par with Canada and the U.S.
• U.S. safety inspections and border enforcement efforts are severely inadequate.

Small Business Impact: No.

Commenter Proposed Solution(s):

• DOT should require on-site, at the place of business, full safety compliance reviews of Mexican motor carriers applying to operate nationwide before they are awarded interstate operating authority.
• DOT should put into place at all border crossings adequate safety measures including:
  - Permanent inspection facilities and space to conduct Level 1 inspections;
  - Weigh-in-motion systems and fixed scales to enforce U.S. size and weight requirements;
  - Sufficient number of trained inspectors to cover all hours of cross-border commercial vehicle operations;
  - Sufficient number of inspectors in place to conduct a meaningful number of inspections;
  - Technology infrastructure to allow telephonic and computer links to databases to verify the validity of all drivers licenses and safety performance monitoring of all carriers.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93)
124. **Hours of Service for Truckers**

**Regulating Agency:** DOT/Federal Motor Carrier Safety Administration (FMCSA)

**Citation:** 49 CFR 350, 390, 394, 395, and 398

**Authority:** Interstate Commerce Commission Termination Act of 1995

**Description of What Existing/Proposed Regulation Does:** The current rules impose strict limits on the number of hours that commercial motor vehicle (CMV) drivers in interstate commerce may be on duty. The rules permit only limited exceptions. Almost all interstate CMV drivers are currently required to prepare and file a paper logbook called the record of duty status (RODS). The NPRM issued in May 2000 would have, among other things, replaced the current 18 to 23-hour on-duty/off-duty work cycle with a 24-hour work cycle and required electronic on-board recorders for certain carriers.

**Commenter Description of Issue(s):**

- FMCSA’s May 2000 NPRM generated many adverse comments.
- FMCSA did not present data supporting its assertion that fatigue contributes to accidents or that its proposal would address fatigue or accidents.
- Depending on the causes of accidents, the proposal may increase fatal accidents.
- The PRA burden associated with this rule is over 10 million hours.

**Small Business Impact:** Yes

**Commenter Proposed Solution(s):**

- FMCSA should issue a supplemental NPRM instead of a final rule.
- FMCSA should collect data on the causes of accidents (e.g., road congestion, road quality).
- Improve enforcement of current rules and adopt flexible new rules.
- Adopt a “thirty-six hour three day” regulation allowing 10 hours of driving per day.
- OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

**Estimate of Economic Impacts:** One commenter argued DOT has overestimated the benefits and underestimated the costs. The commenter estimates the net costs of the NPRM to be $1 billion annually.

**Commenter(s):** American Road & Transportation Builders Assoc. (1); Mercatus (73); Rep. Doug Ose (108); Bernard Gray (111); Bill Hutchings (113).
125.  Federal Transit Administration (FTA) Buy America Requirements

Regulating Agency: Department of Transportation/FTA

Citation: 49 CFR Part 663

Authority: 49 USC 5323

Description of What Existing Regulation Does. Requires that each grantee procuring transit vehicles undertake a dual certification and audit process (both pre-award and post-delivery) to assure that Buy America requirements are met when vehicles are purchased.

Commenter Description of Issue(s):

• Dual certification and review represents administrative redundancy for every grantee for every vehicle procurement effort.
• For 6,000 transit agencies and most States, this dual process is repeated every time a separate bid process is undertaken Requirements also place an excessive administrative burden on manufacturers.

Small Business Impact: N/A.

Commenter Proposed Solution(s): Have manufacturers self-certify that Buy America requirements are being met, similar to other self certification processes.

Estimate of Economic Impacts: None provided.

Commenter(s): State of Wisconsin Department of Transportation (90)
126. **Set-Aside for Intercity Buses**

**Regulating Agency:** Department of Transportation/FTA

**Citation:** None provided.

**Authority:** 49 USC 5311

**Description of What Existing Regulation Does:** The Federal Transit Act requires that 15 percent of the annual formula allocation under the nonurbanized grant program be spent on intercity bus needs. The requirement is effective unless the Governor certifies that all intercity needs in the state are being met.

**Commenter Description of Issue(s):** The requirement translates into less discretion and flexibility in addressing projects of local priority and significance; less funding is available to meet other small urban and rural transit needs.

**Small Business Impact:** N/A

**Commenter Proposed Solution(s):** Intercity bus service should remain eligible but the 15 percent set-aside in 49 USC Section 5311 (f) should be repealed.

**Estimate of Economic Impacts:** NA

**Commenter(s):** State of Wisconsin Department of Transportation (90)
127. Vessel Financing Assistance

Regulating Agency: Department of Transportation/Maritime Administration

Citation: 46 CFR Section 298 et. seq

Authority: 46 USC 1101 through 1294

Description of What Existing Regulation Does: The Commenter's suggestions refer to Title XI of the Maritime Act and involves project selection and the approval of loan guarantees for shipbuilders and shipowners.

Commenter Description of Issue(s): Commenter identifies six adjustments to maritime policy, all within existing authority of the Department of Transportation, and pertaining primarily to a re-sequencing and prioritization of existing elements in the Title XI process, which would restore Title XI as a fiscally sound and viable instrument for the expansion of merchant marine and American-flag cruise industry.

Small Business Impact: N/A

Commenter Proposed Solution(s): Adopt six specific steps relating to the application and approval process for Letters of Commitment and Letters of Compliance; the preparation of impact statements, constraints on shipyard subsidies, and complementary maritime policy and legislative initiatives.

Estimate of Economic Impacts: Would give U. S. access to the multi-billion cruise market and free Title XI program from widely perceived stigma of subsidy and corporate welfare for shipbuilders.

Commenter(s): World City America Inc. (58).
128. Corporate Average Fuel Economy (CAFE) Standards

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: 49 CFR 538


Description of What Existing Regulation Does: DOT is required to issue light truck fuel economy standards for each model year. The CAFE standard must be set at the “maximum feasible” average fuel economy level, which is based on a consideration of four factors: technological feasibility, economic practicability, the effect of other motor vehicle standards on fuel economy, and the nation’s need to conserve energy. The current standard is 20.7 miles per gallon (mpg) for light trucks and 27.5 mpg for passenger cars.

Commenter Description of Issue(s):

• The increased use of light-duty trucks and SUVs for personal use has led to an average fuel efficiency for SUVs, minivans, and pickups of only 17.4 mpg, compared to 28 mpg for new cars.
• The existing standards are now obsolete in light of the availability of more fuel-efficient cars, including hybrid-electric and electric vehicles.
• If CAFE standards are raised, manufacturers are likely to raise the prices of their larger vehicles, making it considerably more expensive for families and recreationists to purchase vehicles necessary to tow travel trailers.
• Smaller vehicles have been shown in numerous studies to be less safe than larger ones.

Small Business Impact: No

Commenter Proposed Solution(s):

• NHTSA should pursue changing the CAFE standards to 40 mpg to clean up the air from vehicle emissions while lowering our dependency on oil.
• NHTSA should not raise CAFE standards for light trucks.

Estimate of Economic Impacts:

• The U.S. could save about 1 billion barrels of oil annually by raising CAFE standards over a ten-year period to a technologically feasible 40 mpg for the entire fleet of new cars and light trucks.
• Increasing the fuel efficiency of motor vehicles will reduce U.S. reliance on foreign oil at a time when this reliance is especially problematic. There may be a slightly negative economic impact for the petroleum industry.

Commenter(s): Center for Progressive Regulation (70); OMB Watch (77); Mr. & Mrs. Ken Belknap (136).
129. Head Restraints

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard 202, Head Restraints


Description of What Existing Regulation Does: Head restraints are the uppermost part of a seat, and protect the head and neck from injuries often suffered in vehicle crashes. NHTSA issued a proposed rule on January 4, 2001, that would upgrade the standard for head restraints for passenger cars and for light multipurpose vehicles, trucks, and buses.

Commenter Description of Issue(s):

• According to Public Citizen, the NHTSA proposal would toughen a standard that was issued in 1969 by adding new strength requirements, limiting the size of gaps and openings in head restraints, and applying the rule to outward-facing back seats.
• Since the January 2001 NPRM, there has been no further action on the rule, even though NHTSA has had over a year to review comments. A NHTSA official estimated that a final rule may be issued in the fall of 2002, almost two years after the proposed rule.

Small Business Impact: No.

Commenter Proposed Solution(s): This is an important safety protection that should not be delayed any longer. NHTSA should promulgate the final rule.

Estimate of Economic Impacts: According to NHTSA, 805,581 whiplash injuries occur annually, costing about $5.2 billion each year.

Commenter(s): OMB Watch (77).
130. Tire Pressure Monitoring Systems

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: 49 CFR Part 571

Authority: Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act

Description of What Existing Regulation Does: NHTSA's June 2002 final rule required manufacturers to install "direct" TPMS (which directly measure pressure with sensors in each tire) or "indirect" TPMS (which measure pressure indirectly by detecting and comparing the rotational speed of wheels making use of information generated by antilock brake systems (ABS)).

Commenter Description of Issue(s): OMB has written NHTSA indicating that it should require the use of indirect TPMSs, which do not have tire pressure sensors and which rely on the presence of ABS to detect and compare differences in the rotational speed of a vehicle's wheels.

Small Business Impact: No.

Commenter Proposed Solution(s): OMB should support the use of direct monitoring systems that prevent 30 more deaths and over 4,000 fewer injuries per year a cost of approximately $30.00 more per vehicle than the less protective alternative that OMB favors.

Estimate of Economic Impacts: Commenter stated that:

• NHTSA estimates that the direct monitoring systems would prevent 10,635 injuries and 79 deaths at an average cost of $66.33 per vehicle. However, if the average per vehicle fuel and tread life savings ($32.22 and $11.03, respectively) over the lifetime of the vehicle are factored in, the average net cost of direct systems drops to $23.08 per vehicle. The net cost per equivalent life saved is $1.9 million for direct monitoring systems.

• NHTSA estimates that indirect monitoring systems would prevent 6,585 injuries and 49 deaths at an average cost of $30.54 per vehicle. When the average per vehicle fuel and tread wear savings ($16.40 and $5.51, respectively) over the lifetime of the vehicle are factored in, the average net cost drops to $8.63 per vehicle.

Commenter(s): Center for Progressive Regulation (70).
131. **Advanced Airbags**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA)

**Citation:** 49 CFR Part 571

**Authority:** Transportation Equity Act for the 21st Century (TEA 21)

**Description of What Existing Regulation Does:** The rule requires advanced-technology air bags designed to minimize safety risks to children and small adults, provide improved occupant protection in frontal crashes, and encourage industry innovation. It provides for an unbelted crash test at 25 mph, which NHTSA issued as an interim final rule in May 2000 because the agency has not made a final determination on the unbelted test speed.

**Commenter Description of Issue(s):**
- NHTSA’s one-size-fits-all approach will not meet the preferences or protect the safety of all consumers under all conditions. Both the costs and benefits of different vehicle components, including safety features, are borne by individual consumers, who in recent years have become increasingly aware of the benefits and potential dangers of air bags.
- Although the risk tradeoffs are particular to the characteristics and behavior of vehicle occupants, NHTSA’s regulation would not allow consumers to make their own decisions regarding these tradeoffs.
- Air bags continue to provide disproportionate benefits to occupants who are not wearing seat belts and they are actually likely to increase the chance of severe injury for properly belted occupants.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**
- NHTSA should consider allowing informed consumers to make their own personal risk tradeoff decisions by, for example, permitting manufacturers to offer manual on-off switches for air bags in any vehicle. That would allow consumers (rather than a complex computer algorithm in the vehicle) to deactivate an air bag if necessary to reduce the risk to certain occupants or under certain driving conditions.
- If NHTSA is concerned that consumers would not be adequately informed as to the safety of different options, it could better focus its efforts on providing information about the characteristics and effectiveness of different occupant safety systems under different conditions.

**Estimate of Economic Impacts:** Commenters did not quantify economic impacts, but made the following points:
- NHTSA’s estimates of the cost-effectiveness of its proposal are well documented and generally reasonable, however, the individual nature of occupant restraint decisions highlights the problem with evaluating cost-effectiveness based on averages.
- Unlike some other areas in which the Federal government takes action, both the costs and benefits of occupant restraints are borne by the same individual—the occupant.

**Commenter(s):** Mercatus (73).

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard 301, Fuel System Integrity

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: Under this standard, NHTSA requires tests that simulate crashes and define performance criteria for fuel systems of light vehicles to reduce the occurrence and spread of vehicle fires. In November 2000, NHTSA proposed a revised fuel system safety standard that would require compliance with a more stringent rear-impact test. NHTSA indicated that the new tests would provide more realism, increase safety, and reduce manufacturer costs.

Commenter Description of Issue(s):
• According to NHTSA, about 4 percent of deaths in light vehicles occurred in crashes involving fire, and about 12,941 occupants per year are exposed to fire in passenger cars and light vehicles. About 1,062 (8 percent) of those exposed received moderate or severe burns.
• As Public Citizen explains, the rule would limit the amount of fuel that is allowed to spill from the vehicle's fuel system in three different crash scenarios.
• One unresolved issue in the agency proposal is the height of the deformable moving barrier used in the rear impact tests. The FMVSS 214 barrier, when lowered an additional two inches, may not be able to show the underride damage that often occurs when a small passenger vehicle rides beneath the chassis of a larger passenger vehicle, resulting in actual impacts with the target vehicle's fuel tank.
• It is clear the extent to which protection from fires due to spilled fuel, regulated by FMVSS 301, interacts with and can be improved by requirements in other crash avoidance and crashworthiness standards. Many fires could be avoided by increasing roll stability for the entire passenger vehicle fleet to prevent rollover crashes.
• The fuel system retention requirement in the current standard is much too weak and permits fuel to escape at a dangerous rate and in a dangerous amount.

Small Business Impact: No.

Commenter Proposed Solution(s):
• NHTSA has had over a year to review the comments on the proposed rule. It should write a final rule as soon as possible so that fuel systems will be upgraded to avoid deaths and injuries from fire.
• NHTSA should adopt stringent rear impact test procedures which produce safer fuel system performance by preventing fuel system breaches from high-speed collisions.
• NHTSA should use a rear impact test barrier which simulates passenger vehicle underride crashes in which a target vehicle's fuel tank is directly impacted.
• NHTSA should require that fuel tanks be mounted only forward of the rear axles of all passenger vehicles.
• NHTSA should adopt simultaneous improvements to the seat back and head restraint standards so that overall rear impact safety is addressed by comprehensive systems engineering countermeasures.
• NHTSA needs to revise the fuel leakage limits currently authorized in FMVSS 301 because quantities permitted to be released increase the chances of post-crash fires.
• NHTSA needs to establish fail-safe door latch and lock requirements, simultaneous with the adoption of a new side impact fuel integrity test, to ensure that doors can be easily opened by occupants after a crash.
• NHTSA should continue its rulemaking program on fuel integrity by next offering proposals to ensure continuing fuel system safety despite vehicle aging.
• NHTSA should require fuel flow shutoff measures and other performance requirements for preventing tank filler pipe rupture in crashes.
**Estimate of Economic Impacts:** Commenter stated that this rule would greatly reduce the occurrence of passenger exposure to fire in a vehicle crash, thereby reducing many burns and some deaths.

**Commenter(s):** OMB Watch (77); Public Citizen/Advocates for Highway and Auto Safety (93).
133. Occupant Crash Protection

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 208

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: This standard originally specified the type of occupant restraints (i.e., seat belts) required. It was amended to specify performance requirements for anthropomorphic test dummies seated in the front, outboard seats of passenger cars and of certain multipurpose passenger vehicles, trucks, and buses, including the active and passive restraint systems identified below. The purpose of the standard is to reduce the number of fatalities and the number and severity of injuries to occupants involved in frontal crashes.

Commenter Description of Issue(s):

• Frontal crash testing under the standard should be conducted at speeds above 30 mph. Even though the current frontal crash test has limitations, it was developed to provide a worst-case test condition that is representative of many severe impacts even if it does not replicate the majority of real-world crashes.
• Additional crash test modes need to be added to the standard to ensure that it provides adequate crash testing that is representative of the majority of real-world crashes.
• Improvements can be required to provide better lap/shoulder belt protection for belted occupants. Lap/shoulder belts should be required in all seating positions, not just the outboard seating positions. In addition, existing technology in the form of seat belt pre-tensioners and load limiters would improve the performance of seat belts and their interaction with air bags.
• Although adjustable upper anchorages are required to improve seat belt fit for front seat outboard occupants, no similar requirement exists for rear seat occupants.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should propose adding a high-speed offset frontal crash test requirement.
• NHTSA should increase the speed required for frontal crash tests.
• NHTSA should require that each new passenger vehicle be equipped with front seat pre-tensioners and load-limiters.
• NHTSA should require the installation of adjustable upper anchorages in the rear outboard seating positions.
• NHTSA should consider new methods to remind occupants to use seat belts.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93)
134. Lower Interior Front Impact Protection

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 201

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: The Occupant Protection In Interior Impact standard, FMVSS 201, requires protection for occupants with interior surfaces on the instrument panel (dashboard), seat back, interior compartment doors, sun visors and armrests.

Commenter Description of Issue(s):

• Lower extremity injuries have increased in frequency as occupant survival has markedly improved over the past decade. The increase in the survival rate is largely a result of advances in vehicle crashworthiness fostered by the FMVSS.
• The scope of the lower interior front impact protection standard is currently inadequate because it does not explicitly control the extent of footwell deformation and intrusion leading to this relatively common trauma produced by frontal crashes.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should upgrade FMVSS 201 to improve protection from severe injuries to lower extremities including foot and leg injuries, suffered by surviving front seat occupants.
• NHTSA should make further improvements in instrument panel design, knee bolsters, and other energy absorbing materials to reduce the severity of leg injuries.

Estimate of Economic Impacts: NHTSA has calculated that improvements to the instrument panel, including those required by FMVSS 201 and other changes introduced voluntarily, have reduced fatality and serious injury risk by about 25 percent in current production model passenger vehicles compared to earlier models. The agency estimates that about 700 lives per year are saved in cars alone.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93)
135. Passenger Vehicle Compatibility

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: N/A

Authority: N/A

Description of What Regulatory Prompt Would Do: It would improve front end and side impact energy management in smaller vehicles; modulate the height, weight, and general aggressive character of large vans, pickup trucks, and SUVs; and require improved active and passive occupant restraint systems in cars.

Commenter Description of Issue(s):

- In the crashworthiness arena, the challenge facing regulators and safety engineers is to provide good occupant protection despite a wide variety of possible types of crashes, including those between vehicles of different sizes, weights and designs.
- While some disparity in vehicle size has always existed, especially between passenger vehicles and medium and heavy trucks, there is growing disparity in size and weight among passenger vehicles. In recent years, the rapid growth in sales of light trucks and vans (LTVs), which include sport utility vehicles (SUVs), has aggravated the serious problem of vehicle and crash incompatibility.
- Statistics show that most smaller vehicles are at a distinct disadvantage in preventing life-threatening crash forces from reaching occupants when their vehicles are struck by larger vehicles.

Small Business Impact: No.

Commenter Proposed Solution(s):

- NHTSA should develop safety countermeasures to improve front end and side impact energy management in smaller vehicles.
- NHTSA should develop approaches to modulate the height, weight, and general aggressive character of large vans, pickup trucks, and SUVs.
- NHTSA should require improved active and passive occupant restraint systems in cars.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93)
136. **Rollover Protection**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA)

**Citation:** 49 CFR 575

**Authority:** Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act

**Description of What Existing Regulation Does:** NHTSA has a five-star rating system for informing consumers about the rollover resistance of passenger vehicles. This system is part of NHTSA’s New Car Assessment Program (NCAP). The ratings are based in part on the “static stability factor” (SSF), which is derived by dividing a vehicle's width by twice its height. June 2000, NHTSA issued a request for comment on a proposed rollover consumer information program based on SSF.

**Commenter Description of Issue(s):**

- In 1999, over 9,800 fatal rollover crashes involving light passenger vehicles occurred, including passenger cars and LTVs, in which 10,140 people were killed.
- Vehicles with narrower wheelbases and a relatively high center of gravity are particularly susceptible to rollover. While rollover occurs in cars, especially smaller, lighter models, the highest rollover rates occur among SUVs and pickup trucks. One of the main difficulties with current SUVs and pickup trucks is their relatively high centers of gravity compared with most passenger cars.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- NHTSA should establish a new stability performance standard for vehicles under real-world operating conditions.
- NHTSA should require improved padding on vehicle interiors.
- NHTSA should upgrade the current standard for door latch/hinge performance.
- NHTSA should require innovative anti-ejection glazing.
- NHTSA should upgrade the roof crush standard.
- NHTSA should develop a dynamic rollover test that comports with real-world experience, to improve the comparative information provided to consumers on vehicle rollover.
- NHTSA should propose and adopt a dynamic rollover standard for passenger vehicles.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93)
137. **Roof Crush**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA)

**Citation:** Federal Motor Vehicle Safety Standard (FMVSS) 216

**Authority:** Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

**Description of What Existing Regulation Does:** This standard specifies requirements for roof crush resistance over the passenger compartment.

**Commenter Description of Issue(s):**

- This safety standard is inadequate in real-world crashes and has not undergone major revision since 1971. Roof crush involves the failure or collapse of one or more of the roof supports (A, B and C pillars) and deformation or penetration of the roof into the passenger compartment.
- The present standard only requires that a force equal to one and one-half times the weight of the vehicle be applied to the reinforced sides of the roof structure known as the roof rails.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- NHTSA should upgrade the roof crush standard to include performance requirements that control general roof failure (support structures) and localized roof intrusion.
- NHTSA should upgrade the roof crush standard to require a dynamic crash test that reflects real-world crash experience.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93).
138. Passenger Vehicle Brakes

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 135

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: This standard specifies requirements for vehicles equipped with hydraulic and electric service brakes and parking brake systems to ensure safe braking performance under normal conditions and emergency conditions.

Commenter Description of Issue(s):

• Arguments claiming benefits of international harmonization were offered by both manufacturers and the agency during the protracted rulemaking on FMVSS 135. Unfortunately, not all aspects of the new standard represent improvements over the safety requirements of the original brake standard.
• FMVSS 135 allows manufacturers the option either to provide automatic illumination of the brake status check light, as before, or to provide a manual push-button that the driver must separately press in order to see if the brakes are working. Many drivers will be unaware or forget that the brakes status check light is not automatic and must be manually engaged.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA needs to verify the actual in-service safety performance of brakes designed to meet FMVSS 135, including the demonstration of the actual braking effectiveness of service brakes designed to minimum values permitted by the standard.
• NHTSA needs to demonstrate that consumers are not operating vehicles with dangerous brakes because of the elimination of brake lining and brake status warning requirements.
• NHTSA should carefully review FMVSS 135 and consider restoring important testing and performance safeguards that were deleted when the new standard was adopted.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
139. **Door Locks**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA)

**Citation:** Federal Motor Vehicle Safety Standard (FMVSS) 206

**Authority:** Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

**Description of What Existing Regulation Does:** This standard specifies requirements for side door locks and side door retention components including latches, hinges, and other supporting means, to minimize the likelihood of occupants being thrown from the vehicle as a result of impact.

**Commenter Description of Issue(s):** Despite enormous improvements in motor vehicle occupant restraint use over the past 20 years, the ejection rate of fatally injured passenger vehicle occupants is essentially unchanged. While the rate of ejection for belted occupants is very low, only 2.5 percent of those fatally injured, nearly 30 percent of unbelted occupants die because they are ejected from their vehicles.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** NHTSA needs to establish stringent door latch and lock requirements to ensure that doors, including lift gates, will not open in any type of crash, including lateral and rollover crashes, and yet can be easily opened by occupants to ensure that they can exit a vehicle after a crash.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93).
140. Child Restraints

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 213

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: The child Restraint Systems standard specifies requirements for child restraint systems used in motor vehicles and aircraft. Its purpose is to reduce the number of children killed or injured in motor vehicle crashes and in aircraft.

Commenter Description of Issue(s):

• A majority of the children who die in motor vehicle crashes are unrestrained. In 1999, about half of the children under five were not using a restraint when they died, while a slightly larger percentage (55 percent) of child occupants between the ages of five and nine were unrestrained when they were killed. Many of the children in this particular age group are too large for child safety seats, yet do not fit properly in seat belt systems designed for adults. Finally, an overwhelming majority of the fatalities among children 10-15 years old were unrestrained when they were killed.
• Since the safety environment in passenger vehicles does not adequately address the needs of children over four years old, it should come as no surprise that proper restraint use decreases as children get older. While restraint use has been reported in state surveys at 97 percent for infants and 91 percent for toddlers aged one to four years old, restraint use by children ages five through 15 is only 64 percent. As a result, many children ride unsecured and greatly at risk.
• Although FMVSS 213 covers booster seats recommended for use by children up to 50 pounds and also permits the use of belt positioning booster seats with lap/shoulder belts, the standard does not apply to children who weigh more than 50 pounds or to booster seats recommended by manufacturers for children who exceed that weight limit. However, the vast majority of children between five and nine years old, and who might benefit from the use of booster seats, weigh over 50 pounds.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should expand the scope of the child restraint system standard to children who weigh more than 50 pounds.
• NHTSA should establish minimum safety requirements for child booster seats, belt-adjusting devices, and other forms of child restraints.
• NHTSA should develop a child test dummy representative of a 10-year-old child.
• NHTSA should require that child restraints be dynamically tested.
• NHTSA should require the installation of rear seat adjustable upper anchorages to improve the fit of shoulder belts for taller, larger children.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
141. Tire Safety

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation:
- New Pneumatic Tires for Passenger Cars, FMVSS 109
- Tire Selection and Rims for Passenger Cars, FMVSS 110
- New Pneumatic Tires for Vehicles Other Than Passenger Cars, FMVSS 119
- Tire Selection and Rims for Motor Vehicles Other Than Passenger Cars, FMVSS 120

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulations Do:
- FMVSS 109 specifies tire dimensions and laboratory test requirements for bead unseating resistance; strength, endurance, and high-speed performance; defines tire load rating; and specifies labeling requirements.
- FMVSS 110 specifies requirements for original equipment tire and rim selection on new cars to prevent overloading. These include placard requirements relating to load distribution as well as rim performance requirements under conditions of rapid tire deflation.
- FMVSS 119 establishes performance and marking requirements for tires for use on multipurpose passenger vehicles, trucks, buses, trailers, and motorcycles. Its purpose is to provide safe operational performance levels for tires used on motor vehicles other than passenger cars, and to place sufficient information on the tires to permit their proper selection and use.
- FMVSS 120 specifies tire and rim selection requirements and rim marking requirements. Its purpose is to provide safe operational performance by ensuring that vehicles to which it applies are equipped with tires of adequate size and load rating and with rims of appropriate size, type designation, and manufacturer identification.

Commenter Description of Issue(s):
- NHTSA has abdicated control over the quality and safety performance of both new and retreaded/regrooved medium and heavy vehicle tires. At present, only voluntary industry standards govern the quality of recapped or retreaded truck and bus tires, and there are no tire safety performance standards for vehicles exceeding 10,000 pounds gross vehicle weight rating.
- The agency has done a poor job in providing accurate, reliable consumer information about tire safety and tire-vehicle compatibility. Currently, required tire sidewall information is obscure and difficult to understand for the average consumer, omits important real-world safety information, and is represented by letters and numerals that are very difficult to read because of their small size and low contrast. The TREAD Act required NHTSA to address concerns regarding the lack of clear and useful consumer information on tires by June 2002.
- NHTSA has failed to provide a vigorous consumer registration program to ensure that mandatory buyer registration with a tire dealer will provide the basis for comprehensive, successful defect recalls. Although the agency, in responding to the requirements in the TREAD Act, will address some of these issues, many other tire safety and consumer information items will await agency initiative.

Small Business Impact: No.

Commenter Proposed Solution(s):
• NHTSA should issue realistic safety standards, based on real-world safety performance requirements, for both new and retreaded tires for both passenger vehicles as well as medium and heavy vehicles.

• NHTSA should thoroughly revamp its requirements for tire sidewall information, on the basis of maximum intuitive understanding and legibility, in order to increase consumer comprehension of safety-critical information such as compatible tire size, manufacturing date, wet weather skid resistance, and crash avoidance capabilities for which a rating should be instituted.

• NHTSA should completely revise the UTQGS to provide consumer information on a wide range of safety-relevant tire performance characteristics including, but not limited to, tire tread life, temperature resistance, both dry and wet traction under demanding real-world operating conditions, speed ratings, load capabilities, and safety effects of over- and under-inflation.

• NHTSA should revise and restart the consumer registration and defect recall notification system by mandating dealer registration of each customer tire purchase and periodic submission to NHTSA through original tire manufacturers of all consumer registrations.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
142. Glazing Materials and Crash Avoidance

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 205

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: This standard specifies requirements for glazing materials for use in motor vehicles and motor vehicle equipment for the purpose of reducing injuries resulting from impact to glazing surfaces. The purpose of this standard is to ensure a necessary degree of transparency in motor vehicle windows for driver visibility, and to minimize the possibility of occupants being thrown through the vehicle windows in collisions.

Commenter Description of Issue(s):

• About 13,000 people die each year because they are ejected from their vehicles in crashes and more than 8,000 of those killed are entirely or partially ejected through vehicle window openings. Of this number, about two-thirds of the deaths, or 5,350, are ejected through glazed windows.
• One of the problems with plastics and plastic/glass laminates is abrasion resistance. Without good scratch resistance, in-service degradation of light transmittance can occur to the point where driver visibility is substantially impaired.
• The laboratory test is conducted with the glazing material mounted at a 90-degree angle to the light source. This test does not reflect real-world vehicle designs since many passenger vehicles, both cars and LTVs, now have windshields installed at increasingly severe angles to accomplish fundamental changes in occupant compartment design.
• The detrimental effect on driver visibility is most acute at dawn, dusk, and in severely overcast daytime operating conditions.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should adopt glazing requirements for side windows in passenger motor vehicles which ensure high levels of long-term light transmission for driver visibility at the same time helping to prevent partial and complete occupant ejection, especially in rollover and side impact crashes.
• NHTSA should adopt amendments to FMVSS 205 that would require light transmittance compliance testing at the actual angle of the installed windshield to ensure that the minimum light transmittance performance requirement of 70 percent is maintained regardless of the angle of the glazing as installed.
• NHTSA should eliminate the regulatory exemption for LTVs that allows darker tinted glazing in rear side windows which are important for driver visibility.

Estimate of Economic Impacts: New glazing technologies could dramatically reduce deaths due to ejection. NHTSA's 1995 benefit analysis has shown that about 1,300 deaths from ejection through side windows can be prevented through the use of new hard plastic or plastic/glass laminates. The benefit analysis shows that of these 1,300 ejection deaths prevented, 1,000 of them would occur in passenger vehicle rollover crashes.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
143. Lamps, Reflective Devices, and Associated Equipment

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 108

Authority: 49 USC 301, Motor Vehicle Safety

Description of What Existing Regulation Does: This standard specifies requirements for original and replacement lamps, reflective devices, and associated equipment. Its purpose is to reduce traffic crashes and deaths and injuries resulting from traffic crashes, by providing adequate illumination of the roadway, and by enhancing the conspicuity of motor vehicles on the public roads so that their presence is perceived and their signals understood, both in daylight and in darkness or other conditions of reduced visibility.

Commenter Description of Issue(s):

• A crucial area of safety design for drivers is nighttime roadway illumination by vehicle headlamps. Unfortunately, the photometric criteria in the standard specify only maximum, but not minimum, values for the amount of light produced by headlamps above the horizontal level of the beams. As a result, many manufacturers began importing vehicles conforming to the different headlamp performance standards of Europe and Asia which allow little or no headlamp illumination above the horizon.

• The result is the failure of these headlamps to adequately illuminate the U.S. nighttime traffic control environment. Signs and other traffic control devices which rely on retroreflectorized light from vehicle headlamps were not bright enough for easy and early detection of crucial traffic information.

• Apart from other lighting actions involving taillights, daytime running lights, and the type and design of bulbs used in vehicle exterior lighting systems, another major area of passenger vehicle safety has been the inadequate conspicuity of large trucks. Many motorists crash into the sides and rear ends of commercial vehicles because current lighting standards for trucks and buses are clearly inadequate.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should propose an increase in the amount of illumination produced by passenger vehicle headlamps to improve the detection of traffic control devices, especially in light of the rapid, disproportionate increase in the numbers and percentage of older drivers in the U.S.

• NHTSA should coordinate the supplementary treatment of truck-trailers with retroreflectors with basic reform of the lighting performance standard for medium and heavy vehicles in order to reduce the number and severity of nighttime crashes.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
144. Commercial Vehicle Operator Visibility

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA), Federal Motor Carrier Safety Administration (FMCSA)

Citation: Federal Motor Vehicle Safety Standards108 – Lamps, Reflective Devices, and Associated Equipment;

Authority: 49 USC 301, Motor Vehicle Safety; Intermodal Surface Transportation Efficiency Act

Description of What Existing Regulation Does: FMVSS 108 specifies requirements for original and replacement lamps, reflective devices, and associated equipment. Its purpose is to reduce traffic crashes and deaths and injuries resulting from traffic crashes, by providing adequate illumination of the roadway, and by enhancing the conspicuity of motor vehicles on the public roads so that their presence is perceived and their signals understood, both in daylight and in darkness or other conditions of reduced visibility. FMCSA's "No-Zone" Program educates the public about how to safely share the road with trucks and buses.

Commenter Description of Issue(s):

• The drivers of trucks, both combination and single-unit trucks, and buses, cannot easily detect other vehicles and pedestrians in the vicinity of their vehicles. The length and shape of commercial vehicles, coupled with the inadequacy of most current mirror systems, create "blind spots," large areas to both the side and the rear of these large vehicles, and even immediately to the front, that cannot be seen by the drivers.
• Medium single-unit trucks, such as large step-vans and delivery trucks, operate in congested urban traffic conditions where they often back up to depart parking spaces or delivery yards.
• ITS technologies, including imminent collision warning sensors, such as radar, and the electronic detection of adjacent vehicles (both augmented visual detection as well as warning signals), have been installed in several U.S. trucking and bus fleets. Some of these systems hold considerable promise for reducing the blind spots which plague large truck and bus drivers.
• Mirror design improvements, however, have tended to lag behind innovations in electronically augmented visibility improvements for commercial drivers. NHTSA has periodically addressed the issue of truck mirror design, including issuing a recent preliminary rulemaking addressing the problem of single-unit truck rearward visibility deficiencies. However, no safety standard has been adopted to require, for example, convex mirrors supplemented with electronic detection systems to expand the ability of commercial drivers to monitor the current blind spots alongside and to the rear of their vehicles.
• The "No Zone" campaign counsels passenger vehicle operators not to drive in the vicinity of a large truck either in front of it, to the rear of it, or alongside it. An investigation by the General Accounting Office pointed out that the No Zone campaign has not been able to demonstrate a quantified, affirmative effect of its educational message on passenger vehicle drivers.
• The main emphasis of research and policy development should be the enhancement of side and rear visibility for commercial drivers through the combined application of improved mirrors and automated vehicle and pedestrian detection systems. An industry and government funded education campaign alone is an ineffective and unbalanced approach to solving a major safety hazard.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should conduct rulemaking to adopt substantial improvements in large truck and bus operator visibility for both new and in-service commercial vehicles through a combination of improved mirrors and electronic detection systems.
• FMCSA should revamp the "No Zone" campaign as a strictly educational effort, ensure that statistically defensible measures of effectiveness are adopted, and that meaningful and quantified annual goals are met.
Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
145. **On-Board Crash Recorders**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA)

**Citation:** N/A

**Authority:** N/A

**Description of What Proposed Regulation Would Do:** Would require on-board crash recorders in all passenger vehicles and establish uniform data collection requirements

**Commenter Description of Issue(s):**

- The on-board crash recorder is an important safety technology that could save many lives and reduce the serious consequences of injuries to survivors in motor vehicle crashes. Crash recorder systems not only hold promise in helping to reconstruct the actual circumstances of crashes, but they also collect information that can be immediately transmitted through automatic crash notification systems to emergency medical services personnel, police and hospitals at remote locations.
- Some manufacturers already equip certain models of new passenger vehicles with different types of on-board recorders.
- On-board crash recorders are a good example of technologies that can provide monitoring of commercial vehicle operating systems as well as human performance behind the wheel. Reliable technologies are now available which can accurately verify important safety aspects of commercial vehicles, including brakes and tires, as well as monitor driver performance, especially adherence to regulated maximum limits for driving time.
- On-board recorders, in combination with vehicle GPS, can prevent falsification of commercial driver paper logbooks and reduce the dependence of enforcement personnel on paper documentation for vehicle routing and driver duty status.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- NHTSA should require on-board crash recorders in all passenger vehicles and establish uniform data collection requirements.
- NHTSA should require appropriate data on crash mode and severity be linked to automatic crash notification systems.
- FMCSA should require on-board commercial vehicle technologies which help to accurately verify commercial driver hours-of-service compliance.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93).
146. **Driver Distractions**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA)

**Citation:** N/A

**Authority:** N/A

**Description of What Proposed Regulation Would Do:** Would regulate in-vehicle displays and other in-vehicle technology that can divert driver attention.

**Commenter Description of Issue(s):**

- Widespread cellular telephone use, already a subject of considerable concern to traffic safety advocates, has recently been accompanied by another source of driver distraction: in-vehicle displays. Global Positioning Satellite (GPS) and interactive computer screens, in-vehicle fax machines, and even television sets and computer monitors within the driver's view, collectively referred to as "telematics," have recently been introduced in new models of cars and light trucks.
- It is obvious that these new devices increase the chances of diverting attention from the driving task and lower the ability to perform often complex maneuvers at the wheel.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- NHTSA should develop human factors criteria and determine needs for driver attention.
- NHTSA should regulate the proliferation of in-vehicle displays.
- NHTSA should regulate the proliferation of other in-vehicle technology that can divert driver attention.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93).
147. Pedestrian Crash Protection

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: N/A

Authority: N/A


Commenter Description of Issue(s):

• Each year, nearly 5,000 pedestrians are killed when struck by motor vehicles and tens of thousands of pedestrians are injured, with older people and young children suffering a disproportionate number of deaths and injuries.
• Making basic changes to the aggressive quality of passenger vehicle front ends could save scores of lives and prevent hundreds of serious injuries.
• NHTSA's research has shown that these new designs are both feasible and cost-effective and could dramatically reduce pedestrian injuries by changing the front end designs of cars, pickup trucks, and vans.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should establish a vehicle safety standard to improve protection for pedestrians struck by vehicles.
• NHTSA should include performance requirements in the new standard that provide for less rigid parts on passenger vehicle front ends and that require safer distances between the vehicle hood and engine parts.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
148. Bumper Strength

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: 49 CFR 581

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: This standard establishes requirements for the impact resistance of vehicles in low speed front and rear collisions. The purpose of this standard is to reduce physical damage to the front and rear ends of a passenger motor vehicle from low speed collisions.

Commenter Description of Issue(s):

• Bumpers are only required to provide protection to the vehicle safety systems in low-speed impacts of up to 2.5 mph. Crash tests show that even in such low-speed impacts, the standard does not protect the bumper or other vehicle parts from costly damage. Thus, the bumpers and other vehicle parts often sustain significant damage or are destroyed in low-speed "fender-benders," necessitating extensive repairs or full replacement of the bumper and other parts.

• Vehicle purchasers cannot discern bumper strength merely by looking at a bumper. Consumers can obtain damage estimates derived from bumper crash tests for certain vehicles from private sources. However, accurate information on actual strength, that is, the impact speed at which the bumper will protect the vehicle safety systems without major damage to either the vehicle or the bumper itself, is not available from the government or from most manufacturers.

Small Business Impact: No.

Commenter Proposed Solution(s): NHTSA should require bumpers to withstand impact speeds of 5.0 mph or higher with minimal damage to the vehicle safety systems and the bumpers in order to enhance protection to the vehicle safety systems and reduce overall consumer vehicle repair and part replacement costs.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
149. Commercial Vehicle Brakes

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: Federal Motor Vehicle Safety Standard (FMVSS) 121

Authority: Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

Description of What Existing Regulation Does: The Air Brake Systems standard specifies performance, equipment and dynamometer test requirements for braking systems on vehicles equipped with air brake systems, including air-over-hydraulic brake systems, to ensure safe braking performance under normal and emergency conditions.

Commenter Description of Issue(s):

- The considerable range of weight differences in the same truck-trailer combination are not equally accommodated by current braking design or performance. Instead, brakes are optimized to work best when the truck is near its maximum weight. Consequently, an unloaded tractor-trailer tends to brake unreliably and, in trucks without antilock braking systems, braking distances can be longer than with a fully loaded truck. Another danger is brake locking, especially those on the rear drive axle of the tractor, which can lead to tractor spinout and trailer jackknifing.
- At the other extreme, an overweight truck often demands braking capacity which exceeds brake systems capabilities, especially in rolling terrain where braking on downgrades is repeatedly required.
- Antilock brakes are important safety features of both tractors and trailers because they permit drivers to apply maximum pedal force without the danger of locking the brakes of either the tractor or trailer. Antilock brakes have improved performance in important respects but are not a cure-all for braking deficiencies in the current generation of heavy trucks and buses.
- One of the central problems with larger commercial vehicles is that they rely on air brakes rather than hydraulic brakes. Air brakes require time for air pressure to build up in order to actuate the brake drums on each wheel. Even when all brakes are properly adjusted it is not unusual, especially with multi-trailer combinations such as triples (a tractor pulling three short trailers), to have a several second delay until braking occurs at the last trailer.

Small Business Impact: No.

Commenter Proposed Solution(s): NHTSA should require performance standards in commercial motor vehicles to reduce the time needed to actuate the brake drums in order to induce the installation of brake-by-wire braking systems.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
Consumer Information

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA)

Citation: 49 CFR 575


Description of What Existing Regulation Does: NHTSA requires manufacturers to provide technical information on vehicle and equipment performance and safety. Information on vehicle damage susceptibility, crashworthiness, and vehicle operating costs are to be provided in a readily understandable form that would permit comparisons between different makes and models.

Commenter Description of Issue(s):

• Safety information about vehicle design and equipment is essential to ensure that consumers can make intelligent decisions about their personal safety.
• Information that consumers can use to compare vehicle makes and models would provide consumers with the opportunity to make informed choices about the safety of the vehicles they purchase. Thus, consumer information is essential to a rational marketplace. While the savings to the public cannot be readily quantified, comprehensive safety information would, in all probability, lead to reduced crashes as consumers use the information to purchase safer, better designed vehicles.
• The best NHTSA information program is the New Car Assessment Program (NCAP), which is the only substantive consumer information program to provide comparative crashworthiness ratings of tested vehicles.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should provide consumers with vehicle and equipment information that assists in making comparative judgments on a model-to-model and vehicle-to-vehicle basis.
• NHTSA should provide crashworthiness ratings to consumers at the point-of-sale, preferably in the form of vehicle window stickers.
• NHTSA should develop information to explain important safety concepts and equipment operation in user-friendly terms.
• NHTSA should expand the NCAP program to include additional crash and dynamic test parameters.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
151. Commercial Vehicle Rollover

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA), Federal Highway Administration (FHWA)

Citation: N/A

Authority: N/A

Description of What Proposed Regulation Would Do: Would require performance standards which could significantly reduce the propensity for rollover and require reasonable operational restrictions for multi-unit combinations that restrict tractor-trailers from operating on facilities not designed to accommodate vehicles of that size.

Commenter Description of Issue(s):

• Commercial vehicle rollover causes more than 50 percent of all deaths to truck drivers each year, but is not regulated by a Federal safety standard. Medium and heavy single-unit trucks and buses are considerably more unstable than passenger cars and combination units such as tractor-trailers are especially prone to rollover.

• The problems of tractor-trailer stability and rollover tendency are magnified when the combination truck is composed of the tractor and two ("doubles") or even three ("triples") trailers. In these instances, additional stability problems come into play because of high-speed offtracking and trailer sway.

Small Business Impact: No.

Commenter Proposed Solution(s):

• NHTSA should require performance standards which could significantly reduce the propensity for rollover including requirements for lower center of gravity, improved suspension systems, wider wheelbases and revised design principles for cargo units, including tank trailers.

• NHTSA should develop performance requirements that improve the ability of trailers to respond to curves and quick steering movements without becoming unstable.

• FHWA should require reasonable operational restrictions for multi-unit combinations that restrict tractor-trailers from operating on facilities not designed to accommodate vehicles of that size.

Estimate of Economic Impacts: None provided.

Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
152. **Side Impact Protection**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA) and Federal Highway Administration (FHWA)

**Citation:** Federal Motor Vehicle Safety Standard (FMVSS) 201 and 214

**Authority:** Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety

**Description of What Existing Regulation Does:** Two standards govern side impact protection. The Side Impact Protection standard, FMVSS 214, addresses lower vehicle interior protection of the lower torso. The Occupant Protection In Interior Impact standard, FMVSS 201, requires countermeasures to offset upper interior impact head injuries.

**Commenter Description of Issue(s):**
- Side impacts have increasingly become a leading source of motor vehicle deaths and severe injuries. More than one-third of serious to severe injuries sustained each year by occupants in passenger vehicles are the result of side impacts. A major aspect of the problem is that there is so little protective structure between occupants and collision forces in passenger vehicles.
- A key shortcoming of these standards is the lack of a systems engineering approach to side impact occupant protection. The two standards were developed and issued separately, without specific coordination. As a result, an overall uniform set of countermeasures is usually not implemented by manufacturers who have to comply with the distinct minimum requirements of each standard.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**
- NHTSA should upgrade side impact protection injury performance requirements.
- NHTSA should increase the stringency of both side impact standards, FMVSS 201 and 214, to ensure that superior, dynamic protection systems are installed.
- NHTSA should upgrade side impact test requirements for LTVs when they are themselves struck by LTVs or other large vehicles.
- NHTSA should develop approaches to modulate the height, weight, and general aggressive character of large vans, pickup trucks, and SUVs.
- NHTSA should adopt an additional, more demanding side impact test requirement for both standards that relies on a lateral collision with rigid poles and, in FMVSS 214, use of a moving deformable barrier which is higher, heavier, and stiffer than the existing barrier.
- NHTSA should require side impact air bags for both upper and lower interior side impact standards.
- FHWA should require placement of protective barriers and crash cushions where appropriate on Federal-aid highways.
- FHWA should require retrofit of vertical supports on Federal-aid highways so that only break-away poles and other more forgiving highway appurtenances are used.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93).
153. .08 Alcohol Incentive Program

Regulating Agency: DOT/National Highway Traffic Safety Administration (NHTSA) and Federal Highway Administration (FHWA)

Citation: 23 CFR Part 1225; July 1, 1999, Federal Register, page 35570

Authority: Transportation Equity Act for the 21st Century (TEA 21)

Description of What Existing Regulation Does: TEA-21 established incentive grants to encourage States to establish 0.08 percent blood alcohol concentration (BAC) as the legal limit for drunk driving offenses. Any State that has in effect and is enforcing a 0.08 percent BAC law is eligible to receive incentive funds.

Commenter Description of Issue(s):

• NHTSA appears to be applying the compliance criteria in the preamble of its July 1, 1999, final rule rather than the text of the regulation itself. The preamble language quotes compliance criteria purportedly from an interim final rule rather than the final rule. Specifically, it states under the 5th compliance criteria: “Both Criminal and ALR Laws. A State must establish a 0.08 BAC per se level under its criminal code.” This does not appear in the rule text itself.

• Wisconsin achieves a very high level of conviction, mandatory assessment, and treatment programs under its civil code, as opposed to the criminal code. It avoids the cost of public defenders and criminal procedures and proof beyond a reasonable doubt to obtain a conviction. It would be inconsistent with the purposes of the law and national policy to insist on a “criminal code” provision that is not in the Federal regulation.

Small Business Impact: No.

Commenter Proposed Solution(s): Do not require enactment of first offense .08 per se law as part of the Wisconsin criminal code. NHTSA simply needs to administer the rule differently than we are lead to believe it may.

Estimate of Economic Impacts: Commenter believes proposal would reduce the number of persons killed and injured by drivers at .08 or above and would permit successful conviction, assessment, and treatment of first offenders. Depending on how quantified, the savings to courts, public defenders and human life is substantial.

Commenter(s): State of Wisconsin Department of Transportation (90).
154. **Emergency Response and Automatic Crash Notification**

**Regulating Agency:** DOT/National Highway Traffic Safety Administration (NHTSA), Federal Highway Administration (FHWA), and Federal Motor Carrier Safety Administration (FMCSA)

**Citation:** N/A

**Authority:** N/A

**Description of What Proposed Regulation Would Do:** Would require automatic crash notification (ACN) technology as standard equipment on all passenger and commercial vehicles.

**Commenter Description of Issue(s):**

- It is estimated that nearly half of all highway fatalities, about 20,000, take place prior to any hospital care. Timely medical intervention has been shown to increase the chances of surviving a crash and reducing the extent of long-term care for those with severe physical injuries. The problem has always been confirming that a crash has occurred and locating the site in time for medical intervention to make a difference.
- A major breakthrough in post-crash emergency response time for all crashes is possible through the use of automatic crash notification systems located in the vehicle.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- NHTSA and FHWA should make ACN a transportation safety priority.
- NHTSA and FHWA should dedicate more resources and funding for ACN development and testing.
- NHTSA and FMCSA should eventually require ACN technology as standard equipment on all passenger and commercial vehicles.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Public Citizen/Advocates for Highway and Auto Safety (93).
155.  Commercial Vehicle Design Compatibility

Regulating Agency:  DOT/National Highway Traffic Safety Administration (NHTSA), Federal Motor Carrier Safety Administration (FMCSA)

Citation:  N/A

Authority:  N/A

Description of What Proposed Regulation Would Do:  The rules would address the safety problems caused by the incompatibility between commercial motor vehicles and passenger vehicles.

Commenter Description of Issue(s):

• The large differences in height, width, and length, between large commercial vehicles and smaller passenger vehicles causes a host of operational problems which often leads to collisions between trucks, buses, and passenger vehicles.
• The enormous difference in weight means that the chances of passenger vehicle occupant survival are tremendously reduced because the crash management capabilities of a car or light truck are unable to protect occupants against the impact forces of the truck, especially at higher collision speeds. This means that crash countermeasures must emphasize crash avoidance to prevent collisions from occurring.
• Crash prevention is a challenge because of the very different operating characteristics of large commercial vehicles. Big trucks and buses perform basic highway maneuvers more slowly than passenger vehicles. Lane changes, acceleration from entry lanes and ramps to make mergers, and braking, among other actions, take more time and space for a large truck or bus than a car, light truck or van.
• Commercial vehicles must be readily visible to drivers of passenger vehicles and commercial vehicle drivers must be able to see nearby passenger vehicles. The characteristic of vehicles that determines how visible they are to other drivers is referred to as vehicle conspicuity.
• Commercial drivers are usually at a distinct disadvantage for seeing other vehicles in their vicinity, because of large blind spots in front of, alongside, and behind their trucks and buses. Although FMCSA and others have called for passenger cars to stay far away from big commercial vehicles because of this problem, it is obvious that under many operating conditions that is simply not feasible.

Small Business Impact:  No.

Commenter Proposed Solution(s):

• NHTSA, which has jurisdiction over newly manufactured trucks and buses, should upgrade performance requirements for truck and bus lighting systems.
• NHTSA should require improved conspicuity treatment for single-unit trucks.
• NHTSA should require improved mirror and electronic vehicle detection systems for trucks and buses.
• NHTSA should improve requirements for rear impact guards to make them lower and more energy-absorbing and extend these requirements to single-unit trucks.
• NHTSA should require side impact guards to prevent side underride of large trucks and trailers by passenger vehicles.
• NHTSA should adopt performance requirements that reduce front end "aggressivity" of bus and truck cab designs.
• FMCSA, which now has jurisdiction over the on-road operation of trucks and buses, should require the retrofit of side impact guards to prevent side underride of large trucks and trailers by passenger vehicles.

Estimate of Economic Impacts:  None provided.
Commenter(s): Public Citizen/Advocates for Highway and Auto Safety (93).
156. Collection of Annual Registration Fees

Regulating Agency: Department of Transportation/RSPA

Citation: 49 CFR 107.612

Authority: 49 USC 5108(g)(2)(B)

Description of What Existing Regulation Does: There are unexpended balances in the Emergency Preparedness Grant (EPG) account which result from over-collection of registration fees from shippers and carriers of hazardous materials. The commenters maintain that DOT is obligated to adjust the amount of the annual fee to reflect any unexpended balances in the EPG account.

Commenter Description of Issue(s):

- Beginning with the Administration's FY 2000 budget request, a proposal was made to divert the unexpended balance in the EPG account to support the DOT hazmat regulatory program.
- Despite Congressional rejection of this approach, the FY 2002 and 2003 budget's have included provisions to maintain this diversion of funds. By the end of FY 2002, the industry maintains that each of 40,000 registrants will have overpaid on average $650, a total of about $18 million.

Small Business Impact: No information provided.

Commenter Proposed Solution(s): A rule to effect the refund of the overpayment was initiated in December 2000. The rulemaking was subsequently suspended while RSPA sought authorization to divert funds to the hazmat program. The Administration should request that RSRA promptly finalize the rulemaking.

Estimate of Economic Impacts: No additional input provided by commenters.

Commenter(s): Institute of Makers of Explosives (184); American Chemistry Council (12).
157. Emergency Preparedness Grants

Regulating Agency: Department of Transportation/RSPA

Citation: 49 CFR 110

Authority: P. L. 96-354, Section 610 (Regulatory Flexibility Act) and P. L. 104-121, Small Business Regulatory Enforcement and Fairness Act (SBREFA)

Description of What Existing Regulation Does: RSPA's Emergency Preparedness Program (EPG) is implemented by administrative and operational rules in 49 CFR 110. The purpose of the EPG is to cover the "unfunded mandate" that States develop emergency response plans and to contribute to the training of emergency responders.

Commenter Description of Issue(s):

- RSPA is required by law to periodically review and seek out comments from small businesses. DOT has scheduled no review in its 10 year plan.
- The program clearly impacts small businesses who pay for the program through annual registration fees. However, businesses feel there is a need for more accountability in the program and more evidence of coordination of all Federal initiatives to ensure that all resources are used as efficiently and equitably as possible.
- Given the amounts available in grants, and high administrative costs of the program, the review should look at whether the program is the most effective way to deliver training to the response community in light of other alternatives available.

Small Business Impact: The commenter notes that about 70 percent of its members are "small businesses." Also, "in view of the thousands of small businesses that contribute millions in fees to the support of the EPG, clearly Part 110 meets the threshold for Section 110 consideration."

Commenter Proposed Solution(s): Urges that OMB request that RSPA revise its Section 110 schedule and provide an opportunity for public review of Part 110.

Estimate of Economic Impacts: Program level of $12.8 million plus administrative expenses. Funds are financed from user fees from registrants that range in amounts up to $2,000 annually.

Commenter(s): Institute of Makers of Explosives (184)
158. Hazardous Materials Training Requirements

Regulating Agency: Department of Transportation/RSPA and Department of Labor/OSHA

Citation: 49 CFR 172.704 and 29 CFR 1910.120

Authority: 49 USC 5101-5127

Description of What Existing Regulation Does. The regulations require training for employees who handle hazardous materials. RSPA's regulations include general awareness/familiarization training, function-specific training, and safety training. OSHA's regulations require names of personnel and alternates responsible for site safety and health and hazards at the site, use of personal protective equipment, work practices, safe use of engineering controls, and medical surveillance requirements. RSPA requires workers receive refresher training once every three years while OSHA requires refresher training annually.

Commenter Description of Issue(s): The requirements of both agencies are similar enough that there should be only one agency regulating hazardous materials training. Members of the PMAA do not know which agency regulations to comply with or, because the regulations of the two agencies are so similar, may believe they are in compliance when they are not.

Small Business Impact: Small business members of PMAA would find RSPA regulations less onerous and would be relieved of duplicative paperwork requirements if they had to comply with only one set of regulations.

Commenter Proposed Solution(s): Propose that one agency regulate hazardous materials training. RSPA regulations appear less onerous. Issue Notice of Proposed Rulemaking asking for comment on benefits and costs of having RSPA regulate employees who handle hazardous materials.

Estimate of Economic Impacts: None provided.

Commenter(s): Petroleum Marketers Association of America (6)
159. **Currency and Foreign Financial Accounts**

**Regulating Agency:** Treasury Department

**Citation:** 31 CFR 103

**Authority:** Bank Secrecy Act, 12 USC 1829, 1951-1959, 31USC 5311-5330

**Description of What Existing Regulation Does:** Records and reports used in criminal, tax and regulatory investigations. The information is used for tracing drug and other illegal proceeds back to their illegal sources and helping to identify the sources, volume, and movements of domestic and international currency. The information collected and retained under these regulations and associated forms assists Federal, state and local law enforcement in the identification, investigation, and prosecution of individuals involved in money laundering, tax, evasion, narcotics trafficking, organized crime, and bank, securities and tax fraud.

**Commenter Description of Issue(s):**

- The PRA burden associated with this rule is over 10 million hours.

**Small Business Impact:** No

**Commenter Proposed Solution(s):** OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Rep. Doug Ose (108).
160. Alcohol Labeling

Regulating Agency: Treasury/Bureau of Alcohol, Tobacco and Firearms

Citation: 64 Fed. Reg. 57,413 (October 25, 1999)

Authority: Federal Alcohol Administration Act, 26 USC 291

Description of What Existing Regulation Does: Manufacturers are effectively banned from providing health information to consumers on wine bottles. Claims are considered misleading unless they are properly qualified, present all sides of the issue, and outline categories of individuals for whom any positive effects would be outweighed by numerous negative health effects.

Commenter Description of Issue(s): A large and growing body of evidence has shown substantial health benefits from the moderate consumption of wine. Current policy makes putting health claims on wine bottles generally impossible.

Small Business Impact: No.

Commenter Proposed Solution(s): ATF should modify its policy to allow truthful information as to health benefits of wine and other alcoholic beverages to be provided on labels to consumers.

Estimate of Economic Impacts: No economic impact information provided. Commenter says health impact would likely be “substantial” given evidence that moderate consumption reduces the risk of heart attack by 30-54 percent.

Commenter(s): Heritage Foundation (78); Competitive Enterprise Institute (186).
161. **Employer Identification Numbers**

**Regulating Agency:** Treasury/IRS

**Citation:** None provided.

**Authority:** None provided.

**Description of What Existing Regulation Does:** Businesses are required to obtain the EIN from vendors if they are required to file any return, document or other statement that calls for the taxpayer identification numbers of other taxpayers.

**Commenter Description of Issue(s):** Some customers demand or threaten to withhold payment unless this number is provided. There is no apparent reason for everyone keeping EINs for everyone else.

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):** None provided.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Antique Rose Flowers and Gifts (110).
162. Flexible Spending Accounts

Regulating Agency: Treasury/IRS

Citation: IRS interpretations of Prop. Reg. S.1.125 (5/7/84)

Authority: Sec. 125 of Internal Revenue Code

Description of Existing Regulation: Employees put aside tax-free funds for health care expenses. Funds must be used and cannot be carried over into the next year.

Commenter Description of Issue(s): Current policy encourages unnecessary year-end spending and inhibits individuals from spending wisely on medical services. Current policy is not based clearly on statute but on IRS interpretation of law and proposed rules. The IRS interpretation has long been disputed.

Small Business Impact: No.

Commenter Proposed Solution(s): Reverse IRS interpretation and allow a rollover of funds in flexible spending accounts.

Estimate of Economic Impacts: “According to the Administration's Budget Blue Book, a $500 per annum roll over of FSAs would amount to a revenue loss of $8.4 billion over 10 years.”

Commenter(s): Heritage Foundation (78).
Government Fleet Fuel Cards

Regulating Agency: Treasury Department/IRS

Citation: 26 CFR 48.6427-9, Notice 89-29 (1989-1 C.B. 669), Letter Rulings 200130047, 200116023, 1999-28018

Authority: 26 USC 4081

Description of What Existing Regulation Does: Current rules describe a process for refund claims when using an “oil company credit card.” Neither the Federal government nor the States tax the essential government functions of the other. Federal tax on gasoline and diesel fuel is applied when the fuel leaves a bulk terminal.

Commenter Description of Issue(s): Government vehicle fleet managers have been steadily changing their purchasing practices to having their drivers procure fuel at retail locations on fleet fueling cards, essentially a type of credit card. Because the purchase price includes the Federal tax, a refund must be obtained. Existing rules use the undefined term “oil company credit card” which apparently does not include fleet fueling cards. It is unclear who, if anyone can make claims when fleet fueling cards are used. In some cases state governments are refusing to refund state motor fuel tax to the Federal government when GSA fueling cards are used.

Small Business Impact: Yes.

Commenter Proposed Solution(s): The person issuing the credit to the government agency, and receiving payment from them, needs to be treated as the seller of gasoline and the ultimate vendor of diesel fuel. This person should be the refund claimant. This would allow states to get refunds from the party having the information to make the claims.

Estimate of Economic Impacts: Both the Federal government and the states are losing refunds. No quantified costs and benefits provided. “This friction is straining intergovernmental tax immunity.”

Commenter(s): Petroleum Marketers Association of America (6).
164. Interest Reporting Requirements

Regulating Agency: Treasury/IRS

Citation: 26 CFR Parts 1 and 31 (proposed)

Authority: None provided.

Description of Proposed Regulation: IRS has proposed to extend information reporting requirement for bank deposit interest paid to nonresident alien individuals who are residents of other foreign countries.

Commenter Description of Issue(s): “The proposed regulation flouts congressional intent. Lawmakers have chosen to exempt foreign bank deposits from taxation and not to require their reporting to the IRS. This makes America a safe haven for foreigners fleeing political and economic repression and has helped attract more than $1 trillion to the U.S. economy.”

Small Business Impact: No.

Commenter Proposed Solution(s): Withdraw proposed regulation.

Estimate of Economic Impacts: No quantified costs and benefits provided. “The regulation would lead to a significant loss of capital to the U.S. economy.”

Commenter(s): Heritage Foundation (78).
165. Domestic Relations Tax Reform Act Rules

Regulating Agency: Treasury Department/IRS

Citation: Temp. Treas Reg. 1.1041

Authority: Domestic Relations Tax Reform Act of 1984

Description of What Existing Regulation Does: A family may use a corporate redemption or a corporate dividend to divide a family business on the occasion of an owners' divorce.

Commenter Description of Issue(s): After conflicting court opinions regarding the current regulation, IRS has proposed a rule that correctly implements the statute except that the effective date would only permit family businesses to avail themselves of its clarifying relief if their transaction was entered into after the effective date of the regulation.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Change the effective date so that all cases that were at issue on August 1, 2000 (the date of the proposed rule) are covered by the final regulation.

Estimate of Economic Impacts: None provided.

Commenter(s): Marjorie O'Connell (181).
166. Monthly Tax Deposits

Regulating Agency: Treasury/IRS

Citation: 26 CFR 31.6302(g)

Authority: Internal Revenue Code sec. 3102 and 6302(g)

Description of What Existing Regulation Does: Employers who must pay more than $50,000 in aggregate employment taxes must pay by the 3rd business day after the pay date. Those for who taxes are less than $50,000 must pay by the 15th of the month following the pay date.

Commenter Description of Issue(s): This is a drastic transition for small business owners who find themselves suddenly owing in 3 days what they had previously owed in 30 or 45 days.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Raise the monthly payment threshold to $100,000 to keep pace with inflation.

Estimate of Economic Impacts: No estimate of impact provided. “Changing the threshold shifts the burden of cash-flow away from the smallest businesses to a level of business that was contemplated when the $50,000 was first set.”

Commenter(s): Small Business Administration, Office of Advocacy (97).
167.  Mortgage Revenue Bond Purchase Price Limits

Regulating Agency: Treasury/Internal Revenue Service

Citation: None provided.

Authority: 26 USC 143(e)

Description of Existing Regulation: States may issue mortgage revenue bonds to provide below market rate mortgages to first-time homebuyers whose incomes are at or below 115 percent of area median income. Home prices are limited to no more than 90 percent of the average purchase price for homes within the area in which the home is located.

Commenter Description of Issue(s): The dollar price limits have not been adjusted since 1994 because of data quality problems.

Small Business Impact: No.

Commenter Proposed Solution(s): Require IRS to update the limits that currently restrict the program.

Estimate of Economic Impacts: None provided.

Commenter(s): National Association of Home Builders (48)
168. **Partnership Investments in Small Business Stock**

**Regulating Agency:** Treasury/IRS

**Citation:** None provided.

**Authority:** 26 USC 1202 and 1045

**Description of What Existing Regulation Does:** Taxpayers, other than corporations, that dispose of Qualified Small Business Stock (QSBS) held more than 6 months are allowed to defer tax on the sale of those assets if they invest the proceeds in other QSBS.

**Commenter Description of Issue(s):** IRS has not modified its regulations to explain how section 1045 would apply to partnerships that dispose of one QSBS and reinvests in another QSBS.

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):** “IRS should amend the regulations connected with sections 1202 and 1045 to address the problem where a partnership is making the transaction so that the provisions will be usable in a fashion that Congress intended.”

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Small Business Administration, Office of Advocacy (97).
169. **Business Use of Home**

**Regulating Agency:** Treasury Department/IRS

**Citation:** None provided.

**Authority:** None provided.

**Description of What Existing Regulation Does:** In order for it to be considered a business expense, a home office or work area must be used exclusively for business purposes.

**Commenter Description of Issue(s):** This rule discriminates against the disabled and poor since food preparation must be done in close proximity to the workplace. An individual with limited mobility cannot practically cook and work in different parts of the home. An individual with more money can buy already cooked foods.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** Eliminate the “exclusive use” rule.

**Estimate of Economic Impacts:** No quantified data on cost and benefits.

**Commenter(s):** Lynn Martin (182).
170. Regulatory Reform for Handling Refrigerants

Regulating Agency: EPA

Citation: 40CFR Part 82, subpart F

Authority: Clean Air Act Sections 608 and 609

Description of What Existing Regulation Does: In 2010, the CAA will phase out new equipment using ozone-depleting HCFCs (R-22) with non-ozone depleting refrigerants. The regulations that have been enacted have allowed contractors to bring to society environmentally safer refrigerants for their refrigeration and air conditioning needs without serious economic impact.

Commenter Description of Issues:

• The issues with HFC R-410A lie in the fact that these systems operate at 60 percent higher pressures than their replacement R-22. Where a R-22 system operated at 260 psig, the new equipment is operating at about 417 psig. The oil used with R-410A will be an ester based, of a much higher grade, be hygroscopic and does not mix well with the mineral oil used in the older systems. Different tools and equipment are also required.

• The industry, and ACCA, has embarked upon numerous voluntary educational and training programs to prepare technicians for this transition, and this will help. But, if we do not keep these new refrigerants, R-410A and other alternates, out of the hands of the non-skilled, non-trained, non-certified (608 and 609 EPA Technician Certifications) consumers, people will be injured, systems will be ruined, and non-compatible refrigerants will be mixed requiring incineration or even illegally vented into the atmosphere.

• People handling HFCs should be certified, just as are those who work with CFCs and HCFCs. Since 1995, ACCA with the support of other organizations has urged the EPA to extend the sales prohibition of alternate refrigerants to certified technicians. They have not acted on this request. The “handy” homeowner who can and is buying 134a over the counter now to charge into his after-market automobile A/C and refrigerator, will soon be able to purchase R-410A to charge into his home air conditioner. And, the dangers of injury are real, because the “handy” homeowner is not aware of the higher pressures, redesigned systems and heavier gauge materials and tools needed for R-410A. The result will be mixing refrigerants in systems so that the refrigerant will become useless, non-reclaimable, and must be destroyed. This not only costs money and wastes resources, but increases the likelihood that refrigerant will be illegally vented to the atmosphere. And even HFCs contribute to global warming. All of this can be prevented.

• The answer lies in removing the April 27, 1995 “stay” (Hamilton Case) which allows non-certified individuals to purchase pre-charged split air conditioners. The “stay” not only runs counter to the goal of 608 regulations, it allows non-qualified, non-trained, non-certified individuals to make the mistakes as outlined above as we transition to the higher pressure HFC-based refrigerants.

• Technological advancement in the industry have also brought instrumentation and equipment that will analyze refrigerant mixtures and purity levels, field recycle these refrigerants, and document their purity levels. ACCA feel that the time has come for the EPA to allow field recycling that includes purity testing and documentation to ARI 700 Standards without the need to be certified as a “reclaimer” by EPA.

Commenter Proposed Solution: ACCA would enthusiastically support and assist in regulatory reform that would simplify and improve the services and installations our contractors can bring to society more economically. Thus, the Clean Air Act can be strengthened by:

• Extending the sales prohibition of “Alternate Refrigerants” to qualified and certified technicians of the 608 (40CFR Part 82, subpart F) and the 609 Certification programs.

• Removing the “stay” that allows homeowners to purchase split systems that contain HCFC and alternate refrigerants (HFC).

• Allowing the contractor to manage refrigerant in the field through “field recycling” to the same standards
as reclaimers are now held to, with the added requirement of field documentation of purity levels.

Commenter: Air Conditioning Contractors of America (92).
171. Chemical Plant Safety Standards

Regulating Agency: EPA

Citation: N/A

Authority: CAA, 42 U.S.C. Sec.7412(r)

Description of What Regulatory Prompt Would Do: EPA should propose regulations that require chemical manufacturers to use "inherently safer technologies" which would eliminate or greatly reduce the vulnerability of facilities producing, using, or storing a significant amount of toxic chemicals.

Commenter Description of Issue(s):

• Chemical companies pose a threat to the workers and communities around them, sometimes unbeknownst to those in greatest danger.
• Requiring disclosure of chemicals and chemical products stored at and used by chemical companies has always been a priority but in the wake of September 11th is even more of a priority, as public awareness of the additional threat of a terrorist attack on a chemical plant has heightened.

Small Business Impact: No.

Commenter Proposed Solution(s): EPA should issue regulations requiring:

• public disclosure of chemical storage and usage,
• substitution of the most dangerous chemicals with safer alternatives where they exist, and
• reduction in storage of large quantities of hazardous chemicals.

Estimate of Economic Impacts: None provided.

Commenter(s): Center for Progressive Regulation (70), OMB Watch (77).
172. Risk Management Plans (Worst Case Scenario)

Regulating Agency: Environmental Protection Agency

Citation: 65 Fed. Reg. 48107

Authority: Clean Air Act, 42 U.S.C. Sec. 112(r)

Description of Existing Regulation: A provision of the Clean Air Act Amendments of 1990 requires facilities to develop “risk management plans” (RMPs), which are supposed to help plants prepare for accidental chemical releases. The law then directed the EPA to make these plans publicly available. RMPs include information that security officials say could assist terrorists in selecting targets and planning attacks on chemical facilities and infrastructure.

Commenter Description of Issue:

• According to a Department of Justice report, RMPs provide most (six out of nine pieces of information) of the information that the Dept. of Defense lists as critical for a terrorist to launch a successful attack on an industrial facility.

• Congress reformed the law in 1999 with legislation requesting that DOJ and EPA issue a rule governing the process for releasing the data in a way that minimized security risks. EPA opted to post the bulk of information from RMPs on the Internet in 2000. The reformed law also mandated that EPA make the entire plans available in 50 Federal reading rooms throughout the nation.

• The Bush administration, sensitive to the security concerns after September 11, has pulled the risk management plans and their summaries of EPA. However, the full information is still easily accessible at Federal libraries.

Small Business Impact: N/A

Commenter Proposed Solution: The regulation making this information so accessible should be reviewed to ensure that they do not continue to pose a safety risk.

Estimate of Economic Impact: Fifteen percent of the facilities that produce RMPs fall into the category of basic infrastructure. Disruption of even one of these facilities could bring considerable hardship to an entire region or locality.

Commenter: Competitive Enterprise Institute (186).
173. Definition of Solid Waste

Regulating Agency: Environmental Protection Agency

Citation: 40 CFR 261.2


Description of What Existing Regulation Does: Establishes EPA’s jurisdiction under RCRA to include spent materials, sludges, by-products, and scrap metal. This definition includes recycled materials that are not immediately returned to an industrial process as substitutes for raw material feedstock.

Commenters Description of the Issue: The current definition of solid waste prevents companies from reusing, recovering and recycling valuable secondary materials; increases the amount of material sent to landfills; and increases use of virgin materials.

Small Business Impacts: Not discussed by commenter.

Commenter Proposed Solution: Revise the definition of solid waste to exempt reuse, recovery, and recycling. Establish a conditional exclusion that identifies practices that are not “discarding” of materials and therefore would not lead to secondary materials being regulated as “wastes”.

Estimate of Economic Impact: None provided.

Commenter: American Chemistry Council (12); Synthetic Organic Chemical Manufacturers Association (19); Small Business Administration, Office of Advocacy (97); and Association of Connecting Electronic Industries (43).
174. **RCRA Burden Reduction Initiative**

**Regulating Agency:** Environmental Protection Agency

**Citation:** 40 CFR 264.16(e), 264.71(a)(5), 264.739(b), 265.193, & 266.102-103, 111-112

**Authority:** Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 et seq.

**Description of What Existing Regulation Does:** Requires facilities that transport, store, or dispose of hazardous waste fuels to retain most of their compliance documents for the life of the facilities. In 2002, EPA published a proposed Burden Reduction Initiative rule that would reduce most of these retention requirements to three years.

**Commenters Description of the Issue:**

- The majority of hazardous waste facilities has been subject to record-keeping requirements for 10-15 years and is currently storing thousands of documents.
- These documents are only useful for a limited period of time, beyond that time requiring retention of the records is unnecessarily burdensome.

**Small Business Impacts:** Some hazardous waste facilities are small businesses.

**Commenter Proposed Solution:**

- Finalize the Burden Reduction Initiative changing many of these record-keeping requirements to three years.
- Reconsider the proposal to continue requiring facilities to retain both the latest closure cost and latest adjusted closure cost estimate in the facility operating record—only the most accurate of the two estimates should be maintained.

**Estimate of Economic Impact:** Commenter did not quantify impacts, but stated that the office space and capital costs to retain records are significant.

**Commenter:** Schreiber & Yonley Associates (representing the Region 7 Boiler and Industrial Furnace Working Group (18).
175. RCRA Subtitle C Hazardous Waste Regulations

Regulating Agency: Environmental Protection Agency

Citation: 40 CFR 262


Description of What Existing Regulation Does: RCRA Subtitle C regulates hazardous waste from generation to disposal.

Commenters Description of the Issue:

• Academic research institutions are substantively different from the other types of hazardous waste generation, transport, storage, treatment, and disposal facilities regulated under RCRA.
• Academic research institutions often have a large number of independent waste generation points, making it difficult to implement a uniform waste management program.
• These institutions are subject to both RCRA and OSHA standards for managing hazardous chemicals, these requirements are duplicative in many cases.

Small Business Impacts: None are reported.

Commenter Proposed Solution:

• EPA should implement a performance-based model for achieving RCRA compliance at academic institutions.
• This model should be based upon how well the institution implements the consensus best practices developed through the Howard Hughes Medical Institute Initiative.

Estimate of Economic Impact: Not provided.

Commenter: Federation of American Societies for Experimental Biology (8).
176. Best Available Retrofit Technology

Regulating Agency: EPA

Citation: 64 Fed. Reg. 35714

Authority: CAA, 1997 Regional Haze Rule

Description of Existing Regulation: EPA's regional haze rule includes a requirement for best available retrofit technology (BART) for certain types of existing stationary sources. The BART requirement applies to "major stationary sources" from identified categories that were built between 1962 and 1977 and have the potential to emit more than 250 tons per year or more of any air pollutant. EPA's proposed BART rule set guidelines for states to identify those sources that must comply with the BART requirement and to conduct analyses to determine the level of control technology that represents BART.

Commenter Description of Issue(s): EPA issued a proposed rule on June 20, 2001, and has yet to issue a final rule.

Small Business Impact: No.

Commenter Proposed Solution(s): EPA should issue a final rule.

Estimate of Economic Impacts: None provided.

Commenter(s): OMB Watch (77).
177. **1997 EPA Standards for Ozone and Particulate Matter**

**Regulating Agency:** EPA/OAR

**Citation:** 62 Fed. Reg. 38, 865 and 62 Fed. Reg. 38, 652

**Authority:** Clean Air Act, 42 U.S.C. §§7408-09

**Description of Existing Regulation:** In 1997 EPA issued new National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter. The revised health-based standards added a new annual standard for fine particulate matter (PM$_{2.5}$) and replaced the existing 1-hour ozone standard with a new 8-hour standard.

**Commenter Description of Issue(s):**

- One commenter cited the delays in implementation of both standards as the problem and also recognized two outstanding matters EPA must respond to with respect to the ozone standard: (1) EPA must finalize its response to the D.C. Circuit’s ruling that EPA must consider the potentially beneficial health effects of ozone in setting a NAAQS; and (2) EPA must issue a decision responding to the U.S. Supreme Court’s directive that EPA rework its plan for implementing the new ozone standard.
- Another commenter identified concerns raised by a number of parties, including EPA’s Clean Air Scientific Advisory Committee about EPA’s estimated costs and benefits of these rules. The commenter asserts that concerns about the claimed net benefits of the new standards have not been adequately addressed.
- With regard to the PM$_{2.5}$ standard, the evidence of health effects is based on two studies finding a weak statistical correlation between ambient concentrations and increased mortality. This evidence does not provide a sufficient factual basis for the claimed benefits.
- With regard to the ozone standard, EPA’s attempt to downplay the evidence that the tightened standard would increase ground-level ultraviolet B (UVB) radiation and related health effects is in direct contradiction to its treatment of those same effects in the context of Title VI of the CAA dealing with stratospheric ozone depletion.

**Small Business Impact:** No

**Commenter Proposed Solution(s):**

- EPA should immediately proceed to implement the new NAAQS for PM$_{2.5}$ and that EPA issue final decisions on the ozone standard itself and the implementation of the ozone standard. The commenter also felt that EPA should require the governor of each State to designate areas as non-attainment, attainment, or unclassifiable, pursuant to section 107(d)(1)(A) of the CAA, within 120 days of the court of Appeals’ ruling on fine PM and within 120 days of issuing a final ozone standard in response to the court remand.
- The second commenter recommended that OMB assess problems with EPA science on ozone and particulate matter before the agency finalizes the rule.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Center for Progressive Regulation (70) and Competitive Enterprise Institute (186).
178. Protections for Farm Children from Pesticide Exposures

Regulating Agency: EPA

Citation: N/A


Description of What Regulatory Prompt Would Do: EPA should designate farm children as a major identifiable subgroup and population at special risk to be protected under the FQPA.

Commenter Description of Issue(s): Hundreds of thousands of children live on farms, play or attend schools on or near agricultural lands, and have family members who routinely handle pesticides. Approximately one million children of farm workers spend considerable time on farms. These children are routinely exposed to dangerous levels of the 950 million pounds of pesticides that are applied to agricultural land annually.

Small Business Impact: No

Commenter Proposed Solution(s): EPA should identify children living on and near farms as a “major identifiable subgroup” for all FQPA determinations and designate these children as a “population at special risk” who must be protected in order to fulfill the FQPA requirement that pesticide tolerances provide a “reasonable certainty that no harm will result to infants and children from aggregate exposure to pesticide chemical residue.”

Estimate of Economic Impacts: The commenter asserts that “Even the narrowly [sic] economic benefits of this action will far outweigh costs if total health benefits of reducing health care costs, reduced health risks to farm children, and associated benefits to their parents and neighbors (e.g., reduced health effects and fewer lost work days) are considered appropriately.”

Commenter(s): Center for Progressive Regulation (70).
179. Definition of Volatile Organic Compound (VOC)

Regulating Agency: EPA

Citation: 40 C.F.R. 51.100

Authority: CAA, 42 U.S.C. 7401 et seq.

Description of Existing Regulation: At 40 C.F.R. 51.100(s) volatile organic compound (VOC) is defined as “any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.”

Commenter Description of Issue(s): The definition of volatile organic compound (VOC) as found in 40 C.F.R. 51.100(s) and as applied by the U.S. EPA has no volatility element and therefore disregards whether a compound is even volatile at all. VOCs are of concern because they are ozone precursors, and a compound must be volatile to be an ozone precursor. EPA recognized this when they promulgated a rule on VOC Emission Standards for Consumer Products in 1996 and included a volatility threshold as part of the rule. The definition of VOC is extremely broad as stated in 40 C.F.R. 51.100(s)

Small Business Impact: No.

Commenter Proposed Solution(s): EPA should include a vapor pressure threshold of 0.1 mm Hg below which a carbon compound would not be considered volatile and would not meet the definition of Volatile Organic Compound.

Estimate of Economic Impacts: None provided

Commenter(s): Copper & Brass Fabricators Council, Inc. (16).
180. Motor Vehicle Emission Standards for Greenhouse Gases (Carbon Dioxide)

Regulating Agency: EPA/OAR

Citation: N/A

Authority: Clean Air Act, 42 U.S.C. 7521

Description of What Regulatory Prompt Would Do: EPA should amend the emission standards for new motor vehicles to contain emissions limitations on carbon dioxide.

Commenter Description of Issue(s): The emission of greenhouse gases (especially carbon dioxide) from automobiles and other mobile sources is a major source of overall greenhouse gas emissions in the United states. EPA has promulgated standards for new motor vehicles and motor vehicle engines under the Clean Air act, but the existing standards do not regulate carbon dioxide emissions.

Small Business Impact: No

Commenter Proposed Solution(s): EPA should amend the emission standards for new motor vehicles to contain emissions limitations on carbon dioxide. The standards should reflect the greatest degree of emission limitation achievable through the application of technology which the Administrator determines will be available for the model year to which such standards apply.

Estimate of Economic Impacts: None provided.

Commenter(s): Center for Progressive Regulation (70).
181. **Heavy-Duty Engines and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements**

**Regulating Agency:** Environmental Protection Agency

**Citation:** 40 CFR 80.500

**Authority:** Clean Air Act, various sections

**Description of Existing Regulation:** The final rule requires a reduction in the sulfur content of highway diesel fuels from 500 parts per million (ppm) to 15 ppm. The regulation phases in reduction by requiring low-sulfur fuel comprising 80 percent of the fuel produced beginning in 2006 and 100 percent beginning in 2010 and to begin offering both fuels by September 1, 2006.

**Commenter Description of Issue:**

- Would disrupt fuel market and increase supply costs through more expensive refining and increased storage costs to downstream marketers.
- Dual market would require installation of additional tanks to hold both diesel types and would also require the use of additional fuel trucks to bring both types to retailers.
- Capital investment needed to supply both fuels will be inessential after final deadline.
- Market demand for the new fuel will be uncertain and will likely lead to demand-supply imbalances.
- Phase-in may defer purchases of new trucks that would be incompatible with the older and less expensive fuel type.
- Improved air quality with the rule will prevent respiratory illnesses.

**Small Business Impact:** Yes, petroleum marketers and retailers will need to make capital investments in storage tanks to accommodate provision of both fuel types.

**Commenter Proposed Solution:**

- Re-open for comment the part of the rule that addresses the phase-in period.
- Move forward with original rule to reduce pollution

**Estimate of Economic Impact:** Expenses incurred by purchasing additional storage tanks, tearing up concrete foundation to install second tank, re-piping and re-manifolding of new tank lines, and the purchase of new pumps and monitors. There will also be compliance costs and the increased costs to acquire product. Survey conducted by National Association of Truck Stop Owners on costs required to carry two grades of diesel had following results:

<table>
<thead>
<tr>
<th>Cost Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over $100,000</td>
<td>45 percent</td>
</tr>
<tr>
<td>Over $75,000</td>
<td>15 percent</td>
</tr>
<tr>
<td>Over $50,000</td>
<td>16 percent</td>
</tr>
<tr>
<td>Less than $50,000</td>
<td>24 percent</td>
</tr>
</tbody>
</table>

Reduction in diesel emissions projected to reduce premature mortality and the incidence of a range or respiratory problems.

**Commenter:** Petroleum Marketers Association of America (6); NATSO (41); and OMB Watch (77).
182. Protection from Pollution from Diesel Engines

Regulating Agency: Environmental Protection Agency

Citation: 66 Fed. Reg. 5002

Authority: Clean Air Act

Description of Existing Regulation: EPA announced it would move forward a final rule to reduce sulfur levels by 97% in mid-2006. EPA subsequently informed the Senate that EPA would convene an independent panel to reexamine the rule.

Commenter Description of Issue: Improved air quality projected to prevent respiratory illnesses

Small Business Impact: No assessment made.

Commenter Proposed Solution: EPA should move forward with original rule to reduce pollution

Estimate of Economic Impact: Reduction in emissions estimated to save more than 8,300 lives and prevent nearly 800,000 asthma attacks and other respiratory problems, according to Natural Resources Defense Council. No calculation of estimated costs was provided

Commenter: OMB Watch (77).
183. Proposed Tier 2 Motor Vehicle Emission Standards and Sulfur Gasoline Control Requirements

Regulating Agency: Environmental Protection Agency

Citation: 40 CFR parts 80, 85-86

Authority: Clean Air Act Section 202

Description of Existing Regulation: The Tier 2 Rule establishes stringent emission standards restricting NOx and PM emissions from light-duty vehicles. The rule also requires a significant reduction of sulfur in gasoline in order to assure that the fuel is compatible with the control equipment.

Commenter Description of Issue:

• The Tier 2 rule is driven by ground-level ozone, which is expected to pose health threats to certain individuals with pre-existing respiratory conditions in a few urban areas on certain summer days when atmospheric conditions combine to create elevated ozone levels.

• EPA’s own analysis predicts that a national proposal would actually increase ozone levels in parts of the nation. Regional and state programs would be more cost-effective.

Small Business Impact: None provided.

Commenter Proposed Solution:

• EPA should leave decisions regarding the sulfur content of gasoline to individual states, with possible cooperation and recommendations from OTAQ. IF EPA feels that Federal regulations are necessary, it should evaluate a petroleum industry proposal to provide low sulfur gasoline for the Eastern half of the nation.

Estimate of Economic Impact:

The commenter projected that EPA data shows that consumers in certain regions will pay as much as ten times more per ton of Nox emissions removed then EPA’s estimated national average. The corresponding benefit will be very small and ozone levels could potentially worsen as a result of these emission standards.

Commenter: Mercatus Center (George Mason University) (73).
184. Withdrawal of State Delegations

Regulating Agency: EPA

Citation: N/A


Description of What Regulatory Prompt Would Do: Encourage EPA to subject all state programs to rigorous oversight and stand ready to assume responsibility for permitting and enforcement when a state's performance is poor.

Commenter Description of Issue(s):

- The major environmental laws allow EPA to delegate the authority to implement Federal regulatory programs to the states. Despite clear evidence that programs in many states have fallen far below the Federal floor, EPA has withdrawn a state's authority on only one occasion. Examples of poor performance include failure to issues or renew permits under the CAA and CWA for major facilities emitting millions of tons of toxic pollution in a timely fashion.
- Such negligence damages the environment and public health and creates an atmosphere of lawlessness that places companies operating in a more responsible manner at a competitive disadvantage.

Small Business Impact: No

Commenter Proposed Solution(s): EPA should subject all state programs to rigorous oversight and stand ready to assume responsibility for permitting and enforcement when a state's performance is poor.

Estimate of Economic Impacts: None provided.

Commenter(s): Center for Progressive Regulation (70).
185. New Source Review

Regulating Agency: Environmental Protection Agency

Citation: 40 C.F.R. Pt. 60

Authority: Clean Air Act, 42 U.S.C. Sec. 7411

Description of Existing Regulation: New Sources Review (NSR) is a program established under the Clean Air Act that requires major stationary sources to install state-of-the-art air pollution controls whenever an owner or operator of such a source undertakes a major modification at the source that would result in a significant increase in one or more of the criteria pollutants.

Commenter Description of Issue:

• It is estimated that pollution from old coal-powered plants cause roughly 30,000 premature deaths per year. A recent study by the AMA concludes that people residing in the most heavily polluted metropolitan areas have a 12% increased risk of dying of lung cancer compared to people in the least polluted areas.
• The current NSR requirements for power plants and boilers do not regulate carbon dioxide emissions, however, CO2 is the main contributor to global warming and the U. S. currently emits 25% of the world’s carbon dioxide.
• NSR regulations are too vague and complex, making it difficult to determine when a facility triggers the NSR permitting process.
• Once triggered, the NSR permitting process can take over a year, preventing facilities to respond to market conditions in a timely manner.
• NSR stops projects that enhance energy efficiency, affordability and reliability.

Small Business Impact: No

Commenter Proposed Solution:

• Revise the NSR standards to include carbon dioxide controls.
• Propose a definition of routine maintenance, repair and replacement that accurately and fairly reflects the types of RMRR activities that are routine within specific industries.
• Propose a more realistic emissions increase test to determine whether an activity constitutes a major modification.
• Revise NSR to eliminate disincentives that prevent projects that enhance energy efficiency, affordability and reliability.
• Provide a clear guideline with an investment level cutoff.

Estimate of Economic Impact: none provided

Commenter: OMB Watch (77); Alamo Cement Co. (188); Hanson Permanente Cement (189); Indiana Manufacturers Assosc. (187); Ajay Kumar (196); National Federation of Independent Business (30); Copper and Brass Fabricator’s Council (16).
186. Risk Assessment for Rodenticides

Regulating Agency: EPA

Citation: N/A

Authority: FIFRA

Description of Rule: EPA’s ecological risk assessment for rodenticides, when completed, will serve as the basis for the identification of mitigation measures.

Commenter Description of Issue(s): The risk assessment methodology used by EPA in preparing the current draft risk assessment document does not reflect sound scientific principles, is not consistent with ecological risk assessments prepared previously by EPA, and is generally neither legally nor scientifically valid. Further, it is not consistent with OMB’s data quality guidelines and any mitigation measures based on the assessment, as drafted, would be insupportable.

Commenter Proposed Solution(s): OMB should consult with EPA about the ecological risk assessment, review the comments submitted on the document to date, and urge EPA to withdraw the assessment in its entirety because it is premised on a scientifically indefensible model for assessing risk.

Estimate of Economic Impacts: None Provided

Commenter(s): Rodenticide Registrants Task Force (36).
187. Ban on Chromated Copper Arsenate (CCA)

Regulating Agency: EPA

Citation: 67 FR Number 36, pp. 8244

Authority: FIFRA §6(f)(1)

Description of Existing Regulation: On February 12, 2002 EPA announced a voluntary decision by industry to move consumer use away from a variety of pressure-treated wood that contains arsenic by December 2002. By January 2004, EPA will not allow CCA products for affected residential uses. To carry out this action, on February 22, 2002, EPA issued a notice of receipt of requests from registrants of affected chromated copper arsenate (CCA) products to cancel certain products and to amend to terminate certain uses of other CCA products. EPA indicated that it intended to grant these requests at the close of the comment period for the announcement unless the Agency received substantive comments that would merit further review.

Commenter Description of Issue(s):

• EPA has not concluded that CCA-treated wood poses any unreasonable risk to the public or the environment.
• EPA decided to ban the product a year before its updated risk assessment was scheduled to be completed.
• EPA issued the ban because the producers of the chemical voluntarily agreed to phase it out. That should not preempt others from selling the product in the future and does not take into consideration the concerns of consumers and the 350 wood treatment plants that use CCA.

Small Business Impact: No

Commenter Proposed Solution(s): EPA should complete its scientific assessment, allow adequate time for public comment on that assessment, propose a rule, and allow comment on the proposal.

Estimate of Economic Impacts: Estimated retooling costs are $40,000 to $200,000 per facility. Costs could escalate if rulings cause people to dismantle pressure-treated wood structures.

Commenter(s): Competitive Enterprise Institute (186).
188. TRI Alternate Reporting Threshold (Form A)

Regulating Agency: EPA/Office of Environmental Information

Citation: 40 CFR 372 (59 FR 38524, Jul 28, 1994)

Authority: Emergency Planning and Community Right-to-Know Act, Sec 313

Description of What Existing Regulation Does: EPCRA 313 establishes requirements for manufacturing facilities to report annually to EPA on their releases and management of approximately 600 listed toxic chemicals. This information is then made available by EPA to the public. Most facilities report detailed information on each eligible chemical using the 5-page Form R. However, facilities that manage as waste less than 500 lbs of a listed chemical may use a short Form A, which includes a much smaller subset of the information in the detailed Form R. Form A is not available for persistent, bioaccumulative toxic (PBT) chemicals.

Commenter Description of Issue(s): Form A is underutilized because the eligibility requirements are too restrictive.

Small Business Impact: Yes. Many facilities that report to TRI are small businesses, and these are most likely to experience significant impacts from the burden associated with such reporting.

Commenter Proposed Solution(s): Expand eligibility for use of Form A by 1) raising eligibility threshold from 500 to 5,000 lbs; and 2) base eligibility determination on quantity of chemical released to the environment, rather than quantity managed as waste. For many facilities, the majority of what is “managed as waste” is actually recycled or treated so that it never reaches the environment.

Estimate of Economic Impacts: Commenter estimates that this change would reduce paperwork for an additional 30,000 to 50,000 facilities. Commenter believes that the detailed info that would be lost on releases below 5,000 lbs “would be of no benefit to affected communities.”

Commenter(s): Small Business Administration, Office of Advocacy (97).
189. **Collection of Health Screening Data**

Regulating Agency: EPA/OPPTS

Citation: N/A

Authority: 15 U.S.C. §§2603, 2618

**Description of What Regulatory Prompt Would Do:** OMB should prompt EPA to use its legal authorities under the Toxic Substances Control Act, 15 U.S.C. §§2603, 2618, to collect health screening data for chemicals.

**Commenter Description of Issue(s):** According to a 1983 study by the National Academy of sciences, the vast majority of chemicals (90 percent) do not have even preliminary health screening data.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** EPA should exercise its legal authorities under the Toxic Substances Control Act, 15 U.S.C. §§2603, 2618, to collect health screening data for chemicals.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** John Applegate, Indiana University School of Law; Wendy Wagner, University of Texas School of Law (100).
190.  Export Notification Requirements

Regulating Agency: EPA/OPPTS

Citation: 40 CFR Part 707.60-707.75

Authority:  TSCA §12(b)

Description of Existing Regulation: TSCA Section 12(b) requires that persons notify EPA if they export or intend to export to a foreign country chemical substances or mixtures subject to the certain provisions of TSCA. EPA must then notify the government of the country of destination of the first notification for each regulated chemical, including the regulatory action taken by EPA or the availability of test data submitted on the substance or mixture. Annual notices of the first shipment are required. EPA’s rule interprets TSCA Section 12(b) as applying to persons exporting shipments that contain the substance as an impurity or minor mixture component.

Commenter Description of Issue(s):

• Exports containing a trace component of a covered chemical pose negligible risk and yet are responsible for the majority of notifications.
• Because the majority of notifications are for chemicals posing negligible risk, receiving embassies discount those notices that are sent.
• In recent years the number of Section 12(b) notifications have increased as additional substances are subjected to testing requirements. The need to address this issue now is particularly acute as EPA continues to move forward with proposed testing initiatives involving hundreds of chemicals.

Small Business Impact: No

Commenter Proposed Solution(s): EPA should establish a de minimis threshold of 1 percent for a listed chemical in a mixture below which the chemical is exempted from reporting, and a cutoff of 55 gallons or less of the chemical or 100 lbs, whichever measure applies, below which no 12(b) chemical notification is required. Such a change would focus the attention of foreign governments on shipments that are more likely to pose risks to human health and the environment.

Estimate of Economic Impacts: None provided.

Commenter(s): American Chemistry Council (12).
191. Amendments to EPA's PCB Spill Cleanup Policy

Regulating Agency: EPA/OPPTS

Citation: 40 C.F.R. §761.120-135


Description of Existing Regulation: EPA's Spill Cleanup Policy rule, published in 1987, establishes requirements for the cleanup of spills resulting from the release of materials containing PCBs at concentrations of 50ppm or greater. The limits in the Policy relate to responding to a spill once it has been discovered: (1) cleanup requirements for "low concentration spills" must be completed within 48 hours after the responsible party was notified or became aware of the spill (id. at §761.125(b)(1)(iii)); (2) spill cleanup response to "high concentration spills" must be initiated "as soon as possible and within no more than 24 hours (or within 48 hours for PCB Transformers) after the responsible party was notified or became aware of the spill." (id. at §761.125(c)(1)). Materials cleaned up in accordance with the Policy are "decontaminated" and can continue to be used and distributed in commerce without restriction. Compliance with the Policy's response requirements is considered "adequate cleanup" under the PCB disposal regulations and creates a presumption against enforcement for the underlying spill event and the need for further cleanup under TSCA.

Commenter Description of Issue(s): EPA has made several attempts to improperly limit the scope of the Agency's "TSCA PCB Spill Cleanup Policy Rule" to spills that are less than 72 hours old. Imposing an absolute restriction on the Policy to spills that are less than 72 hours old substantially narrows the circumstances under which it is available to the public and simultaneously narrows the legal rights that the Policy has historically provided to the regulated community. The Cleanup Policy is a rule as defined under the APA, and any substantive change to the rule requires compliance with the notice and comment requirements of the APA.

Small Business Impact: No.

Commenter Proposed Solution(s): The pronouncements, made in the form of "guidance" by the PCB program office (e.g., in the 2000 EPA PCB Q&A Manual and PCB Home Page), which unilaterally incorporate a 72-hour policy into the Cleanup Police should be rescinded.

Estimate of Economic Impacts: None provided.

Commenter(s): Utility Solid Waste Activities Group (38).
192. Storage for Reuse Regulation (PCBs)

Regulating Agency: EPA/OPPTS

Citation: 40 C.F.R. §761.35


Description of Existing Regulation: This regulation restricts storage for reuse of “PCB Articles.” The regulation limits the storage of such articles to five years, unless a waiver is granted by EPA or the equipment is consolidated in a centralized facility designed to hold PCB wastes.

Commenter Description of Issue(s):

• The regulation imposes restrictions on the storage for reuse of “PCB Articles”, which includes a wide-range of electrical equipment critical to the reliable supply of electricity. Consolidating PCB Articles in a “storage for disposal” facility is impractical because such equipment must be kept on hand at service centers and similar dispersed locations throughout utility transmission and distribution systems to ensure quick access to spare equipment to replace equipment damaged in storms, accidents or system failures.

• Despite acknowledging the reasons in which extended storage for reuse is warranted, and emphasizing instances within the utility industry where storage for reuse of PCB-containing equipment - well beyond five years - is warranted EPA promulgated the final rule without an exemption for utilities.

• The rule was remanded to EPA because EPA filed to respond to comments of USWAG and others urging this exemption. It has been two years since the rule was remanded and there is no schedule for responding to the remand.

Small Business Impact: No.

Commenter Proposed Solution(s): EPA should rescind the rule as applied to the utility industry.

Estimate of Economic Impacts: Virtually every utility in the country (including thousands of rural electrical cooperatives) necessarily store PCB Articles for reuse as spare equipment. The vast majority of these entities will be required to file variance requests to continue to store this equipment-- individual variance requests will need to be filed for hundreds of thousands of pieces of equipment across the country. Rejections of variance requests or imposition of additional controls on extended storage could compel premature discard of equipment and preventing utilities from storing spare equipment at dispersed sites may prevent them from being able to respond as quickly to power outages.

Commenter(s): Utility Solid Waste Activities Group (38).
193. RCRA Cement Kiln Dust (CKD) Rule

Regulating Agency: EPA/OSWER

Citation: 60 FR 7366 and 64 FR 45631

Authority: RCRA section 3001(b)(3)(A)(iii)

Description of What Regulation Would Do: In 1995, EPA issued a regulatory determination that Cement Kiln Dust posed a risk to human health and the environment and therefore should not be exempt from regulation under RCRA. In 1999, EPA published a proposed rule that would regulate Cement Kiln Dust.

Commenters Description of Issue: Commenters assert that EPA’s regulatory determination and proposed rule unfairly characterizes Cement Kiln Dust as hazardous, damaging its competitiveness in the marketplace and making cement producers more likely to be singled out for state regulation or lawsuits.

Commenters Proposed Solution: EPA should reverse the regulatory determination and withdraw the proposed regulation of CKD.

Small Business Impacts: None described

Economic Impacts: None provided for the proposed rule. Commenters indicate that a final rule would have an annual cost of approximately $50 million.

194. Spill Prevention Plans

Regulating Agency: EPA

Citation: 40 C.F.R. 112

Authority: Oil Pollution Act of 1990, 33 USC 2701-2761

Description of What Existing Regulation Does: Requires facilities that store oil above certain threshold levels in proximity to waterways to prepare and implement spill prevention, control, and countermeasures plans.

Commenter Description of the Issue:

• Thresholds for aboveground storage capacity (660 gallons in a single tank or 1320 gallons aggregate) are too low.
• Interpretation of ‘oil’ includes water-based machining fluids that are 95 percent water and vegetable oils.
• Aggregate capacity includes drums that may be spread over many acres of a site.
• ‘Proximity to waterway’ is defined too conservatively, a small stream a mile away would trigger the requirements of the rule.

Commenter Proposed Solution:

• Thresholds should be raised to relieve burden on small businesses.
• A more precise definition of 'reaching a waterway' should be developed.
• EPA should clarify that 'aggregate' means oil that is stored in a single location within a site.

Small Business Impacts: Commenter indicates that this rule is especially burdensome on small businesses, but does not provide examples or quantification.

Economic Impacts: None provided.

Commenter: Copper and Brass Fabricators Council (16).
195. NPDES and Sewage Sludge Monitoring Reports

Regulating Agency: EPA

Citation: 40 CFR 122

Authority: Clean Water Act, Sec 402

Description of What Existing Regulation Does: This collection authorizes the collection of Discharge Monitoring Reports (DMRs) from National Pollutant Discharge Elimination System (NPDES) permittees. These reports are the primary vehicle by which EPA and the States oversee compliance with the discharge requirements of the Clean Water Act. Industry-specific requirements to monitor particular pollutants are contained in individual effluent guidelines. In recent years, EPA has increasingly included alternatives to monitoring in new or revised guidelines. For example, facilities in the pulp and paper industry are allowed to submit information on operating parameters (that is routinely gathered by facilities anyway) in lieu of monitoring Chemical Oxygen Demand (COD), once they have completed an initial two-year monitoring period to determine the appropriate range of parameter values. Facilities in several other industries are allowed to develop a management plan for toxic chemicals in lieu of monitoring.

Commenter Description of Issue(s): The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: Yes, many affected facilities are small businesses.

Commenter Proposed Solution(s): OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: The current reporting burden of this collection is 14.2 million hours.

Commenter(s): Rep. Doug Ose (108).
196. Watershed Rule (Total Maximum Daily Load)

Regulating Agency: EPA/Office of Water

Citation: 65 FR 43585 (July 2000 final rule); 66 FR 53043 (October 2001 delay of effective date).

Authority: Clean Water Act, Sec 303(d)

Description of Regulation: The rule revised existing requirements for States to prepare lists of impaired waters and to develop total maximum daily loads for the waters on these lists.

Commenter Description of Issue(s):

- TMDLs are a tool to allow States and local watersheds to conduct locally led watershed planning. EPA is responsible only for the scientific validity of the total pollutant load identified in the TMDL (AFBF).
- Water quality standards have yet to play an effective role in protecting the nation’s waters. The July 2000 rule is an important step forward in using TMDLs to achieve water quality standards (CPR).
- Prescriptive, procedural approach in July 2000 rule is likely to undermine the benefits of a watershed approach. Rule gives too much centralized authority to EPA (Mercatus).
- TMDLs have not so far played a major role in attaining water quality standards. Many States have failed to implement TMDLs and are being sued as a result (OMB Watch).

Small Business Impact: Not directly. Rule only applies to States, however small businesses could be impacted by State implementation of TMDLs.

Commenter Proposed Solution(s):

- EPA should approve total pollutant loads only; EPA should not approve load and wasteload allocations (AFBF).
- EPA should adopt and implement the July 2000 rule that is currently on hold (CPR, OMB Watch).
- EPA should adopt a locally based approach based on the rule of law and protection of environmental rights that allows for flexibility to implement innovative local solutions and recognition of regional differences in benefits and costs (Mercatus).

Estimate of Economic Impacts: Commenter Mercatus believes cost of “least flexible” approach would range from $2.45 to $5.26 billion per year. Commenters CPR and OMB Watch state that half the nation’s waters remain too polluted for fishing and swimming, largely due to nonpoint source pollution, and that TMDLs are an effective mechanism for achieving water quality goals and addressing nonpoint sources.

Commenter(s): American Farm Bureau Federation (24), Center for Progressive Regulation (70), Mercatus Center (73), OMB Watch (77).
197. TRI Lead

Regulating Agency: EPA/Office of Environmental Information

Citation: 40 CFR 372

Authority: Emergency Planning and Community Right-to-Know Act, Sec 313

Description of Regulation: This rule lowered the reporting threshold under TRI for lead and lead compounds to 100 lbs, pursuant to a finding that lead is a persistent, bioaccumulative, toxic (PBT).

Commenter Description of Issue(s):

• Elimination of de minimis exemption causes facilities to spend resources tracking minute quantities of lead that may be contained in production inputs. (CBFC)
• Retroactive application of rule to January 1, 2001 causes significant hardship to businesses that are not prepared to track lead usage at the level of detail required by the rule (SGCD, NFIB).

Small Business Impact: Yes. Many impacted businesses are small and these will experience disproportionately high costs to comply with the rule.

Commenter Proposed Solution(s):

• Restore de minimis exemption for lead reporting (CBFC)
• Defer reporting requirements until January 1, 2002 (SGCD, NFIB).

Estimate of Economic Impacts: Commenter CBFC estimates 10 to 20 hours saved per form submission, with little loss in useful information.

Commenter(s): Copper and Brass Fabricators Council (16), Society of Glass and Ceramic Decorators (20), National Federation of Independent Businesses (30).
198.  Arsenic in Drinking Water

Regulating Agency: EPA/Office of Drinking Water and Ground Water

Citation: Final Rule issued January 19, 2001

Authority: Safe Drinking Water Act, Sec 1412(b)

Description of Regulation: This rule lowers the maximum contaminant level (MCL) for arsenic to 10 ppb.

Commenter Description of Issue(s):

- Rule does not identify a level of arsenic that “poses an unreasonable risk to health” which the commenter believes EPA should do as a matter both of law and of good public policy. (NRWA)
- Rule did not authorize the use of small system variances. (NRWA)
- According to EPA’s own estimates, costs of rule significantly exceed benefits. Resources used for compliance could be better used for other public health purposes (Mercatus).
- Commenter believes that quantified benefits analysis fails to capture significant benefits of controlling arsenic, both because of missing health endpoints and because of various technical flaws (e.g., discounting for latency) (NRDC).
- Commenter believes scientific basis of standard is flawed (Parris).

Small Business Impact: Yes. Most impacted water systems are small and these will experience disproportionately high costs to comply with the rule.

Commenter Proposed Solution(s):

- Define level of arsenic in drinking water that poses an unreasonable risk to health (NRWA).
- Identify affordable variance technologies for small systems (NRWA).
- Provide communities with information about arsenic levels and hazards, but do not impose uniform national standard (Mercatus).
- OMB should clearly identify flaws in quantified analysis in order to “dispel the suspicion that the administration simply set aside the use of biased techniques in this one instance due to political considerations.” (NRDC)
- EPA should use more up-to-date science (Parris).

Estimate of Economic Impacts: Commenter Mercatus estimates that rule will impose net costs, over and above benefits, of $600 million per year. Commenter NRDC believes benefits are significantly greater than quantified estimates.

Commenter(s): National Rural Water Assn (44), Mercatus Center (73), Natural Resources Defense Council (80), George Parris (191).
199. **Concentrated Animal Feeding Operations**

Effluent Guidelines for Concentrated Animal Feeding Operations (CAFOs)

**Regulating Agency:** EPA/Office of Water

**Citation:** NPRM, 66 FR 2959, Jan 12, 2001

**Authority:** Clean Water Act, Sec 402

**Description of What Proposed Regulation Would Do:** The proposed rule would strengthen discharge standards for concentrated animal feeding operations and establish for the first time standards related to the land application of manure and process wastewater by CAFOs. These standards would then be included in NPDES permits for affected facilities.

**Commenter Description of Issue(s):**

- Proposed standards will be costly to farmers and unnecessary because of existing State programs (AFBF).
- Existing standards are out-of-date and inadequate. CAFO discharges cause significant water quality problems, including eutrophication, toxic algal blooms, fish kills, alterations in species composition, and drinking water contamination (CPR).
- While regulation of “nonpoint sources such as CAFOs” makes sense in theory, EPA’s proposed approach is unlikely to yield cost-effective improvements in water quality. EPA’s analysis does not support uniform nationwide regulation (Mercatus).
- Commenter cites Sierra Club estimates that CAFOs have polluted 35,000 miles of rivers in 22 states and contaminated ground water in 17 states (OMB Watch).

**Small Business Impact:** Yes. Some potentially affected livestock operations are small businesses.

**Commenter Proposed Solution(s):**

- EPA should maintain 1,000 animal unit threshold, maintain 25-year, 24-hour storm exemption, not include land application requirements in NPDES permits, and not require co-permitting of integrators (AFBF).
- Final rule should require individual permits, eliminate 25-year, 24-hour storm exemption, bring dry poultry operations under the NPDES permit program, and make it clear that the land application area is part of the CAFO (CPR).
- EPA should instead foster “community based management of watersheds.” EPA can do this by conducting a comparative cost-benefit analysis of 1994 CAFO strategy and draft final rule, challenging the legal mandate that CAFO water pollution must be addressed through regulation, and addressing scientific deficiencies that currently inhibit development of more efficient and effective CAFO pollutant prevention and reduction strategies (Mercatus).
- EPA should finalize and implement proposed rule (OMB Watch).

**Estimate of Economic Impacts:** Commenter Mercatus states that EPA’s analysis shows that proposed rule would impose net social costs of $664 to $804 million. Commenter OMB Watch states that only 2,500 out of the 39,000 CAFOs that would potentially be regulated by the proposed rule currently have NPDES permits. Commenters CPR and OMB Watch state that strong regulatory requirements will force operators to internalize costs of water pollution that are currently born by the fishing, tourism, and health care industries.

**Commenter(s):** American Farm Bureau Federation (24), Center for Progressive Regulation (70), Mercatus Center (73), OMB Watch (77).
200. **Stormwater Construction General Permit**

**Regulating Agency:** EPA/Office of Water

**Citation:** Issued pursuant to 40 CFR 122.26

**Authority:** Clean Water Act, Sec 402(p)

**Description of What Existing Regulation Does:** The existing General Permit establishes requirements for control of stormwater discharges from construction sites disturbing 5 or more acres of land (Phase I). EPA is currently working on a new General Permit that will become effective on March 1, 2003 and will apply to sites disturbing 1 or more acres (Phase II). Permit includes various notification and reporting requirements and requires preparation of a Storm Water Pollution Prevention Plan (SWPPP), which describes best management practices operator will implement to minimize discharges of pollutants, particularly sediment, from the site.

**Commenter Description of Issue(s):**

- CWA Sec 402(l)(2) exempts oil and gas exploration operations from stormwater permitting requirements. However, both the existing General Permit for Region 6, and the draft permit being prepared by EPA HQ that will apply nationally, require oil and gas facilities to obtain permit coverage for construction of their exploration facilities, even though the facilities are exempt once constructed. Commenter believes this violates intent of CWA exemption. Most oil and gas facilities are between 1 and 5 acres, so will be affected for the first time by the new Phase II permit.
- Permit imposes significant costs and time delays on operators, who often must be prepared to act rapidly in fast-moving, competitive industry. These costs were not considered in the development of the Stormwater Phase II Rule, which extended permitting requirements to site between 1 and 5 acres.

**Small Business Impact:** Yes. Many impacted facilities are small businesses.

**Commenter Proposed Solution(s):**

- Clarify that Sec 402(l)(2) exemption applies to all phases of oil and gas exploration, including construction of the facility.
- Alternately, provide an automatic waiver in the permit for sites based on certain characteristics, such as topology, soil type, and distance from receiving waters, and/or allow coverage of multiple wells using a single SWPPP.

**Estimate of Economic Impacts:** Commenter estimates cost of hiring a consultant to prepare a SWPPP at $3,000 to $8,000 per well, which adds significantly to the current average construction cost of $40,000. In addition, potential inclusion of requirements related to historic preservation may necessitate an archaeological survey, at an estimated cost of $3,000 to $5,000 per site. Commenter estimates that 4,000 to 4,500 “intents to drill” are approved per month in Oklahoma alone.

**Commenter(s):** Chesapeake Natural Gas (60), Henry Hood/Chesapeake Energy Corp (203).
201. **Stormwater Phase I**

**Regulating Agency:** EPA/Office of Water

**Citation:** 40 CFR 122.26

**Authority:** Clean Water Act, Sec 402(p)

**Description of What Existing Regulation Does:** The rule establishes National Pollutant Discharge Elimination System (NPDES) permitting requirements for the control of stormwater discharges from 1) municipal storm sewer systems serving more than 50,000 persons, and 2) industrial facilities, including construction sites disturbing 5 or more acres of land. For industrial facilities, rule includes various notification and reporting requirements, and requires preparation of Storm Water Pollution Prevention Plan (SWPPP).

**Commenter Description of Issue(s):** SWPPP was supposed to be based on low-cost best management practices, such as good housekeeping, preventive maintenance, employee training, spill prevention, and proper materials handling. However, program has evolved so that SWPPPs are now often required to include construction of major systems for capture and treatment of stormwater before discharge to surface waters, with minimal environmental benefits.

**Small Business Impact:** Not clear.

**Commenter Proposed Solution(s):** Refocus program on low-cost, low-technology BMPs, as originally intended.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Copper and Brass Fabricators Council (16).
202. Stormwater Phase II

Regulating Agency: EPA/Office of Water

Citation: 40 CFR 122.26

Authority: Clean Water Act, Sec 402(p)

Description of What Existing Regulation Does: The rule establishes National Pollutant Discharge Elimination System (NPDES) permitting requirements for the control of stormwater discharges from 1) municipal storm sewer systems serving 50,000 or fewer persons, and 2) construction sites disturbing 1 to 5 acres of land.

Commenter Description of Issue(s):

- Rule is based on inadequate science (i.e., only two, non-peer reviewed studies both of which were designed to prove the pre-determined conclusion that construction sites between 1 and 5 acres are a significant source of pollutants).
- Imposes significant costs on construction, which drives up price of residential housing.

Small Business Impact: Yes. Most impacted construction operators are small businesses.

Commenter Proposed Solution(s): Rescind construction site portion of rule until better scientific justification developed.

Estimate of Economic Impacts: Estimated cost of total rule (municipal and construction site combined) is $848 to $981 million. Estimated cost for one-acre site is $2,143, for three-acre site is $5,535, for five-acre site is $9,646. Commenter calculates that this adds about $1,000 to price of average new home, which reduces new home sales among low-income households by 20,000 units per year.

Commenter(s): National Association of Home Builders (48).
203. Removal Credits for Publicly Owned Treatment Works (POTWs)

Regulating Agency: EPA/Office of Water

Citation: 40 CFR 403.7

Authority: Clean Water Act, Sec 307(b)(1)

Description of What Existing Regulation Does: The rule establishes requirements for POTWs to grant “removal credits” to facilities discharging industrial wastes into the treatment system. Under the national pre-treatment program, industrial facilities that discharge to POTWs must meet pretreatment standards that generally include concentration limits on specific pollutants. The CWA provides that if a particular pollutant can be removed by the treatment processes at the POTW, the POTW may grant a “removal credit” to the facility that reduces the level of treatment required at the facility to account for the treatment that will occur anyway at the POTW. Before a POTW can grant removal credits to its industrial dischargers, however, it must obtain “removal credit authority” from EPA.

Commenter Description of Issue(s):

• Commenters believe that the very low percentage of POTWs that have removal credit authority is due to the unnecessarily burdensome requirements associated with obtaining such authority. For example, POTWs must base removal rates on the average of the lowest half of removal measurements. (CBFC) This leads to industrial facilities being required to install redundant treatment for pollutants that are being adequately removed by the POTW, and also causes the POTW to lose potential revenues from treating these waste streams.
• Requirement to have sludge disposal standards before pollutant is eligible for removal credits substantially limits number of pollutants for which such authority is even potentially available. (SOCMA)

Small Business Impact: Yes. Many industrial dischargers are small businesses, and these are most likely to experience significant impacts from the need to install redundant treatment systems for relatively low-volume waste streams.

Commenter Proposed Solution(s):

• Revise the removal credit regulations to more accurately reflect actual pollutant removals by the POTWs, and to facilitate application for and granting of removal credit authority to POTWs. (CBFC)
• Revise the regulations to allow granting of removal credits for pollutants if EPA has determined that risk from sludge disposal does not warrant establishment of standards.

Estimate of Economic Impacts: None provided.

Commenter(s): Copper and Brass Fabricators Council (16), Synthetic Organic Chemical Manufacturers Association (19).
204. Sanitary Sewer Overflows

Regulating Agency: EPA/Office of Water

Citation: 40 CFR 122

Authority: Clean Water Act, Sec 301(b)(1)(B)

Description of What Existing Regulation Does: Currently, all discharges from a Publicly Owned Treatment Works (POTW) are required to achieve effluent limitations based upon secondary treatment, as defined by the Administrator. EPA has interpreted this to include any discharge from the collection system (sewers). In practice, however, most sewer systems experience occasional discharges due to a variety of factors. Some of these (inadequate maintenance) can be corrected by the operator; others (grease illegally discharged by a private business) are beyond the reasonable control of the operator. All such discharges (called “sanitary sewer overflows”) are currently treated as violations of the CWA. EPA is currently working on a proposed rule that would strengthen the planning and maintenance requirements for sewer operators and clarify the legal status of discharges that are beyond the reasonable control of the operator.

Commenter Description of Issue(s):

• Commenter believes this important rule is being held up at EPA in part because the cost-benefit analysis is being reworked. Commenter believes cost-benefit analysis is “being used to delay progress on this rule with endless procedural red tape.”
• Commenter is further concerned that the rule may be reworked in a way to provide fewer protections than it should.

Small Business Impact: Yes. Many POTWs are operated by municipalities with fewer than 50,000 people, which is the SBA definition of a “small government.”

Commenter Proposed Solution(s): Propose in a timely manner a meaningful rule to regulate SSOs.

Estimate of Economic Impacts: None provided.

Commenter(s): Natural Resources Defense Council (80).
205. **Effluent Guidelines for Metal Products and Machinery**

**Regulating Agency:** EPA/Office of Water

**Citation:** NPRM, 66 FR 424, Jan 3, 2001

**Authority:** Clean Water Act, Sec 402

**Description of What Proposed Regulation Would Do:** The proposed rule would strengthen discharge standards for facilities that manufacture or repair metal products and machinery. The rule would tighten existing limitations on discharges of pollutants such as metals, oil and grease, and various organics. These standards would then be included in NPDES permits for affected facilities.

**Commenter Description of Issue(s):**

- According to EPA’s analysis, costs of the proposed rule ($1.9 billion per year) far outweigh benefits ($0.7 billion per year).
- There are numerous flaws in the supporting analysis and impacts on affected facilities are “grossly mischaracterized.”
- Current standards are already sufficient to protect both the environment and public health.

**Small Business Impact:** Yes. Most potentially affected dischargers are small businesses. EPA proposed production-related applicability thresholds in several subcategories to try to lessen the impact on small businesses, but many small businesses remain within scope.

**Commenter Proposed Solution(s):** OIRA should review the rule.

**Estimate of Economic Impacts:** Rule could be “devastating” to small businesses. Commenter estimates that “total compliance cost for an average business is approximately 6.5% of total sales.” Facilities are not able to pass costs along because of competitive pressures.

**Commenter(s):** National Federation of Independent Businesses (30); Crown Battery (192); Indiana Manufacturers Assn (193).
206. Drinking Water Standards for Emerging Contaminants

Regulating Agency: EPA/Office of Drinking Water and Ground Water

Citation: N/A

Authority: Safe Drinking Water Act, Sec 1412(b)

Description of What Regulation Would Do: In Aug 1998, EPA published its first Drinking Water Contaminant Candidate List, as provided for in the SDWA amendments of 1996. This is a list of 60 contaminants that EPA is currently considering for regulation. Commenter is proposing that EPA move forward expeditiously with development of standards for the contaminants on the list.

Commenter Description of Issue(s): Commenter believes regulation of these contaminants provides a “meaningful opportunity for health risk reduction because the contaminants occur in tap water at levels that may have adverse health effects.”

Small Business Impact: Yes. Most water systems impacted by drinking water regulations are small and these generally experience disproportionately high costs to comply with the rule.

Commenter Proposed Solution(s):

• Issue standards for “many contaminants that are not currently regulated, but that pose significant health risks.”
• Commenter is particularly concerned about perchlorate, which “contaminates tap water in millions of homes at levels above those that EPA’s draft risk assessment says are safe.”

Estimate of Economic Impacts: No quantitative estimates provided. Commenter states that “treatment technologies to control many of these contaminants are already available and their costs have been assessed for removing other contaminants.”

Commenter(s): Center for Progressive Regulation (70).
207. Drinking Water Standards for Radionuclides

Regulating Agency: EPA/Office of Drinking Water and Ground Water

Citation: 40 CFR 141 and 142

Authority: Safe Drinking Water Act, Sec 1412(b)

Description of What Existing Regulation Does: Rule establishes maximum contaminant levels (MCLs) for radionuclides in drinking water. Covers several hundred specific isotopes in several broad categories (e.g., beta emitters, gamma emitters, etc).

Commenter Description of Issue(s):

• Commenter states that rule will make drinking water unaffordable for several counties in Texas, even though there have been no reported cases of bone cancer, which commenter states is the most significant health risk from radionuclides, in these areas. (TXDA)
• Commenter believes that the scientific and technical basis for the rule is flawed. (M Ford)
• Commenter indicates that EPA analysis shows that net benefits are negative. (M Ford)
• Commenter is concerned that rule may force water systems to either abandon quality sources of water, or install expensive filtering systems that create hazardous radioactive waste. (M Ford)

Small Business Impact: Yes. Many impacted water systems are small and these generally experience disproportionately high costs to comply with the rule.

Commenter Proposed Solution(s):

• Stay enforcement of the standard pending resolution of current litigation. (TXDA)

Estimate of Economic Impacts: None provided.

Commenter(s): Texas Dept of Agriculture (89), Michael Ford (144).
208. Radon in Drinking Water

Regulating Agency: EPA/Office of Drinking Water and Ground Water

Citation: NPRM issued Nov 2, 1999 (64 FR 59246)

Authority: Safe Drinking Water Act, Sec 1412(b)(13)

Description of What Regulation Will Do: This rule will establish requirements for the control of radon in drinking water. The NPRM included a maximum contaminant level (MCL) of 300 pCi/L and an “alternate” MCL of 4,000 pCi/L for water systems in States that adopt an approved “multimedia mitigation” (MMM) program to reduce radon exposure in indoor air.

Commenter Description of Issue(s):

• Commenter believes final rule is long overdue (statutory deadline for promulgation of final rule was Nov 2000). (CPR)

• Commenter believes high costs to small communities may force them to abandon public water system and force residents to turn to untreated surface waters. Commenter also question basis of estimate that rule would save 62 lives per year. (CEI)

Small Business Impact: Yes. Most impacted water systems are small and these will experience disproportionately high costs to comply with the rule.

Commenter Proposed Solution(s):

• Promulgate final rule expeditiously. (CFR)

• Closely review agency science and cost calculations. Ensure standard set solely based on risks related to radon in drinking water, not other sources of radon exposure. (CEI)

Estimate of Economic Impacts: Commenter CPR states that radon from drinking water accounts for 1-2 percent of radon in homes, which is highly carcinogenic, and proposed standard would cost less than $20 per household per year for over 90% of affected households. Commenter CEI states that NPRM presented national costs of $407 million per year and benefits of $362 million per year, but that according to GAO, the agency has likely underestimated costs significantly.

Commenter(s): Center for Progressive Regulation (70), Competitive Enterprise Institute (186).
209. **TRI Form R Reporting**

**Regulating Agency:** EPA/Office of Environmental Information

**Citation:** 40 CFR 372

**Authority:** Emergency Planning and Community Right-to-Know Act, Sec 313

**Description of What Existing Regulation Does:** The rule establishes requirements for manufacturing and other related facilities (e.g., electric utilities, mining operations, waste treatment facilities) to report annually to EPA on their releases and management of approximately 600 listed toxic chemicals. This information is then made available by EPA to the public. Requirements apply to facilities in listed SIC codes that have 10 or more employees and manufacture, process, or otherwise use listed toxic chemicals in quantities exceeding certain thresholds. For most chemicals, thresholds are 25,000 lbs for manufacture and processing, and 10,000 lbs for otherwise use. For about 25 persistent, bioaccumulative, toxic (PBT) chemicals, EPA has established much lower thresholds through rule making. "PBT" chemicals have a reporting threshold of 100 lbs, while "highly PBT" chemicals have a reporting threshold of 10 lbs. For dioxin, the threshold is 0.1 grams.

**Commenter Description of Issue(s):**

- Facilities are required to report not only releases to the environment but also "off-site transfers." Commenter believes this unduly inflates reported quantities and gives misleading impression of risk associated with facility's waste management. Commenter states that most off-site transfers are either incorporated into products, recycled, fundamentally altered in a way that minimizes environmental impact (e.g., incineration), or disposed of in a protective manner without release to the environment. (SOCMA)
- Commenter believes that TRI collects too much information of marginal value with inadequate quality control. TRI data not very useful in practice for evaluating risks to communities. (Mercatus)
- Environmental releases from chemical and petroleum wholesalers (two sectors added to the program in 1997) are insufficient to warrant reporting. These releases constitute less than 0.3 percent of the total for all affected industries and reported releases do not vary significantly from year to year. (SBA)

**Small Business Impact:** Yes. Many facilities that report to TRI are small businesses, and these are most likely to experience significant impacts from the burden associated with such reporting.

**Commenter Proposed Solution(s):**

- Either eliminate requirement to report off-site transfers, or at least separate and distinguish off-site transfers from environmental releases so that public does not misconstrue the actual impact of a facility's operations. (SOCMA)
- Focus the program on collecting high quality data that is really useful in evaluating risks. (Mercatus)
  Possible revisions include:
  - reduce frequency of reporting
  - modify reporting thresholds to focus on large releases
  - focus on fewer sources that generate the majority of releases
  - reestablish de minimis exemption for lead
- Either eliminate reporting requirements for chemical and petroleum wholesalers, or reduce frequency to once every 5 years. (SBA)

**Estimate of Economic Impacts:** Commenter estimates that eliminating reporting requirements for chemical and petroleum wholesalers would save "as much as $100 million."
Commenter(s): Synthetic Organic Chemical Manufacturers Association (19), Mercatus Institute (73), Small Business Administration, Office of Advocacy (97).
210. TRI: Lowering of Reporting Thresholds for PBT Chemicals

Regulating Agency: EPA/Office of Environmental Information

Citation: 40 CFR 372.28

Authority: Emergency Planning and Community Right-to-Know Act

Description of What Existing Regulation Does: The rule establishes lower reporting thresholds under the Toxic Release Inventory (TRI) for about 25 chemicals identified as “persistent, bioaccumulative, toxics” (PBTs). Under the statutory reporting thresholds, non-PBT chemicals must be reported if the facility manufactures or processes more than 25,000 lbs per year or otherwise uses more than 10,000 lbs per year. For PBT chemicals, these thresholds have been lowered to either 100 lbs per year (for “PBT” chemicals) or 10 lbs per year (for “highly PBT” chemicals).

Commenter Description of Issue(s):

- Commenter believes coverage of PBT rule is too broad and the requirements are unduly burdensome. (ACC)
- Removal of de minimis exemption creates unnecessary burden and distorts TRI data (since it was only done for PBTs). (API)
- Petroleum bulk terminals disproportionately impacted. (API)
- No analysis of benefits of rule or relative risk of PBTs was provided during rulemaking. (API)

Small Business Impact: Yes. Many impacted facilities are small businesses, and these are most likely to experience significant impacts as a result of expanded TRI reporting requirements. SBA has had a strong interest in reducing the burden of TRI reporting on small businesses for some time.

Commenter Proposed Solution(s):

- Eliminate distinction between “PBT” and “highly PBT” and establish lower reporting thresholds only for chemicals meeting the current “highly PBT.”
- Set threshold at 100 lbs for these chemicals (instead of current 10 lbs), and set threshold at 0.002 lbs TEQ for dioxin (approximately one gram instead of current 0.1 grams).
- Promulgate exemption from lower reporting thresholds for petroleum bulk terminals; EPA stated it was considering such an exemption in the preamble to the final rule. (API)
- Reinstate the de minimis exemption for PBTs. (API) Note that Commenter # 16 (CBFC) made the same request for the TRI/Lead rule.
- Reevaluate need for lower thresholds for PBTs based on first year's data. If there are lots of "zero reports" this may be an indication that lower thresholds are not necessary. (API)

Estimate of Economic Impacts: Estimated cost of total TRI program is $660 million per year, of which $120 million per year is accounted for by the lower reporting thresholds for PBT chemicals (excluding lead, which was addressed in a separate rule making). Commenter believes that suggested changes would "substantially reduce" the $120 million cost for PBT related reporting.

Commenter(s): American Chemistry Council (12), American Petroleum Institute (22).
211. **Groundwater Rule**

**Regulating Agency:** EPA/Office of Drinking Water and Ground Water

**Citation:** NPRM published May 10, 2000 (65 FR 30193)

**Authority:** Safe Drinking Water Act, Sec 1412(b)(8)

**Description of What Regulation Will Do:** This rule will establish requirements for control of microbial pathogens in groundwater systems. NPRM was based on a “multi-barrier” approach that will rely on a series of increasingly stringent requirements for systems determined to be at higher levels of risk for contamination. All systems will be required to conduct regular “sanitary surveys” and monitoring, higher risk systems will be required to undergo more comprehensive “vulnerability assessments,” and the highest risk systems will have to install disinfection.

**Commenter Description of Issue(s):**

- Commenter supports attempt to target requirements based on risk, but believes that the current approach will generate inadequate benefits to justify costs. Enhanced monitoring alone (which all systems will have to do) may cost more than benefits of entire rule. Rule also relies too heavily on disinfection. (Mercatus)
- Commenter believes rule is important to address public health risk from fecal contamination of groundwater systems. (CPR)

**Small Business Impact:** Yes. Most impacted systems are small and these will experience disproportionately high costs to comply with the rule.

**Commenter Proposed Solution(s):**

- Focus more on “simple yet sound sanitary practices, including well construction and siting.” (Mercatus)
- Consider exempting transient, and non-transient, non-community systems. (Mercatus)
- Issue final rule “on time” (next year). (CPR)

**Estimate of Economic Impacts:** No quantitative estimate provided.

**Commenter(s):** Mercatus Institute (73), Center for Progressive Regulation (70).
212. Disinfection Byproducts Rule

Regulating Agency: EPA/Office of Drinking Water and Ground Water

Citation: Final Rule published Dec 16, 1998 (63 FR 69390)

Authority: Safe Drinking Water Act, Sec 1412(b)(8)

Description of Regulation: This rule establishes maximum contaminant level goals (MCLGs) and maximum contaminant levels (MCLs) for various disinfection byproducts (DBPs), which are formed when disinfectants, added to drinking water to kill microbial pathogens, react with organic compounds in the raw water. Under the SDWA, MCLGs are supposed to be set, using the best available science, at a level where there is no known health effect, including an adequate margin of safety. MCLs are then supposed to be set as close to the MCLG as “feasible,” taking cost into account, and may also be adjusted based on benefit-cost considerations. EPA has a long-standing policy of setting an MCLG of zero for carcinogens, based on the default linear, no threshold dose-response model. However, EPA's 1996 draft risk assessment guidelines allow the use of other models for carcinogens where there is adequate information on the “mechanism of action” to dismiss the default model. In the case of chloroform (one of the DBPs regulated by the rule), EPA initially proposed to set a non-zero MCLG, based on strong scientific evidence that the linear no-threshold model was inappropriate, but then reversed this decision in the final rule based on "policy considerations." The chloroform MCLG was subsequently remanded by a Federal judge, because, by the agency's own assessment, it was not supported by “best available science” as required by the SDWA.

Commenter Description of Issue(s): EPA has withdrawn the MCLG of zero for chloroform, but has not replaced it with a non-zero MCLG. The non-zero MCL (which is the binding regulatory standard) remains in effect.

Small Business Impact: Yes. Most impacted systems are small and these will experience disproportionately high costs to comply with the rule.

Commenter Proposed Solution(s):

• OIRA should review the rule to ensure that it is based on best available science.
• EPA should set a non-zero MCLG for chloroform, using best available science.

Estimate of Economic Impacts: No quantitative estimate provided.

Commenter(s): Competitive Enterprise Institute (186).
213. **Employer Information Report EEO-1**

**Regulating Agency:** Equal Employment Opportunity Commission

**Citation:** 29 C.F.R. Part 1602.7

**Authority:** 42 U.S.C. Section 2000(e)(8), 2000(e)(12); 44 U.S.C. Section 3501 et seq; 42. U.S.C. Section 12117

**Description of What Existing Regulation Does:** This regulation requires every employer subject to Title VII of the Civil Rights Act of 1964 that has 100 or more employees, or is a Federal government contractor meeting certain criteria, to annually file an Employer Information Report EEO-1 (EEO-1 Report) with the EEOC.

**Commenter Description of Issue(s):** Currently employers must report employee data in nine occupational categories, subdivided by five racial/ethnicity categories, which are further subdivided by gender. The current form expires in November 2002. Proposed changes to the form would expand the occupational and racial/ethnicity categories, increasing the cost and time associated with filing the EEO-1. These changes are burdensome and unnecessary.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** Make as few changes that increase employer burdens to the form as possible.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Brent Bedford (65); Olgetree, Deakins, Nash, Smoak, and Stewart (33).
214. **Waivers under the Age Discrimination in Employment Act**

**Regulating Agency:** Equal Employment Opportunity Commission

**Citation:** 29 C.F.R. 1625.23

**Authority:** 40 U.S.C. Sections 626(f) and 628

**Description of What Existing Regulation Does:**

- This regulation contains the provision that an individual alleging that a waiver agreement, covenant not to sue, or other equivalent arrangement was not knowing and voluntary under the Age Discrimination in Employment Act (ADEA) is not required to tender back the consideration given for that agreement before filing either a lawsuit or a charge of discrimination with EEOC.
- The Older Workers Benefits Protection Act, a waiver of an individual's right to sue under the ADEA is only valid if it meets certain criteria designed to ensure the waiver is knowing and voluntary.
- The EEOC's regulations go beyond the Supreme Court decision that held that an individual who accepts consideration in exchange for a release of claims cannot be required to return or "tender back" the consideration as a condition precedent to bringing suit under the ADEA.

**Commenter Description of Issue(s):**

- The Court did not address whether an employee must tender back the consideration before challenging an agreement that on its faces meets the Older Workers Benefits Protection Act (OWBPA).
- The regulation eviscerates ADEA waiver agreements by permitting employees and former employees to both sue employers under the ADEA while simultaneously keeping money they received in exchange for a promise not to file such a suit.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Amend 29 CFR Part 1625.23 so that it only permits an employee to bring action in court challenging a waiver without “tendering back” the consideration where the waiver is facially invalid under OWBPA.
- Revise 29 CFR to omit the words "covenant not to sue".

**Estimate of Economic Impacts:**

- The solution will increase the likelihood employers would use waivers and therefore reduce the likelihood of costly litigation.
- The regulation causes employers to question whether or not offering valuable consideration in exchange for minimally effective waivers is a sound business decision. If the consideration is of little value, they will decide to use their money elsewhere.
- The current regulations provide disincentive for employers to offer special severance benefits, which are given when employees sign a waiver.

**Commenter(s):** Equal Employment Advisory Council (2); Ogletree, Deakins, Nash, Smoak, and Stewart (33); US Chamber of Commerce (32); Brent Bedford (65)
215. Affirmative Action and EO Survey (2nd Nomination) – Definition of an Applicant

Regulating Agency: Equal Employment Opportunity Commission

Citation: 29 CFR 1607 (EEOC); 41 C.F.R. Part 60-2 (DOL)

Authority: 42 U.S.C. 2000(e)(8), 2000(e)(12) (EEOC); Executive Order 11246 (DOL)

Description of What Existing Regulation Does: The current regulations establish the purpose and contents of affirmative action programs, methods to determine availability of jobs to minority groups and women, and set forth requirements for affirmative action programs. This issue is statutorily under the purview of EEOC; however, OFCCP functions under EEOC regulations in this instance, and has issued its own guidance on the definition of an applicant.

Commenter Description of Issue(s):
• The survey’s requirement that employers compile data on applicants has proven burdensome. The definition of an “applicant” is too expansive in scope.
• The precise definition of the term “applicant” depends on an employer’s recruitment and selection procedures, and in the context of Internet employment selection procedures, the current definition of an applicant is too broad.

Small Business Impact: No.

Commenter Proposed Solution(s):
• Define applicant as person who applies for a specific position and meets the basic qualifications of that position.
• Clarify the definition of “applicant” to limit the impact of unsolicited applications. A definition which excludes unsolicited applications for positions that are not open and individuals who lack the minimum qualifications necessary will reduce the administrative burden and decrease the statistical impact of unsolicited applications on an employer’s adverse impact analysis.

Estimate of Economic Impacts: None given.

Commenter(s): U.S. Chamber of Commerce (32); Brent Bedford (65); CNF Inc. (59); Gill Studios (61); Brent Bedford (65); Olgetree, Deakins, Nash, Smoak, and Stewart (33).
216. Regulation of Ground Penetrating Radar and other Ultrawide Band Devices (UWB)

Regulating Agency: FCC


Authority: Sections 4(i), 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended.

Description of What Existing Regulation Does: The rules govern Ground Penetrating Radar (GPR), which is a technique used by geophysicists to inspect the condition of roads and bridges, locate underground pipes and utilities, conduct safety inspections of structures for faults and potential failures, locate groundwater and bedrock, and map contaminants. FCC is completely banning antennas from 960 MHz to 3.1 Ghz, concerned will interfere with GIS systems

Commenter Description of Issue(s):

• Rule bans the use of Ground Penetrating Radar (GPR) by geophysicists, the only group that uses this technology.
• Regulation inaccurately groups GPR with “through the wall” imaging systems.
• Eliminates a highly valuable service, necessary for public safety and vital to the continuation of a long standing industry

Small Business Impact: Yes.

Commenter Proposed Solution(s): FCC and wireless companies have acknowledged that GPR operates “below 15" levels, and will not interfere with UWB systems.

Estimate of Economic Impacts: Ruling will put commenter and several thousand other GPR service providers and manufacturers out of business. Since commenter represents the small group using these devices, the group lacks the necessary representation to change this ruling

Commenter(s): Mark G. Kick (174), Ken Maser, PHD, PE (138), Frank Scott (126), Doria Kutrubes (121), Daran Rehmeyer (119).
217. Telephone Number Portability

Regulating Agency: FCC

Citation: CC Docket No. 99-200 and WT Docket 01-184, 47 CFR Part 52, Subpart C, Sections 52.51-52.33.

Authority: Section 251(b)(2) of the Communications of 1934, as amended.

Description of What Existing Regulation Does: Requires Commercial Mobile Radio Service (CMRS) providers and manufacturers, including cellular, broadband PCS, ESMR, as well as providers and manufacturers of wireless data services and products, to implement Local Number Portability (moving a cell phone number from one service provider to another).

Commenter Description of Issue(s):

• FCC imposed the portability requirement upon CMRS providers with no showing of competitive justification and improperly linked the ability of wireless carriers to port with the technical solution required for thousands-block number pooling. Negatively affects CMRS providers and manufacturers, including cellular, broadband PCS, ESMR, as well as providers and manufacturers of wireless data services and products. Also notes that FCC has not conducted the required cost benefit analysis.

• FCC has failed to implement existing regulation requiring cellular phone number portability, which already has been implemented in regular phones. FCC has granted numerous extensions to cellular providers.

Small Business Impact: Yes

Commenter Proposed Solution(s):

• Consider both the costs and benefits associated with wireless local number portability and use this analysis to determine whether the regulatory mandate is truly warranted. CTIA urges the FCC to forbear from the LNP mandate, or in the alternative, to grant a transition period to avoid the very real risks to the network integrity caused by the flash-cut simultaneous deployment of two mandates: porting and pooling.

• Require that FCC implements existing regulation.

Estimate of Economic Impacts:

• Will cost over $900 million to install and $500 million in annual recurring costs to maintain. The wireline Local Number Portability mandate has already resulted in $3 billion in end-user costs.

• Increases costs on small businesses by forcing business owners to decide between putting up with bad service or spending money to change providers, pay off several months of their old plan, advertise a new numbers, change stationary and other miscellaneous costs.

Commenter(s): Cellular Telecommunications and Internet Association (103); Gary Scott (127).
218. **Appropriate Regulatory Treatment for Broadband Access to the Internet over Cable Facilities**

**Regulating Agency:** FCC

**Citation:** Notice of Proposed Rulemaking (NPRM), CS Docket No. 02-52, published April 17, 2002, 67 FR 18848

**Authority:** Sections 1, 2(a), 3, 4(i), 4(j), 303, and 601 of the Communications Act of 1934, as amended; 47 U.S.C. 151, 152(a), 153, 154(i), 154(j), 303 and 521, and Section 706 of the Telecommunications Act of 1996, 47 U.S.C. 157.

**Description of What Proposed Regulation Would Do:** Raises the question whether the Commission should continue the market-based approach to open access it has employed in regard to cable broadband, or intervene to require some form of open access.

**Commenter Description of Issue(s):** Mercatus Center recommends that the Commission should continue the market based approach.

**Small Business Impact:** Yes

**Commenter Proposed Solution(s):** Mercatus Center states that the FCC should continue the market based approach and mandatory open access. The Center for Regulatory Effectiveness recommends that OMB review this regulation.

**Estimate of Economic Impacts:** The Mercatus Center states: “Regulation will pose significant costs (compliance, the costs of litigation and lobbying to shape or circumvent the regulation, and perverse incentives created by regulation.”

**Commenter(s):** Mercatus Center (73), Center for Regulatory Effectiveness (83).
219. Open Network Architecture Reporting Requirements

Regulating Agency: FCC

Citation: (2 FCC Red Vol 10, 3035) FCC 87-102, 3/87, CC Docket 85-229, 3057 @156; FCC 91 382, 11/91, CC Docket 88-2, 7677 @ Appendix B, and (104 FCC 2d 958) FCC 86-252, 5/86, CC Docket 85-229, @ Introduction.1

Authority: Section 4(i) of the Communications Act of 1934, as amended.

Description of What Existing Regulation Does: Bell Operating Companies (BOCs) are required to post their CEI plans and amendments on their publicly accessible internet sites. The requirement extends to CEI plans for new or modified telemessaging or alarm monitoring services and for new or amended payphone services. If the BOC receives a good faith request for a plan from someone who does not have internet access, the BOC must notify that person where a paper copy of the plan is available for public inspection. The CEI plans will be used to ensure that BOCs comply with Commission policies and regulations safeguarding against potential anticompetitive behavior by the BOCs in the provision of information services.

Commenter Description of Issue(s): In order to govern the Bell Operating Companies (BOCs) participation in the enhanced services marketplace, the FCC established a regulatory framework of nonstructural safeguards by imposing Comparably Efficient Interconnection (CEI) and Open Network Architecture (ONA). ONA has 3 separate reporting requirements. Each BOC must pay a contractor to aggregate the information provided by the BOC and distribute it back to the BOCs, for each BOC to file with the FCC.

Small Business Impact: No.

Commenter Proposed Solution(s): Requirement that all BOCs file separate semi-annual matrix reports should be withdrawn. BOCs should be permitted to separately file reports with the Commission, which can subsequently consolidate the information.

Estimate of Economic Impacts: Each BOC is charged thousands of dollars annually for the common report and each BOC incurs additional expenses to file the report. These expenses would be eliminated if the consolidated filing were withdrawn.

Commenter(s): United States Chamber of Commerce (32).
220. Conditions Applicable to All International Section 214 Authorizations

Regulating Agency: FCC


Authority: Section 214 of the Communications Act of 1934, as amended.

Description of What Existing Regulation Does: The collection of overseas telecommunications traffic data which enables the Commission to fulfill its regulatory responsibilities under the Communications Act of 1934, as amended. All common carriers engaged in the provision of overseas telecommunications service are required to file an annual report on the telecommunications traffic. The reported data is used for international planning, facility authorization, monitoring emerging developments in communications services, analyzing market structures, tracking the balance of payments in international communications services; and market analysis purposes. Carriers file the report pursuant to the guidelines set forth in Section 43.61 and submit the data for compilation by the Wireline Competition Bureau (formerly the Common Carrier Bureau).

Commenter Description of Issue(s): Forces carriers to file annual reports of overseas telecom traffic for all international Section 214 authorizations, has neither been justified by the Commission as necessary in the public interest nor is it beneficial.

Small Business Impact: No

Commenter Proposed Solution(s): The Commission should eliminate Section 63.21, which requires carriers holding Section 214 authorizations to file international interexchange service reports, or a Section 43.61 report., the Commission should modify the rule by narrowing the scope of Section 43.61 and clarify that only facilities-based carriers are required to file Section 43.61 reports.

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
Complaints, Applications, Tariffs, and Reports Involving Common Carriers

Regulating Agency: FCC

Citation: 4 CFR 1.815


Description of What Existing Regulation Does: Requires each licensee with 16 or more full time employees to file an annual employment report.

Commenter Description of Issue(s): Report duplicates the reports that carriers must file with the Federal and state EEO agencies and the annual reporting requirement serves no FCC regulatory purpose.

Small Business Impact: Yes

Commenter Proposed Solution(s): Commission should eliminate this provision

Estimate of Economic Impacts: None provided.

Commenter(s): Cellular Telecommunications and Internet Association (103).
222. Content of Applications

Regulating Agency: FCC

Citation: 47 CFR 1.923; 47 CFR 1.923(b)(ii)

Authority: Sections 4(i), 303(g), 303(r) and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), and 332(c)(7).

Description of What Existing Regulation Does: Applicants filing ULS Forms 601 and 603 are required to provide all requested information, including information regarding “pending” non-FCC litigation. Any information collection requirements for the FCC Form 601 is approved by OMB under OMB Control Number 3060-0798. Information collection requirements for the FCC Form 603 is approved by OMB under OMB Control Number 3060-0800.

Commenter Description of Issue(s):

• Until there is an adverse judgment, requiring information on pending litigation is not material to a licensee's qualifications. Requiring information related to non-FCC litigation results in “offlining” applications, burdening staff, and delaying swift action on routine filings.

• The Forms require a significant amount of data regarding foreign ownership even when Commission has approved such ownership and the question has little, if any, correlation to the FCC’s Section 310(b) analysis required prior to approval of such ownership.

• Section 1.924(d) requirement that an CMRS provider obtain approval for wireless facilities within the FCC Quiet Zone Rules for the Arecibo Observatory, when the Observatory is willing to provide written approval for wireless modifications, resulting in delays of service in Puerto Rico.

• Section 1.935 requirement that applications obtain FCC approval of agreements to withdrawal applications, petitions, informal objections, or other pleadings against an application, which causes lengthy delays and is unnecessary because the FCC has he authority to request documents in specific cases.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Question regarding non-FCC pending litigation on ULS (on Forms 601 and 603) should be deleted, because there is no reason why the collection of such information from carriers is necessary in a competitive market.

• Questions relating to foreign ownership should be replaced with a simple Yes/No question as to whether the applicant complies with Section 310(b).

• “Quiet Zone” provision should be eliminated because it creates unnecessary service delays.

• Delete Section 1.935

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
223. Competitive Bidding Proceedings, 47 CFR Section 1.2105(c)(1) of the Commission's Rules (Anti-Collusion)

Regulating Agency: FCC

Citation: 47 CFR 1.2105(a)(2)(ii)(B) does not contain information collection requirements. Section 1.2105(c)(1) is approved by OMB under OMB Control Number 3060-0995.

Authority: 47 U.S.C. Sections 154(i) and 309(j) of the Communications Act of 1934.

Description of What Existing Regulation Does: Requires that any auction applicant that makes or receives a communication of bids or bidding strategies prohibited by 47 CFR Section 1.2105(c)(1) to report such a communication to the Commission promptly.

Commenter Description of Issue(s):

• Section 1.2105: Collecting such detailed ownership information is unnecessary because the information will be relevant only if the applicant is a high bidder and at that time the applicant is required to submit a long form application disclosing ownership data.
• Section 1.211(b): Requires applicants for transfers of control or assignments of licensee obtained through competitive bidding to file certain transaction documents and other materials. Requirement is duplicative and unnecessary given the FCC already has separate rules governing unjust enrichment, which are sufficient to ensure that auction winners benefiting unfairly from bidding credits disgorge such benefits.

Small Business Impact: Yes

Commenter Proposed Solution(s): Eliminate above referenced sections

Estimate of Economic Impacts: None provided

Commenters: Cellular Telecommunications and Internet Association (103).
Regulating Agency: FCC

Citation: FCC 00-346, CC Docket No 00-175, Biennial Review of Biennial Review 2000 Comments of the Cellular Telecommunications Industry Association (“CTIA Biennial Review 2000 Comments”), at 11-14.


Description of What Existing Regulation Does: The Telecommunications Act of 1996, which was intended to promote competition and reduce regulation to secure lower prices and higher quality services for American telecommunications consumers and encourage the rapid deployment of new telecommunications technologies. The 1996 Act significantly amended the Communications Act of 1934 to permit and encourage competition in various communications markets. Congress anticipated that, as competition developed, market forces would reduce the need for regulation. Therefore, in addition to requiring the Commission to take certain actions to open markets to competition, Congress required the Commission to review certain of its regulations every two years and to modify or repeal those regulations that are no longer “necessary in the public interest.”

Commenter Description of Issue(s): FCC must streamline NEPA compliance and review procedures that do not respond effectively and quickly to market and government demands for the swift deployment of competitive wireless services.

Small Business Impact: No

Commenter Proposed Solution(s): Streamline the process:

• CTIA recommends that the Commission exempt towers or structures built prior to March 16, 2001, from the Section 106 review process.
• Pursuant to 47 CFR § 1.1308(b) NOTE 2, the Commission must solicit the comments of the Department of Interior with respect to threatened or endangered species or designated critical habitats, and the State Historic Preservation Officer (“SHPO”) and ACHP with respect to historic properties, in accordance with their established procedures.
• Commission eliminate its practice of allowing SHPOs to delay their response to the Commission's solicitation of comments.

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
225. Access to Telecommunications Service

Regulating Agency: FCC

Citation: Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems, CC Docket No. 94-102, Fourth Report and Order (rel. Dec. 14, 2002).

Authority: 47 CFR Section 20.18(c) and accompanying note (waivers authorized under 47 CFR 0.131 and 0.331).

Description of What Existing Regulation Does: To bring the benefits of emergency and advanced telecommunications to people with disabilities, the Commission has imposed several regulatory mandates under Part 6, Part 7, and Section 20.18(c) of the Commission's Rules.

Commenter Description of Issue(s): The FCC continues to rely on regulatory fiat, rather than competition, to bring wireless technological innovations and solutions to consumers with disabilities. Indeed, the underlying assumption is that consumers benefit more from heavy-handed regulation than the proven track record of innovations that characterize competitive wireless services. This regulatory philosophy has resulted in inefficient and short-term solutions that do not meet consumers' needs nearly as well as new technologies.

Small Business Impact: No.

Commenter Proposed Solution(s): The FCC should eliminate accessibility rules that impose backward compatibility (i.e., making advanced digital technologies compatible with antiquated technologies, rather than supporting a regulatory philosophy that encourages consumers with disabilities to migrate from antiquated technologies to advanced digital technologies that offer the functions and benefits they desire). To the extent that competitive alternatives exist, the FCC should treat telecommunications services and their close-substitutes information services alike, and not apply Parts 6 and 7 of the Commission's Rules to these similar services.

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
226. Construction, Marking, and Lighting of Antenna Structures

Regulating Agency: FCC

Citation: 47 CFR Part 17.

Authority: Sections 4(i), 303(r) of the Communications Act of 1934, as amended; 47 U.S.C. 154(i) and 303(r).

Description of What Existing Regulation Does: Sets forth the requirements for construction and coordination of wireless communications facilities

Commenter Description of Issue(s): The FCC has failed to synchronize the FAA and FCC regulations. For example, the Advisory Circulars, the FAA recommendations for painting and lighting of antenna structures that are mandatory under the FCC Rules, impose obligations with respect to notification of modifications that conflict with Section 17.23. Furthermore, the Commission should work with the FAA to adopt the FCC’s 20-foot rule exemption, a proposal made in the 2000 Biennial Review

Small Business Impact: No.

Commenter Proposed Solution(s): Coordination between the FAA and FCC.

Estimate of Economic Impacts: None provided.

Commenter(s): Cellular Telecommunications and Internet Association (103).
227. 911 Services

Regulating Agency: FCC

Citation: 47 CFR § 20.1847 CFR Part 64, Subpart AA


Description of What Existing Regulation Does: In this proceeding, the Commission designated 911 as the universal emergency assistance number throughout the United States and also set up transition periods to implement 911 in order to allow wireline and wireless carriers the time to complete the necessary modifications to deliver 911 calls to the appropriate local emergency authority in those areas where dialing 911 had not been in use.

Commenter Description of Issue(s): FCC should update the regulations to reflect recent changes.

Small Business Impact: No

Commenter Proposed Solution(s):

• Modify Section 20.18 to reflect changes the FCC has made to its rules with respect to the deployment of Phase I and Phase II Enhanced 911 (“E-911”) services.
• Amend its E-911 rules to account for the widespread use of non-initialized (or more properly, non-subscribed) phones.

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Industry (103).
228. Operational and Technical Requirements and Cellular Radiotelephone Service

Regulating Agency: FCC

Citation: 47 CFR § 22.303, 47 CFR § 22.367(a), 47 CFR § 22.941, 47 CFR § 22.919., 47 CFR § 22.942

Authority: Sections 1, 4(i), 11, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 161, and 303(r).

Description of What Existing Regulation Does: The various rule sections govern retention of station authorizations, identifying transmitters, wave polarization, system identification numbers, electronic serial numbers, and limitations of interests in licensees for both channel blocks in Rural Service Areas (RSAs). The Commission initiated a Year 2000 Biennial Regulatory Review to Modify or Eliminate Outdated Rules Affecting the Cellular Radiotelephone Service and the Commercial Mobile Radio Services (proposed rulemaking) in WT Docket No. 01-108, FCC 01-153.

Commenter Description of Issue(s): The wireless marketplace is drastically different than what it was when the Part 22 rules were promulgated, and the Commission should eliminate unnecessary cellular rules in view of the introduction of new technologies and the increased competition between wireless carriers.

Small Business Impact: No.

Commenter Proposed Solution(s): The FCC shall undertake a comprehensive review of the Part 22 cellular rules as well as other portions of Part 22. Examples include:

- Section 22.303 requires cellular providers to mark every transmitting facility with a station call sign and Section 22.367 imposes a vertical polarization requirement on cellular licensees.
- Clarify Section 22.919 to allow carriers to use alternative mechanisms to the Electronic Serial Numbers ("ESN"), i.e., SIM cards.
- Eliminate section 22.953 which requires the filing of both full-sized maps and reduced maps with minor modifications

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
Required New Capabilities Pursuant to the Communications Assistance For Law Enforcement Act (CALEA)

Regulating Agency: FCC

Citation: Order on Remand, CC Docket No. 97-213, 17 FCC Rcd 6896 (2002); 67 FR 21999, May 2, 2002 (47 CFR 22.953 has been replaced by 47 CFR 22.1103).


Description of What Existing Regulation Does: With the exception of seven capabilities, this requires cellular telecommunications carriers to provide to a Law Enforcement Agency (LEA), by June 30, 2000, the assistance capability requirements of CALEA, see 47 U.S.C. 1002. Additional time is permitted for these carriers to provide to a LEA the seven additional capabilities. Specifically, by November 19, 2001, packet-mode communications information must be provided; and by June 30, 2002, the following capabilities must be provided:

- Content of subject-initiated conference calls;
- Party hold, join, drop on conference calls;
- Subject-initiated dialing and signaling information;
- In-band and out-of-band signaling;
- Timing information;
- Dialed digit extraction, with a toggle feature that can activate/deactivate this capability.

Commenter Description of Issue(s): The deadline for cellular telecommunications providers to comply with CALEA is not valid.

Small Business Impact: No

Commenter Proposed Solution(s): Modify Section 22.1103 to reflect the D.C. Circuit's decision vacating part of the Commission's rules and suspending the compliance deadline for the outstanding punch-list items pending completion of the Commission's remand proceeding. The Commission should clarify Section 22.1103 to account for changes in CALEA capability deadlines for cellular telecommunications carriers.

Estimate of Economic Impacts: None Provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
230. Personal Communications Services (PCS), Subpart B – Applications and Licenses and Part 24, Subpart J – Required New Capabilities Pursuant to the Communications Assistance for Law Enforcement Act (CALEA)

Regulating Agency: FCC

Citation: 47 CFR 24.16; 47 CFR 22.935-40; 47 CFR 24.903(b)


Description of What Existing Regulation Does: Principles of regulatory symmetry require the Commission to treat comparable services the same and that any difference in regulation must be based upon relevant differences in circumstances or competition.

Commenter Description of Issue(s): Inconsistencies between the regulation regulating the cellular industry and the PCS industry.

Small Business Impact: No.

Commenter Proposed Solution(s):

• Section 24.16 of the PCS rules does not contain the same two-step process for resolving renewal challenges that is included in the cellular renewal rules. Since the issue continues to be relevant, the Commission should modify the rules governing the PCS license renewal process as part of the still-pending 2000 review and in accordance with the legal standard of review appropriately defined in the Fox decision.
• Modify the PCS rules, Section 24.903, and conform the CALEA capabilities requirement for broadband PCS telecommunications carriers to the compliance deadlines established in the Commission’s recent Order on Remand.

Estimate of Economic Impacts: None provided.

Commenter(s): Cellular Telecommunications and Internet Association (103).
# 231. Reports of Communications Common Carriers and Certain Affiliates

**Regulating Agency:** FCC

**Citation:** 47 CFR § 43.53; 43.61; See 47 CFR § 63.21.


**Description of What Existing Regulation Does:** This information collection is approved by OMB under OMB Control Number 3060-0901. Common carriers must file copies of all contracts entered into with a communications entity in a foreign point for the provision of common carrier service between the United States and that foreign point. Carriers are exempt from this requirement if the carrier enters into such a contract with a carrier that lacks market power in the relevant foreign point.

**Commenter Description of Issue(s):** The reporting requirement for the transmission or reception of international telegraph communications is no longer necessary.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):**

- Eliminate Section 43.61, which requires carriers to report actual traffic and revenue data for international traffic and overseas traffic (between the United States and U.S. territories), as a duplicative obligation to carriers holding Section 214 authorizations.
- Eliminate the International Circuit status report requirement in Section 43.82 as it is also duplicative of the Section 214 reporting requirements.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Cellular Telecommunications and Internet Association (103).
232. Abbreviated Dialing Codes (N11 Service Codes)

Regulating Agency: FCC

Citation: Third Report and Order and Order on Reconsideration, CC Docket No. 92-105 (July 31, 2001)


Description of What Existing Regulation Does: The Commission has assigned abbreviated dialing codes, or N11 service codes, to enable callers to connect to a location that otherwise would be accessible only via a seven or ten-digit telephone number. The Commission has established the following N11 code-assignments for the eight N11 codes: For example, 211 was assigned for community information and referral services and 311 was assigned nationwide for non-emergency police and other government services.

Commenter Description of Issue(s): The Commission's mandate for 511 travel services provided by “a governmental entity” inhibits carriers from competing in these services and from designing a service based on customer demand.

Small Business Impact: Yes

Commenter Proposed Solution(s): In a recent Order, the Commission committed to reexamine in 2005 its assignment of the 511 and 211 service codes, access to traveler information services and access to community information and referral services. The Commission should expedite this review and modify its rules to account for competitive CMRS implementation.

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
233. Fees to Consumers for Switching Long Distance Carriers

Regulating Agency: FCC

Citation: Notice of Proposed Rulemaking adopted by FCC on 3/14/02. Published in FCC Red Vol. 17, No. 8 at page 5568 (17 FCC Red 5568). Published in Federal Register May 15, 2002 (67 FR 34665).
Authority: 47 U.S.C. Sections 151, 154(l), (j), 201-205, and 303.

Description of What Proposed Regulation Would Do: The FCC is initiating a rulemaking to ensure that fees charged to consumers for changing long distance carriers are reasonable.

Commenter Description of Issue(s): None provided, however CRE recommends that OMB review this regulation based on the “substantial economic importance of independent agency regulation and the paucity of accompanying analysis.”

Small Business Impact: No.

Commenter Proposed Solution(s): None provided

Estimate of Economic Impacts: Substantial

Commenter(s): Center for Regulatory Effectiveness (83).
234. Remedying Interference to Public Safety Communications in the 800 MHz band

Regulating Agency: FCC

Citation: 47 CFR Part 90

Authority: Sections 4(i), 303(f) and (r), and 332 of the Communications Act of 1934, as amended; 47 U.S.C. 154(i), 303(f) and (r) and 332

Description of What Regulation Would Do: The FCC is initiating a rulemaking to explore options for remedying interference in public safety communications in the 800 MHz band. The NPRM also seeks comment on terms and conditions of licenses in the 900 MHz band if it is used for relocation.

Commenter Description of Issue(s): None provided, however CRE recommends that OMB review this regulation based on the "substantial economic importance of independent agency regulation and the paucity of accompanying analysis."

Small Business Impact: Yes.

Commenter Proposed Solution(s): None provided.

Estimate of Economic Impacts: Substantial.

Commenter(s): Center for Regulatory Effectiveness (83).
235. Mitigation of Orbital Debris

Regulating Agency: FCC

Citation: NPRM adopted by the FCC on 3/14/02. NPRM publication May 3, 2002 (67 FR 22376). OMB approved this collection under OMB Control Number 3060-1013 on 6/25/02.

Authority: Sections 1, 4(i), 301, 303, 308, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 151, 154(i), 301, 303, 308, 309, and 310.

Description of What Proposed Regulation Would Do: The FCC is initiating a rulemaking proposing a requirement that all FCC-licensed satellite systems submit information concerning their plans to mitigate orbital debris.

Commenter Description of Issue(s): None provided, however CRE recommends that OMB review this regulation based on the “substantial economic importance of independent agency regulation and the paucity of accompanying analysis.”

Small Business Impact: Yes.

Commenter Proposed Solution(s): None provided.

Estimate of Economic Impacts: Substantial.

Commenter(s): Center for Regulatory Effectiveness (83).
236. Customer Proprietary Network Information

Regulating Agency: FCC

Citation: 47 CFR 64.2007

Authority: Section 222 of the Telecommunications Act of 1996.

Description of What Existing Regulation Does: This information collection requirement is approved by OMB under OMB Control Number 3060-0715. The requirements implement the statutory obligations of section 222 of the Telecommunications Act of 1996. Among other things, carriers are permitted to use CPNI, without customer approval, under certain conditions. All telecommunications common carriers must provide subscriber list information gathered in their capacity as providers of telephone exchange service to any person upon request for the purpose of publishing directories.

Commenter Description of Issue(s): Regulations were not updated to reflect recent court decision. While the Commission takes the position that the Tenth Circuit’s decision applied only to a single provision of the CPNI rules, 47 C.F.R. 64.2007(c), the court vacated the entire Section 64.2007 rulemaking as constitutionally inadequate.

Small Business Impact: No.

Commenter Proposed Solution(s): Commission must eliminate all of its rules on the use of CPNI that were vacated by the Tenth Circuit.

Estimate of Economic Impacts: None provided.

Commenter(s): Cellular Telecommunications and Internet Association (103).
237. Private Land Mobile Radio Services—Subpart H—Policies Governing the Assignment of Frequencies

Regulating Agency: FCC

Citation: 47 CFR § 90.175(i)(8)

Authority: Sections 1, 4(i), 301, 302, 304(f), and (r), 309(j) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 1, 154(i), 301, 302, 303(f) and (r), 309(j) and 332.

Description of What Existing Regulation Does: Section 91.175 sets forth the general frequency coordination requirements for licensees regulated by Part 90 of the Commission's Rules. Section 90.175(i)(8) identifies applications that do not require frequency coordination.

Commenter Description of Issue(s): Frequency coordination is not always required.

Small Business Impact: No

Commenter Proposed Solution(s): The Commission should modify its rules to clarify that applications removing a frequency from a license do not require frequency coordination. The Commission should also clarify in subparagraph (8) that the auctioned-over SMR General Category frequencies (channels 1-150) do not require frequency coordination by including Section 90.615 to the list of exceptions in Section 90.175(i)(8).

Estimate of Economic Impacts: None provided

Commenter(s): Cellular Telecommunications and Internet Association (103).
238. Selection and Assignment of Frequencies

Regulating Agency: FCC

Citation: 47 CFR § 90.621(b)(4) and (5).

Authority: Sections 154(i) and 309(j) of the Communications Act of 1934, as amended.

Description of What Existing Regulation Does: The Commission's Rules provide that a co-channel licensee may reduce the separation between the co-channel systems if it submits letters of concurrence with an application. The rule requires 800 MHz Specialized Mobile Radio (SMR) applicants who wish to locate stations closer than the required mileage separation from existing co-channel stations to file additional information and in some instances, a waiver. This is approved under OMB Control number 3060-0441.

Commenter Description of Issue(s): Requirement that each co-channel licensee submit a letter of certification that this system is “constructed and fully operational” leads to unnecessary delays.

Small Business Impact: No

Commenter Proposed Solution(s): The Commission should:

• Eliminate the requirement in Section 90.621(b)(5) for each co-channel licensee submitting a letter of concurrence to certify that its system is “constructed and fully operational.”
• Eliminate the loading requirement in Section 90.658 as an obsolete reporting rule for Specialized Mobile Radio (“SMR”) base station licensees.
• Section 90.629(e) should be eliminated since this provision only applied to a specific proceeding whereby the Commission extended certain SMR licenses in March 1996.
• Eliminate Section 90.653, an obsolete SMR licensing rule that was codified in 1982.

Estimate of Economic Impacts: Will increase spectrum flexibility and reduce delays in pending construction

Commenter(s): Cellular Telecommunications and Internet Association (103).
Regulating Agency: FCC

Citation: 47 CFR § 90.653


Description of What Existing Regulation Does: Regulation authorizes and sets forth the procedure for 800 MHz and 900 MHz licensees to partition and disaggregate their spectrum.

Commenter Description of Issue(s): None provided.

Small Business Impact: No.

Commenter Proposed Solution(s): The Commission should:

• Modify its rules to reflect that geographic area licenses may be consolidated and aggregated, as well as partitioned and disaggregated, just as it has done for Part 22 and Part 24 licensees.
• Modify Sections 90.813(f) and 90.911(f) to clarify that the partitionee/disaggregatee, as well as the original licensee, is allowed to certify that it will satisfy the requirements for "substantial service" for the entire market.

Estimate of Economic Impacts: None provided.

Commenter(s): Cellular Telecommunications and Internet Association (103).
240. Generator Interconnection Agreements

Regulating Agency: Federal Energy Regulatory Commission

Citation: 18 CFR part 35

Authority: Federal Power Act 16 USC §791-793

Description of What Proposed Regulation Would Do: Provide guidance for standard generator interconnection agreement and procedures that would be applicable to all large public utilities that own or operate transmission facilities under the Federal Power Act.

Commenter Description of Issue(s): The cost of regulations issued by independent agencies is similar to the cost imposed by regulations issued by agencies subject to EO 12866. Independent agencies do not conduct a rigorous cost benefit analysis commensurate with their economic importance.

Small Business Impact: No.

Commenter Proposed Solution(s): OMB should review regulations issued by independent agencies.

Estimate of Economic Impacts: None provided.

Commenter(s): Center for Regulatory Effectiveness (83).
241. Regulation C

Regulating Agency: Federal Reserve

Citation: Regulation C 12 CFR 203.4(a)(12)

Authority: Home Mortgage Disclosure Act 12 USC 2801

Description of What Existing Regulation Does: Lenders are required to report the annual percentage rate (APR) spread on home related loans. The APR spread is the difference between a loan's APR and the yield on a comparable maturity Treasury security.

Commenter Description of Issue(s): Lenders must use a formula to compute the APR spread for loans, determine whether or not the spread actually exceeds the prescribed threshold, and then determine whether the APR spread should be reported. Federal Reserve did not permit public comment before making this change from the previous requirement to report all APRs.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Rescind the changed rule that requires reporting the APR spread.

Estimate of Economic Impacts: Financial institutions may incur an increase in costs need to update reporting software. The cost may be passed on to the public through lower savings rates and higher lending rates.

Commenter(s): National Association of Federal Credit Unions (51).
242. Regulation D

Regulating Agency: Federal Reserve

Citation: Regulation D 12 CFR 204

Authority: Federal Reserve Act 12 USC 3105

Description of What Existing Regulation Does: Sets out requirements for "restricted" verses "unlimited" withdrawals.

Commenter Description of Issue(s): Increased use of automatic and electronic services and the difficulty in monitoring the payees on checks cause problems for financial institutions. Regulation contains inconsistent and complicated definitions.

Small Business Impact: No.

Commenter Proposed Solution(s): Federal Reserve should prepare and issue for public comment a comprehensive study on revisions to Regulation D.

Estimate of Economic Impacts: Minimal impact in conducting a study. Significant economic benefits can result from revising Regulation D.

Commenter(s): National Association of Federal Credit Unions (51).
243. Monetary Policy Reserves

Regulating Agency: Federal Reserve

Citation: Regulation D

Authority: Monetary Control Act of 1980

Description of What Existing Regulation Does: Reserve requirements are imposed on depository institution transaction accounts and other accounts to facilitate the conduct of monetary policy by the Federal Reserve. All credit unions with over $5.5 million in deposits are subject to reporting. The rule directs how institutions must calculate the amount of reserves that must be held.

Commenter Description of Issue(s): The rule defines terms and conditions of deposit accounts since this determines how the reserve requirements apply. Some of the distinctions separating transaction from non-transaction accounts appear to be arbitrary.

Small Business Impact: No.

Commenter Proposed Solution(s): Encourage the Federal Reserve to review Regulation to determine its usefulness in the conduct of monetary policy and whether it can be simplified.

Estimate of Economic Impacts: None provided.

Commenter(s): Credit Union National Association (52).
244.  **Electronic Account/Loan Applications**

**Regulating Agency:** Federal Reserve and NCUA

**Citation:** Regulation Z 12 CFR 226.17(g) and 12 CFR 707.4(a)

**Authority:** 15 USC 1601 and 12 USC 4301

**Description of What Existing Regulation Does:** Customers opening accounts and making closed-end credit applications electronically must receive disclosures before an account can be opened or loan be made. When such transactions are made by mail or telephone delays in the disclosures are permitted.

**Commenter Description of Issue(s):** There may be situations in which a consumer wishes to apply for a deposit account or credit via electronic means but would prefer not to receive the related disclosures electronically. In such a situation, a financial institution would be required to delay the opening of the deposit account or consummation of a closed-end loan if the consumer did not consent to receiving disclosures electronically. This may discourage the use of electronic account and loan applications.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** The same delay of providing disclosures that is permitted for mail/telephone/FAX should apply to electronic submissions.

**Estimate of Economic Impacts:** Discouragement of customers using electronic means of opening accounts and getting loans will result in higher costs to financial institutions. The costs may likely be passed on to the public in terms of lower returns on savings and higher rates on loans.

**Commenter(s):** National Association of Federal Credit Unions (51).
245. Truth-in-Lending/RESPA

Regulating Agency: Federal Reserve and HUD

Citation: Regulation Z

Authority: Truth-in-Lending and Real Estate Settlement Procedures Acts

Description of What Existing Regulation Does: Provides for disclosures to consumers regarding the mortgage borrowing and real estate settlement process.

Commenter Description of Issue(s): Consumers as well as financial institutions have found that the overlapping requirements in regulation under the Truth-in-Lending Act and the Real Estate Settlement Procedures Act often result in confusion in the mortgage lending process. In the past, the Federal Reserve Board and others have attempted to review duplicative requirements under the regulations but greater simplification in mortgage loan disclosures without the loss of important information about loan rates and terms would be beneficial to consumers and financial institutions.

Small Business Impact: No.

Commenter Proposed Solution(s): Greater simplification would be beneficial.

Estimate of Economic Impacts: None provided.

Commenter(s): Credit Union National Association (52).
246. Definition of Electronic Address

Regulating Agency: Federal Reserve and National Credit Union Administration

Citation: 12 CFR 202, 205, 213, 226


Description of What Existing Regulation Does: Defines “electronic address.”

Commenter Description of Issue(s): Electronic address defined in “official staff commentary” as an e-mail address not limited to receiving communication transmitted solely by the creditor. This specifically excludes addresses that are contained in a financial institution's website. This is a requirement, therefore, requires the use of a specific technology and is contrary to the wording and intent of the “E-Sign Act.”

Small Business Impact: No.

Commenter Proposed Solution(s): Expand the definition of electronic address to include website electronic addresses and not limit the definition to solely traditional e-mail addresses.

Estimate of Economic Impacts: No quantified costs. Financial institutions will likely need to purchase and administer e-mail content encryption software to prevent to prevent third parties from reading e-mail messages.

Commenter(s): National Association of Federal Credit Unions (51).
247. **Collection of Data on Race and Ethnicity**

**Regulating Agency:** Federal Reserve

**Citation:** Regulation C, Appendices A and B to Part 203

**Authority:** Home Mortgage Disclosure Act 12 USC 2801

**Description of What Existing Regulation Does:** Governs collection of race, ethnicity and sex data on applicant when application is made by mail or internet.

**Commenter Description of Issue(s):** Federal Reserve has proposed a requirement that would make lenders request this data when receiving this data over the telephone. Requiring such questions to be asked when receiving an application over the telephone is tantamount to taking what already is a race-neutral, ethnicity-neutral and gender neutral process and imposing upon it the very biases sound public policy weeks to root out. Applicants may believe that their responses will influence the lender's decision. This could motivate borrowers to provide inaccurate information.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** Do not adopt this policy in any final rulemaking amending Regulation C.

**Estimate of Economic Impacts:** Financial institutions will likely incur an increase in costs to update reporting software and provide training to employees to ask these questions. The costs may be passed on to customers.

**Commenter(s):** National Association of Federal Credit Unions (51).
248. Regulation P—Privacy of Consumer Financial Information

Regulating Agency: Federal Reserve

Citation: 12 CFR 216

Authority: 15 USC 6801-09

Description of What Existing Regulation Does: Obligations of a financial institution to provide notice to its customers about its privacy policies and practices and the right of a consumer to prevent a financial institution from disclosing nonpublic personal information about him or her to nonaffiliated third parties by “opting out” of that disclosure.

Commenter Description of Issue(s). The rule strikes a reasonable balance between efficient business operations and a growing desire for privacy. However, agencies responsible for rulemaking have needlessly complicated the interpretation of nonpublic personal information in spite or Congress' clearly stated definition. This could have long-run negative consequences.

Small Business Impact: No.

Commenter Proposed Solution(s): A more constructive approach to the entire issue of information privacy may rest in clearly delineating ownership rights in the information and then clearly protecting those rights. In this way, individuals and financial institutions can develop approaches to privacy that are more closely tailored to individual circumstances.

Estimate of Economic Impacts: Rule costs American producers and consumers of financial products at least $200 million per year in ongoing compliance costs, which translates into long-run costs of more than $3.2 billion.

Commenter(s): Mercatus Center (73).
249. **Fair Packaging and Labeling Act**

**Regulating Agency:** FTC

**Citation:** 16 CFR 500

**Authority:** Fair Packaging and Labeling Act (FPLA)

**Description of What Existing Regulation Does:** The FTC enforces consumer disclosure requirements under the FPLA that established requirements for the manner and form of labeling consumer commodities. The FTC rules specifically require disclosure of product identity, net quantity of contents and the name and location of the company responsible for the product.

**Commenter Description of Issue(s):**

- Imposes significant paperwork disclosure burden.
- FTC estimates the burden of this collection to be 12 million hours annually (about 1.2 million disclosures)

**Small Business Impact:** No information provided.

**Commenter Proposed Solution(s):** OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

**Estimate of Economic Impacts:** No additional input provided by commenter.

**Commenter(s):** Representative Douglas Ose (108).
250. Cooling Off Period for Sales Made at Home or Other Locations

Regulating Agency: FTC

Citation: 16 CFR 429.0-429.3

Authority: 15 U. S. C. 41-58

**Description of What Existing Regulation Does:** The requirement provides a three-day right of rescission for door-to-door sales and sales made at home. The regulation covers any transaction over $25.00 and applies to transactions made which have been initiated by the customer calling the supplier of the service. The rule applies to services such as plumbing or air conditioner repair unless the seller obtains a waiver from the customer.

**Commenter Description of Issue(s):**

- Creates significant problems in emergencies such as broken air conditioning or plumbing where it is infeasible to make a quote and then wait 3 days.
- The waiver provision and notice of cancellation provisions are in many cases impractical (the contractor is let into the house by a teenage son or daughter or maid and they cannot legally sign the required documents, yet the homeowner is expecting the work to be done).
- Other ways to avoid the three-day rescission are also impractical (to have the homeowner go to the contractor's premises or a bank to sign the forms).
- Some States, such as Texas, go further and even disallow people to waive their 3-day right of rescission.

**Small Business Impact:** No information provided.

**Commenter Proposed Solution(s):** The regulation should be changed to provide the waiver of the right of rescission if the customer initiates the contact.

**Estimate of Economic Impacts:** No additional input provided by commenter.

**Commenter(s):** Air Conditioning Contractors of America (92).
251. Truth In Lending Act

Regulating Agency: FTC

Citation: 12 CFR 226

Authority: 15 USC 1601

Description of What Existing Regulation Does: The Truth in Lending requirements are designed to further comparison credit shopping and informed credit decisionmaking by requiring accurate disclosure of the costs and terms of credit to consumers. The requirements are promulgated by the Board of Governor’s of the Federal Reserve System (Regulation Z).

Commenter Description of Issue(s):

- The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: No information provided.

Commenter Proposed Solution(s): OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: No additional input provided by commenter.

Commenter(s): Representative Douglas Ose (108).
252. Retail Electricity Competition Plans

Agency: FTC

Citation: None provided.

Authority: N/A

Description of What Existing Regulations Do: In recent years, many states and the Federal government have taken steps to encourage competition in the generation sector of the electric power industry. In 2001, 24 states and the District of Columbia had set dates to allow customers to choose their electric power supplier. In light of reliability problems and increases in electricity prices in California and the western states generally, however, some States delayed, or considered delaying, implementation of retail competition plans.

Commenter Description of Issue(s): Electric Restructuring has the potential to create net benefits, but not all restructuring plans are equally effective in moving from monopoly to competition. In particular, California’s restructuring plan has hampered the development of a competitive market, while Pennsylvania’s plan has been the most successful at promoting competition and producing consumer savings.

Small Business Impact: No.

Commenter Proposed Solution(s): None provided.

Estimate of Economic Impacts: Similar experiences in other industries shows that competition and deregulation produce price reductions between 10 percent and 25 percent, along with significant service quality improvements.

Commenter(s): Mercatus (73).
253. Disposition of Federal Records

Regulating Agency: National Archives and Records Administration (NARA)

Citation: 36 CFR Part 1228

Authority: 44 U.S.C. SS 2104(a), 2904, 2907, 3102, 3103

Description of What Existing Regulation Does: Subject regulation guides agencies in the disposition of Federal records; that is, the "who, what, where, and why" of records storage.

Commenter Description of Issue(s):

• The primary concern: perceived “burdensome facility and fire safety standards” that “make it almost impossible for an agency to store records in a commercial facility.”

• A secondary, or perhaps root cause, issue describes NARA’s service as extremely poor, which causes agencies to prefer storage in a commercial facility. Some examples of poor service cited:
  - NARA’s inability to retrieve records efficiently and respond to requests for information in a timely fashion.
  - NARA’s inability to support electronic requests.
  - NARA’s employees are not properly equipped and its system is not computerized.
  - Many NARA facilities do not have phones to take status inquiries.
  - There are reports of NARA failing to keep track of records checked out of its facilities resulting in misplaced records.

• A third issue reported is that agencies wanting to transfer records to NARA facilities are told that the facilities are full and that it will be several years before NARA can accept new records for storage.

Small Business Impact: Yes. Per the commentaries:

• The December 1999 regulations prohibit agencies from storing records in commercial facilities that do not immediately meet the increased fire safety standards, and require agencies to transfer their records to compliant facilities with a short time after the regulations are implemented. However, no commercial facilities meet these criteria and NARA is not accepting records. The end result is that agencies have no means of storing temporary records.

• These regulations severely impact our ability to pursue business with the Federal government for records and information storage. We are also concerned about the impact these regulations will have on future trends in the industry. If the industry is forced to implement these standards in order to receive Federal contracts, it is conceivable that these facility requirements will needlessly permeate the industry. If that happens, small businesses will be unable to compete with the larger companies that can more easily absorb the up-front costs of retrofitting facilities.

Commenter Proposed Solution(s): “The Federal government should not be dictating how the private sector does business, particularly when issuing such burdensome facility and fire safety standards. If anything, the government should look to the industry to see if the commercial standards in place are working before forcing a change….Reexamine this issue and recommend deleting the sections of NARA’s regulations that are so unreasonable.”

Estimate of Economic Impacts: No specifics provided; general reference to cost of retrofitting facilities to meet the required burdensome facility and fire safety standards.
Commenter(s): Comments on this rule were received by approximately 497 individuals, many of whom represent and/or are members of the Professional Records and Information Services Management (PRISM) International. The letters were almost exactly the same in wording.
254. Federal Employees Health Benefits

Regulating Agency: Office of Personnel Management

Citation: 5 CFR 890

Authority: 5 USC 89

Description of What Existing Regulation Does: OPM regulations do not permit CHAMPUS/Tricare supplemental insurance plans to join the FEHB program.

Commenter Description of Issue(s):

• The Federal government is wasting approximately $16 billion per year in unnecessary premiums.
• Federal civil service employees that are retired military are misled into signing up for a costly health plan.

Small Business Impact: N/A.

Commenter Proposed Solution(s): Allow former military civil servants to select CHAMPUS/Tricare as their primary health insurance plan.

Estimate of Economic Impacts: Not detailed although commenter asserts that government is wasting $16 billion per year.

Commenter(s): J.M. Collins (159).
Regulating Agency: SEC

Citation: 17 CFR 229.10-229.702


Description of What Existing Regulation Does: This rule allows the SEC to enforce its authority to require proxy disclosures in the public interest or for the protection of investors. Currently, SEC may require disclosure of environmental liabilities of firms only where they are “economically material.”

Commenter Description of Issue(s):

• SEC refuses to assert a larger role in requiring environmental disclosures.
• Environmental characteristics of firms should be included because environmental performance is correlated with economic performance.
• Investors are concerned with the social performance of firms and would benefit from enhanced environmental disclosures.

Small Business Impact: No.

Commenter Proposed Solution(s): SEC should expand its investor disclosure rules to require release of information regarding environmental performance (i.e., status of the company’s permits, whether it has been the subject of an environmental enforcement action, and the emissions it reports to the Toxic Release Inventory).

Estimate of Economic Impacts: Better environmental disclosure yields benefits.

Commenter(s): Center for Progressive Regulation (70).
256. Disclosure of Mutual Fund After-Tax Returns

Regulating Agency: SEC

Citation: 17 CFR 230, 239, 270, 274

Authority: 15 USC 77e, 77f, 77g, 77j, 77s(a); 15 USC 80a-8, 80a-24, 80a-37; 15 USC 77e, 77j(b), 77s(a); 15 USC 80a-33(b), 80a-37(a)

Description of What Existing Regulation Does: This rule requires mutual funds to report standardized after-tax returns along with the standardized pre-tax returns already reported.

Commenter Description of Issue(s):
- The rule is unlikely to generate net benefits.
- The rule will limit the incentives to produce different kinds of information that could be of value to investors.
- A market failure has not been identified.

Small Business Impact: No.

Commenter Proposed Solution(s): The rule should be withdrawn.

Estimate of Economic Impacts: The new disclosure requirement yields zero to negative net benefits.

Commenter(s): Mercatus Center (73).
257. Disclosure of Order Execution and Routing Practices

Regulating Agency: SEC

Citation: 17 CFR 240

Authority: 15 USC 78c, 78e, 78f, 78k-1, 78o, 78q, 78s, 78w(a), 78mm

Description of What Existing Regulation Does: This rule requires greater disclosure regarding order flow. The rule is intended to address concern that payment for order flow prevents investors from getting the best possible prices and contributes to “market fragmentation” that makes prices in the stock markets less accurate.

Commenter Description of Issue(s):

• The concerns described above are unfounded; there is no evidence that market segmentation reduces the ability of stock prices to incorporate relevant information.
• Firms receiving payment for order flow offer their customers lower trading commissions, greater price certainty, faster executions, and other benefits that could offset any higher spreads that these customers pay.
• SEC provides no evidence of a market failure.

Small Business Impact: No

Commenter Proposed Solution(s):

• The SEC should not impose rules that could discourage payment for order flow.

Estimate of Economic Impacts: Smaller investors will subsidize the trading costs of larger and better-informed investors.

Commenter(s): Mercatus Center (73).
Registration of Broker-Dealers Pursuant to Section 15(b)(11) of the Securities Exchange Act of 1934

Regulating Agency: SEC

Citation: 17 CFR 240, 248, 249

Authority: 15 USC 15(a), 15(b), 17(a), 23(a); 15 USC 6804; 15 USC 17, 23(a)

Description of Proposed Regulation: The proposed rule would implement Section 15(b)(11) of the Securities Exchange Act of 1934 and provide the procedure for futures commission merchants and introducing brokers to register by notice as broker-dealers.

Commenter Description of Issue(s):

• The rule results in a time-consuming, costly duplication of registration procedures.
• The process denies futures intermediaries the ability to obtain notice registration if their intention is to trade security futures products on a registered national securities exchange.

Small Business Impact: No

Commenter Proposed Solution(s):

• The SEC should amend its proposed rule to allow for a less costly and more inclusive process for futures intermediaries.

Estimate of Economic Impacts: The duplicative nature of the information collected by the SEC yields little or no marginal benefit.

Commenter(s): Mercatus Center (73).
Proposed Rule Changes of Self-Regulatory Organizations

Regulating Agency: SEC

Citation: 17 CFR 240, 249

Authority: 15 USC 78a, 3(a)(26), 3(a)(27), 3(b), 6, 15A, 15B, 17A, 19(b), 23(a), 36(a)

Description of Proposed Rule: The rule proposes changes to Regulation 19(b), which governs Self-Regulatory Organizations' abilities to receive expedited treatment of certain internal rule changes from the SEC. Specifically, the Commission proposes to issue a release relating to a proposed rule change within 10 business days of receipt (or within such longer period as to which the SRO consents in writing) and allow the majority of trading rules to be effective upon filing. The amendments are designed to expedite the review of SRO rules, and to allow SROs to more quickly introduce changes to their markets.

Commenter Description of Issue(s):

• Because the SRO preparation phase for a proposed rule change will likely remain unchanged as a result of this rule, the rule essentially maintains the regulatory status quo.

Small Business Impact: No.

Commenter Proposed Solution(s):

• The SEC should consider a more flexible regulatory approach by possibly expanding self-certification.

Estimate of Economic Impacts: The rule's benefits and costs are likely to be minimal.

Commenter(s): Mercatus Center (73).
260. Request for Comment on Issues Relating to Market Fragmentation

Regulating Agency: SEC

Citation: N/A

Authority: 15 USC 78f(b)(5)

Description of What Regulation Would Do: The SEC is concerned that when security trades occur in multiple locations, "market fragmentation" might prevent investors from getting the best possible terms of trade. This request for comment seeks information on the extent to which market fragmentation is a problem and what type of regulatory response (if any) is appropriate.

Commenter Description of Issue(s):

• There is little evidence that problems from market fragmentation are significant.
• To the extent that problems with fragmentation exist, they would not be solved with additional regulations, centrally mandated linkages, or uniform and cumbersome disclosure systems.
• Competition among market centers and participants encourages low trading costs, price discovery, transparency, market efficiency and innovation.

Small Business Impact: No

Commenter Proposed Solution(s):

• The SEC should maximize reliance on competition and replace the monopoly in market data.
• Alternatively, the SEC could foster competition within a system of property rights in which market data are a common pool resource.
• The SEC could approach intermarket linkage by 1) refraining from pressing the industry to develop a monolithic replacement for ITS and 2) approving proposals from individual market centers and dealers to create their own links to other market centers and dealers.

Estimate of Economic Impacts: The benefits of the regulatory options considered are unlikely to outweigh the costs.

Commenter(s): Mercatus Center (73).
261. Confirmations of Securities Transactions

Regulating Agency: SEC

Citation: 17 CFR 240

Authority: 15 USC 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77ssss, 77ttt, 78c, 78d, 78i, 78j, 78l, 78m, 78o, 78p, 78q, 78s, 78w, 78x, 7811(d), 79q, 79t, 80q-20, 80a-23, 80a-29, 80a-37, 80b-3, 80b-4, 80b-11

Description of What Existing Regulation Does: Rule 10b-10 requires broker-dealers to disclose basic trade information to customers regarding their securities transactions. The information required by Rule 10b-10 includes: the date and time of the transaction, the identity and number of shares bought or sold, and the trading capacity (i.e., agent or principal) of the broker-dealer. In addition, depending on the trading capacity of the broker-dealer, the rule requires the disclosure of commissions and, under specified circumstances, mark-up and mark-down information. Transaction confirmations serve several functions, both for investors and for broker-dealers. As a practical matter, broker-dealers often use confirmations as customer invoices or billing statements. In addition, transaction confirmations inform investors of transaction details so they can check for errors or misunderstandings; provide investors with consumer information so they can evaluate the cost and quality of the service they receive from their broker-dealers; disclose possible conflicts of interest that may arise between investors and broker-dealers; and safeguard against fraud by permitting investors to detect problems associated with transactions.

Commenter Description of Issue(s):

• The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: Uncertain.

Commenter Proposed Solution(s): OMB should reconsider this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: SEC estimates that broker-dealers send approximately 3.36 billion confirmations annually. The average cost per confirmation is estimated to be 89 cents, including postage. The average cost to the industry in fiscal year 2000 was estimated to be $2.99 billion.

Commenter(s): Representative Doug Ose (108).
262. Recordkeeping by Registered Investment Companies

Regulating Agency: SEC

Citation: 17 CFR 270, 275

Authority: 15 USC 80a, 80b

Description of What Existing Regulation Does: The Investment Company Act of 1940 requires registered investment companies ("funds") and certain principal underwriters, broker-dealers, investment advisers and depositors of funds to maintain and preserve records as prescribed by SEC rules. The rules require funds and every underwriter, broker, dealer, or investment adviser that is a majority-owned subsidiary of a fund, to maintain accounts, books, and other documents that form the basis for financial statements required to be filed under section 30 of the Act, and of the auditor's certificates relating thereto. The recordkeeping requirements are a key part of the Commission's investment company regulatory program because they allow the Commission to monitor the operations of funds and evaluate their compliance with the Federal securities laws.

Commenter Description of Issue(s):

• The PRA burden associated with this rule is over 10 million hours.

Small Business Impact: Uncertain.

Commenter Proposed Solution(s): OMB should reexamine this (and 14 other) non-IRS rules that impose over 10 million burden hours annually.

Estimate of Economic Impacts: SEC estimated that these rules impose an average burden of approximately 4,800 annual hours per fund. The estimated total annual burden for all 4295 funds subject to the rule therefore was approximately 20,616,000 hours. Based on conversations with fund representatives, however, Commission staff believe that, even absent these requirements, most of the records created pursuant to the rules would generally be created as a matter of normal business custom to, for example, prepare financial statements.

Commenter(s): Representative Doug Ose (108).
263. Investment Advisor Registration Updates

Regulating Agency: SEC

Citation: 17 CFR 200, 275, 279

Authority: 15 USC 80b-1

Description of What Existing Regulation Does: Investment advisors are required to provide annual registration updates through an internet-based system. In addition, investment advisors must register non-broker representatives and complete a form U4 for each representative.

Commenter Description of Issue(s):

• The process is cumbersome and poorly designed.
• Filing the U4 form is unnecessary.
• The process yields little or no benefit.

Small Business Impact: Yes

Commenter Proposed Solution(s): None provided.

Estimate of Economic Impacts: The complicated process and forms waste time and provide no benefit.

Commenter(s): Jerry W. Plant (178).
264. **Contract Bundling**

**Regulating Agency:** Small Business Administration (SBA) and the Federal Acquisition Regulations (FAR) Council

**Citation:** 13 CFR Part 125

**Authority:** 15 U.S.C. 637

**Description of What Regulatory Prompt Would Do:** Address the issue that, when Federal agencies bundle a series of small contracts into a larger contract, the opportunities for small businesses to compete for Federal contracts are diminished.

**Commenter Description of Issue(s):** The commenter accuses several agencies of intentionally bundling contracts for the purpose of avoiding small businesses.

**Small Business Impact:** Yes. Small businesses that rely on Federal contracts suffer when Federal contracting opportunities disappear. However, there is no basis for saying that the benefits to taxpayers or Federal agencies do not justify this harm.

**Commenter Proposed Solution(s):** Implement the President's commitment to small businesses.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Bob Thomas, Cartridge Discounters (114).
265. Nationwide Permits

Regulating Agency: U.S. Army Corps of Engineers

Citation: 66 CFR 4550

Authority: Clean Water Act, Sec 404

Description of What Activity Does: CWA Sec 404 prohibits discharges of dredge or fill material to waters of the US, including wetlands, without a permit issued by the Corps. It also provides that the Corps may issue general permits authorizing categories of activities which it determines will have minimal adverse impacts on the aquatic environment, both individually and cumulatively. Most permits also require mitigation for wetlands that are degraded.

Commenter Description of Issue(s):

• Commenter states that revised permits “will make it easier for developers, mining companies, and others to qualify for general permits to dredge and fill wetlands.” No specific examples are provided. (OMB Watch)
• Commenter is also concerned about recently issued guidance on mitigation granting local Corps officials greater discretion to determine appropriate mitigation requirements on a project-specific basis. (OMB Watch)
• Commenter believes acreage thresholds are too low. Requirement to obtain individual permit for any project impacting more than ½ acre of wetlands has imposed significant burden on transportation projects. (ARTBA)
• Significant delays in construction are introduced by the need to get individual permits (ARTBA).

Commenter Proposed Solution(s):

• Corps should “strengthen its policies regarding wetlands -- by strengthening permit rules and ensuring that new permits will have only minimal impact.” No specific examples are provided. (OMB Watch)
• Reevaluate stringent acreage thresholds. (ARTBA)
• Revise the NWP program to minimize paperwork, seek the best use of manpower and funds, and prevent needless delays at all levels of government. (ARTBA)

Estimate of Economic Impacts: Commenter ARTBA notes that Corps statistics show that wetland acreage created under mitigation requirements far exceeds acreage destroyed by permitted activities. [Note: The accuracy of these statistics has been widely questioned. The Corps has acknowledged that they are not reliable and is working on improving its tracking systems.]

Commenter(s): OMB Watch (77), American Road and Transportation Builders Assn (1).
266. Definition of Fill Material

Regulating Agency: U.S. Army Corps of Engineers and EPA/Office of Water

Citation: None provided.

Authority: Clean Water Act, Sec 404

Description of What Existing Regulation Does: Discharges of “dredge or fill” material are regulated by the Corps under Sec 404; discharges of all other pollutants are regulated by EPA under Sec 402. In recent years, a controversy has arisen over which type of permit is required for so-called “valley fills” associated with mountaintop mining. This type of mining generates a large quantity of “excess spoil” which cannot all be replaced on the original site from which it was removed. The excess is deposited in valleys, where it fills any streams that may run through the bottom of the valley. The Corps and EPA have long maintained that this is a discharge of fill material and requires a Sec. 404 permit. However, prior to the promulgation of this rule, there was a discrepancy between the Corps’s and EPA’s definitions of fill material that led to confusion on this point. The EPA definition said that fill was any material that “had the effect of” filling a stream or raising its bottom elevation while the Corps definition said that fill was any material that was “discharged for the primary purpose of” filling a stream or raising its bottom elevation. The plaintiffs in several court cases argued that valley fills are not created “for the primary purpose of” filling streams, but rather are a form of waste disposal and thus, under the Corps definition, should not be treated as discharges of “fill material.” A Federal district judge agreed. To clarify and reconfirm existing practice, EPA and the Corps issued a joint rule in May 2002 that adopted EPA’s approach to the definition, using an effects based rather than a primary purpose based test. The judge voided the rule and the case is currently under appeal.

Commenter Description of Issue(s): The administration circumvented its own procedures in order to rush the rule out by 1) not conducting a complete environmental impact statement (EIS) to fully examine the serious implications of changing the definition, and 2) concluding OIRA review of the rule in less than 48 hours.

Small Business Impact: Not clear. Some affected mining companies may be small businesses.

Commenter Proposed Solution(s): Rework the rule following a complete EIS and thorough regulatory impact analysis under E.O. 12866.

Estimate of Economic Impacts: Commenter believes the rule will clearly have an impact on the economy of greater than $100 million. This is because OMB and the agencies used the wrong baseline to analyze its costs. Rather than comparing it to existing practice, which the commenter believes was illegal, the agencies should have compared it to compliance with the legal requirements, which presumably would prohibit valley fills under the commenter’s interpretation.

Commenter(s): Natural Resources Defense Council (80).
267. Commercial Mail Receiving Agencies

Regulating Agency: U.S. Postal Service

Citation: 39 CFR 111


Description of What Existing Regulation Does: The final rule requires all Commercial Mail Receiving Agency (CMRA) users to use either "PMB" (private mailbox) or "#" in their addresses rather than the terms apt., suite, unit, etc. USPS asserted that the designation was necessary to deter fraud by ensuring that the public would be aware of a business' true address identity.

Commenter Description of Issue(s):

• The rule requires small businesses to change their business materials to reflect that they are using a CMRA. In addition to the change being costly, it also places a stigma on small businesses that use CMRAs for a business address—especially legitimate home-based businesses.
• There was no indication that fraudulent activity occurred at any greater rate at CMRAs than USPS mailbox facilities, or that the particular requirement would in any way deter fraud.
• The regulation may be in contravention of 39 U.S.C. § 403(c), which bars USPS from discriminating among users of the mails.

Small Business Impact: Yes. The commenter notes that, because small businesses are the primary users of CMRAs, the regulation discriminates against them.

Commenter Proposed Solution(s): Rescind the regulation.

Estimate of Economic Impacts: According to the commenter, "it is nearly impossible to place a value on lost business or other effects that might be related to the stigma associated with complying with the requirements of the regulation."

Commenter(s): Small Business Administration, Office of Advocacy (97).
II. SUGGESTIONS FROM THE PUBLIC FOR
REFORM OF GUIDANCE DOCUMENTS

1. Policy on Beef Contaminated with *E. coli* O157:H7

**Regulating Agency:** USDA/Food Safety and Inspection Service and USDA/Agricultural Marketing Service

**Citation:** Technical Data Supplement (TDS) for the Procurement of Frozen Ground Beef Items (TDS-136, June 2000) and FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef

**Authority:** Federal Meat Inspection Act and Agricultural Marketing Act of 1946

**Description of What Existing Regulation Does:** FSIS requires that establishments verify their HACCP process control by testing for *E. coli* Biotype 1. Through its directives system, FSIS has established a policy that declares a meat product adulterated when testing detects *E. coli* O157:H7. Specifically, if testing detects *E. coli* O157:H7 on raw ground beef, on beef products that have been injected or mechanically tenderized, or on intact cuts that are to be further processed into non-intact cuts, it is considered adulterated. AMS has addressed public concerns about *E. coli* O157:H7 by revising contracts specifications for USDA purchases of ground beef for the National School Lunch Program and other Federal feeding programs to establish zero tolerance for both *E. coli* O157:H7 and *Salmonella* in raw, ground beef and to require slaughter establishments to use an “FSIS recognized” microbial intervention as a critical control point.

**Commenter Description of Issue(s):**

- *E. coli* 0157:H7 is life threatening and industry testing has shown that companies can significantly reduce that hazard during the slaughter process. (77)
- The incidence of *E. coli* in raw beef is so low that sampling and testing cannot reduce the public health risk significantly. No sampling program exists that will ensure that the pathogen is not in the product. (47)
- The zero-tolerance requirements for *E. coli* O157:H7 and *Salmonella* imposed by AMS are not science-based and are unrealistic microbiological criteria. (47)
- The AMS' requirements unnecessarily eliminate some suppliers from the market, thereby limiting supply, and increasing prices paid by the agency. (47)

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):**

- USDA should promulgate regulations to reduce *E. coli* 0157:H7 in the slaughter plant and require plants to test carcasses. (77)
- AMS should adopt the new, science based approach described in the revised TDS document, TDS-136, published for public comment in June 2001. (47)
- FSIS should remove the non-intact whole muscle cuts (tenderized steaks, etc) from the policy, but maintain the current “point source” contamination policy. (47)
- FSIS should modify Directive 10,010.1, *Microbiological Testing Program for Escherichia coli* O157:H7 in Raw Ground Beef, to allow carcass testing at a rate of one per 300 carcasses, to remove the six month penalty provision, and to provide eligibility for reduced sampling through the distribution chain. (47)

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Meat Institute (47); OMB Watch (77).
2. **Medicare Carrier Manual and Medicare Intermediary Manual**

*Regulating Agency:* HHS/CMS

*Citation:* Medicare Carrier Manual Section 2309.4 and Medicare Intermediary Manual Section 3153.3A

*Authority:* None provided.

*Description of Guidance Document:* The referenced sections of the Medicare manuals contain policies and procedures for payment of ambulance services for eligible Medicare beneficiaries. These provisions were developed to prevent the use of illegal kickbacks to beneficiaries.

*Commenter Description of Issue(s):* Office of Inspector General opinions based on provisions in Medicare Carrier and Intermediary manuals have concluded that, while public ambulance suppliers may waive beneficiary deductible and co-payment amounts, private suppliers are required to collect these amounts from beneficiaries. The commenter believes that this gives the public services a distinct competitive advantage because they are able to advertise and provide services at no cost to beneficiaries.

*Commenter Proposed Solution:* Apply the anti-kickback provisions equally to both public and private suppliers of ambulance services by deleting the provisions in the Medicare manuals that permit waivers of co-payments only by public suppliers or revise these provisions to permit waivers by any supplier of ambulance services.

*Estimate of Economic Impacts:* Commenter did not provide economic estimate, but believes that the recommended change would enable private ambulance services to better compete with public ambulance services on the basis of price and quality.

*Commenter(s):* American Ambulance Association (34).
3. Medicare Signature on File Requirement for Ambulance Services

Regulating Agency: HHS/CMS

Citation: Medicare Carrier Manual Section 3057(A)(3)

Authority: None provided.

Description of Guidance Document: Medicare payment policies and procedures currently require that the signature of the beneficiary be obtained prior to release of the ambulance company's medical records to Medicare and other third party payers.

Commenter Description of Issue(s): Frequently, due to the nature of emergency situations encountered by ambulance services, companies are unable to obtain the signature at the time the service is rendered. The manual provision allows the ambulance supplier to obtain the signature from another source (e.g., patients' family, friends, or representatives of the institution providing care) or to sign it themselves if there is no one else. However, ambulance services face claims processing delays and increased costs for those claims for which the patient's signature is not on file.

Commenter Proposed Solution: Commenter recommends either allowing suppliers to state that they have met the signature on file requirement when a signature has been obtained from the patient or any of the allowed patient representatives, or requiring patients to sign a general authorization up front for release of their medical records to CMS for any medical services provided to that beneficiary.

Estimate of Economic Impacts: Commenter expects the recommended change to reduce administrative costs for ambulance suppliers and Medicare carriers/intermediaries.

Commenter(s): American Ambulance Association (34).
4. Medicare Carriers' Manual: Payment to Health Care Delivery System

Regulating Agency: HHS/CMS

Citation: Medicare Carriers' Manual Sections 3060.3 & 3060.5

Authority: None provided.

Description of Guidance Document: The referenced provisions govern the office performance of nuclear diagnostic scans to patients. Physician groups use nuclear diagnostic scans to bill globally for the technical and professional component, even when the professional component or interpretation is provided by an independent contractor. The professional component, however, must be provided on-site.

Commenter Description of Issue(s): The commenter is concerned that physician groups are unable to benefit from utilization of this exception to general prohibitions against reassignment of claims. For the group to bill globally for the professional component of a nuclear diagnostic scan provided by an independent contractor, that nuclear medicine physician must be physically located at the physician group practice location. The additional costs of being physically present rather than providing remote interpretations makes the engagement of nuclear medicine specialists as independent contractors not economically feasible for the physician group.

Commenter Proposed Solution: The commenter recommends that the agency eliminate the requirement that nuclear diagnosis scans be performed on the premises of the clinic, allowing nuclear medicine specialists who are independent contractors to provide interpretations to another physician group without physically going to the site where the technical component of the scan is performed.

Estimate of Economic Impacts: Commenter believes that this restriction leads physicians to choose the less medically beneficial option of interpreting nuclear diagnostic scans themselves, rather than utilize the services of a nuclear medicine specialist.

Commenter(s): Society of Nuclear Medicine (49).
5. **Individual Health Insurance Rules**

**Regulating Agency:** HHS/CMS

**Citation:** Program Memorandum of November 2000

**Authority:** Part A of Title XXVII of the Public Health Service Act and The Health Insurance Portability and Accountability Act of 1996

**Description of Guidance Document:** The Program Memorandum provision referenced states that if an employer makes any financial contribution to the purchase of an individual health care plan, that means that the policy will be deemed to be a group plan for the purposes of Federal regulations and subject to all of the regulatory requirements of group plans.

**Commenter Description of Issue(s):** The structure of the health insurance market, shaped and driven by existing Federal tax policy, frustrates consumer choice and competition. For example, if a consumer wished to use a tax credit for the purchase of an individual policy, his/her employer would have no incentive to contribute to the purchase of the policy – having the effect of restricting access to products in the individual market.

**Commenter Proposed Solution:** The commenter recommends revoking the Program Memorandum.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** The Heritage Foundation (78).
6. **OBRA Guidance to Surveyors—Long Term Care**

**Regulating Agency:** HHS/CMS

**Citation:** CFR 483.20 d

**Authority:** F286

**Description of Guidance Document:** This guidance document contains the policies and procedures to be followed by State nursing home surveyors who are responsible for monitoring compliance with existing regulatory requirements and investigating complaints regarding the quality of patient care. The regulatory provision referenced by the commenter requires nursing homes to maintain fifteen months of Minimum Data Set (MDS) forms in the active medical records of each skilled nursing patient receiving Medicare.

**Commenter Description of Issue(s):** The commenter is concerned that the Medicare regulatory provision requiring the retention of fifteen months of completed Minimum Data Set (MDS) forms in patients' active medical records causes the patients' records/charts to become overly full and difficult to use. This is particularly problematic when a patient experiences several changes in status, necessitating additional administrations of the MDS.

**Commenter Proposed Solution:** None provided.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Kathy Rebola (151); Everall A. Peele (156).

*Regulating Agency:* HHS/OCR

*Citation:* 65 FR 52762

*Authority:* Title VI of the Civil Rights Act of 1964

*Description of Guidance Document:* The guidance document requires HHS Federal funds recipients, including health care providers, to offer oral and written translation assistance to limited English proficient individuals seeking access to services. The guidelines call for assessment of language needs to include identification of the non-English languages likely to be encountered based upon census data, service utilization, and data from schools or community organizations. In addition, a covered entity should also identify the language needs of each limited English proficient patient and make arrangements to access language assistance resources.

*Commenter Description of Issue:* The commenter believes that the financial implications of complying with the HHS LEP guidance could be devastating. Many physician practices, particularly in rural and underserved areas are small businesses. Physicians and their staff are already stretched beyond their limits in complying with cumbersome rules and regulations, resulting in time and attention being taken from actual patient care. While the guidelines are supposed to improve access to care, these guidelines could have the opposite effect.

*Commenter Proposed Solution:* The commenter recommends implementing a moratorium on enforcement of these guidelines until additional consultation could be had with affected parties to determine the best solution.

*Estimate of Economic Impacts:* No economic impact estimate was provided; however, the commenter was particularly concerned that the cost of interpreter services (e.g., $40/hour) could actually exceed the amount the physician receives for his/her services.

*Commenter:* American Osteopathic Association (39); SBA Office of Advocacy (97).
8. Standard of Chemical Quality—Nine Compounds Monitoring Requirement

Regulating Agency: HHS/Food and Drug Administration

Citation: 21 CFR165.110(b)


Description of Guidance Document: FDA published a notice in 1998 stating that EPA monitoring guidance for antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8 TCDD (dioxin) will apply to bottled water. These requirements entail monitoring for four consecutive quarters once every three years and annually for the other two years.

Commenter Description of Issue(s):

• For the four synthetic organic chemicals (diquat, endothall, glyphosate, and dioxin), these tests have resulted in no positive detections to date.
• The EPA standard provides for reduced monitoring when it is proven that compounds are not found in a specific water system.

Small Business Impact: Not addressed.

Commenter Proposed Solution(s):

• FDA should revise its guidance for the four SOC compounds to conform with its good manufacturing practice regulations for all other compounds monitored annually.
• FDA should issue specific bottled water guidance for the nine compounds that will incorporate the monitoring tests into current annual tests required for all other compounds.

Estimate of Economic Impacts: $1.1 million.

Commenter(s): International Bottled Water Association (4).
9. Coverage of Personal Importations

Regulating Agency: HHS/Food and Drug Administration

Citation: FDA Regulatory Procedures Manual #9

Authority: None provided.

Description of What Guidance Does: The law generally prohibits imports of prescription drugs for consumer use. The guidance, however, is vague regarding how FDA will enforce these prohibitions.

Commenter Description of Issue(s):

• The guidance was issued without notice and comment.
• The guidance is sufficiently vague that it has lead to illegally imported drugs that are dangerous to consumers' health and safety.
• Illegal imports harm legitimate American pharmacies and drug companies.

Small Business Impact: Presumably small American pharmacies would be helped if imports were curtailed.

Commenter Proposed Solution(s):

• The guidance should be permanently rescinded.
• Alternatively the guidance should be revised using notice and comment rulemaking.

Estimate of Economic Impacts: Not quantified.

Commenter(s): National Association of Chain Drugstores (23).
10. **Endangered Species Act Survey Protocols**

**Regulating Agency:** DOI/Fish and Wildlife Service

**Citation:** Each survey protocol is issued by a FWS Field Office.

**Authority:** 16 USC 1531 et. seq.

**Description of What Existing Regulation Does:** Survey protocols help determine whether a particular species is present in the vicinity of a proposed project as an indicator of whether consultation under section 7 is needed (for Federal actions) or a Habitat Conservation Plan is needed. Surveys are generally used in circumstances where the presence of a species is uncertain.

**Commenter Description of Issue(s):**

- One of the most contested survey protocols is for the Quino checkerspot butterfly. Other species with similar protocols include the karst invertebrates (cave bugs) in Texas, and the bog turtle in the northeast.
- Even after all of these onerous requirements are met by the landowner at great expense of money and time, there are no limits set on how many times a landowner may be required to go through this process to "disprove" the existence of any of the species on the property. The guidelines merely state that "additional surveys" may be required if no bog turtles are found, but the property contains the type of habitat typical to those species. This could stretch the survey period to over a year or more.
- Most of these survey protocols have been released from FWS in "draft" form, and have not been open to public notice and comment. Although they are "drafts," FWS often implements them as if they were regulations, threatening liability under the ESA if landowners do not comply.
- These survey protocols violate both the ESA and the Administrative Procedures Act (APA) when they are enforced by FWS without first being subjected to public notice and comment. Additionally, the survey protocols violate the ESA by placing the burden on private landowners to "disprove" that a species exists on their property. The burden of proving a species existence lies with FWS. By restricting habitat modification on land where the FWS cannot establish the existence of a listed species, FWS is violating the ESA and Supreme Court interpretations of the "take" prohibitions of the ESA.

**Small Business Impact:** Yes.

**Commenter Proposed Solution(s):**

- The FWS should be required to issue every survey protocol to notice and comment as required under the Administrative Procedures Act. Landowners must be provided the opportunity to comment on procedures that FWS is requiring them to follow on their own property.
- Furthermore, the FWS must remove any ambiguity and clarify that such protocols are guidance. The ESA does not provide FWS the authority to force landowners to conduct these surveys to disprove the existence of a species or habitat in order to not be regulated. The FWS can only provide these documents as guidance to landowners who are seeking assistance on ensuring they are not in danger of violating the ESA with potential actions.
- FWS can amend each protocol to include language expressly stating that these protocols are not regulations or rules, and are therefore, non-binding. FWS must also reaffirm that the protocols are available for voluntary use by landowners in assisting them with avoiding violations of the ESA.

**Estimate of Economic Impacts:**

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• Survey protocols often require months, and sometimes years, to fully complete to the satisfaction of FWS. In the meantime, the FWS will not provide approval for projects and the builder or developer is forced to sustain an economic loss in the meantime. Also, builders and developers can experience a problem with their other necessary local, state, and Federal permits and approvals expiring in the time period that it takes to complete these surveys. The builder or developer must then expend more cost in fees and time spent in order to obtain those permits and approvals again, or have them extended.

• Even after all of the onerous requirements of a survey protocol are met at great expense of money and time, there are no limits set on how many times a landowner may be required to go through this process to “disprove” the existence of any species or habitat on the property.

• Additionally, FWS often releases a list of “approved” consultants to conduct the surveys. The list of approved consultants is often short and therefore substantial time delays are created in the process due to the backlog of surveys needed and the short time frame when surveys are allowed to be conducted.

Commenter(s): Gerald Howard, National Association of Home Builders (48).

Regulating Agency: DOJ

Citation: DOJ memorandum from Criminal Division (January 1994); DOJ memorandums from Federal Bureau of Prisons General Counsel (November 1997; February 1998)

Authority: 18 U.S.C. 1761(a) and 4122(a)

Description of What Guidance Does: This memoranda serves as the basis for allowing the Federal Prison Industries to sell its commercial services to the public in competition with the private sector.

Cementer Description of Issue(s):

- The memoranda decision is arbitrary and capricious.
- The policy decision should be accomplished through passage of a legislative mandate rather than through administrative fiat.

Small Business Impact: No.

Cementer Proposed Solution(s): The memoranda should be rescinded.

Estimate of Economic Impacts: By rescinding the memoranda, the private sector would not be adversely impacted by direct competition from a government entity in the commercial market.

Cementer(s): U.S. Chamber of Commerce (32).
12. **Guidance on Coordination of FMLA with Other Leave Policies**

**Regulating Agency:** Department of Labor, Employment Standards Administration

**Citation:** 29 CFR Part 825.104; 825.106(d); Opinion Letter FMLA 37

**Authority:** Family Medical Leave Act 1993

**Description of What Proposed Guidance Document Would Do:** Provide guidance on coordination of FMLA with other leave policies.

**Commenter Description of Issue(s):**

- Coordination of FMLA with other leave policies is difficult.
- Employees who are eligible for statutory leave protection under the FMLA also have leave rights derived from one or more other sources (other Federal statutes, state laws).
- Employers are required to determine which leave policy will provide employees in various locations with the greatest protection and administer requests accordingly.
- There are seemingly conflicting rules regarding FMLA’s interaction with ADA, in the difference in determining which employees are eligible for coverage based on their ability to perform essential job functions.
- Statutes vary on how they address an employer's ability to reassign an employee seeking intermittent leave.

**Commenter Proposed Solution(s):**

- Congress should revisit the interaction of FMLA to ADA.
- DOL/Congress should provide guidance.

**Estimate of Economic Impacts:** None given.

**Commenter(s):** Guidant Corporation (200).

**Regulating Agency:** Department of Labor, Employment Standards Administration, OFCCP

**Citation:** 41 CFR, Part 60

**Authority:** None provided.

**Description of Guidance Document:** EEO-1 strongly advises that information on ethnicity not be directly asked of employees.

**Commenter Description of Issue(s):** The EEOC says that employers cannot under any circumstances ask candidates about ethnicity, even if the hiring manager never sees it. In addition, the EEO-1 states specifically that you cannot ask an employee about his ethnicity. On the other hand, the OFCCP has told employers that this information is required.

**Commenter Proposed Solution(s):**
- The EEOC says that employers cannot under any circumstances ask candidates about ethnicity, even if the hiring manager never sees it. In addition, the EEO-1 states specifically that an employer cannot ask an employee about his ethnicity. On the other hand, OFCCP has told us that this information is required.
- Rectify the contradictory guidance in some way.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Renee Pearson (172).
14. **Inspection Procedures and Interpretive Guidance for Control of Hazardous Energy (Lockout/Tagout)**

*Regulating Agency:* Department of Labor/OSHA

*Citation:* 29 CFR 1910.147.

*Authority:* Occupational Safety and Health Act, 29 U.S.C.

**Description of What Guidance Does:** The Lockout/Tagout Standard requires employers to control hazardous energy sources using lockout or tagout procedures while employees service, maintain, or repair machines or equipment if activation, start-up or release of energy from an energy source is possible.

**Commenter Description of Issue(s):**

- OSHA has issued more than 100 letters of interpretation of this Standard since it was promulgated in 1989. These interpretations have expanded the requirements of the Standard without public input, resulting in large burdens on employers that were not accounted for in the Regulatory Analysis prepared when the standard was promulgated.

**Small Business Impact:** N/A

**Commenter Proposed Solution(s):**

- Propose OSHA immediately revise the burden estimate for the Lockout/Tagout Standard to reflect the paperwork burden of the requirements as interpreted by the guidance documents.
- Propose OSHA be required to issue its primary guidance documents and field enforcement instructions contemporaneous with the promulgation of final rules.
- Propose primary guidance documents and significant revisions thereto be required to undergo notice and comment procedures.

**Estimate of Economic Impacts:** None provided

**Commenter(s):** Organization Resources Counselors, Inc. (21).
15. **OSHA Directive CPL 2.100, Application of the Permit-Required Confined Spaces (PRCS) Standards**

**Regulating Agency:** Department of Labor/OSHA

**Citation:** 29 CFR 1910.146.

**Authority:** Occupational Safety and Health Act, 29 U.S.C.

**Description of What Existing Regulation Does:** The PRCS Standard requires certain employers to implement permit-required confined space programs. Employers must inspect confined spaces and determine if a confined space contains hazards that would make entry by employees dangerous. If the confined space is found to be hazardous, it must be designated for use by "permit-required-only employees," those who have been trained to enter permit spaces. Employers are required to retain canceled entry permits for at least 1 year to facilitate review of the permit-required confined space program.

**Commenter Description of Issue(s):**

- The guidance document classifies the results of testing done to measure the atmosphere of confined spaces as "exposure records," which must be retained for at least 30 years. Since these results are recorded on permits, the permits are also considered exposure records. This additional burden on employers was not included in the original Standard or the Paperwork.

**Small Business Impact:** N/A

**Commenter Proposed Solution(s):**

- Propose OSHA immediately revise the burden estimate for the PRCS Standard to reflect the retention requirements as interpreted by the guidance documents.
- Propose OSHA be required to issue its primary guidance documents and field enforcement instructions contemporaneous with the promulgation of final rules.
- Proposed primary guidance documents and significant revisions thereto be required to undergo notice and comment procedures.

**Estimate of Economic Impacts:** None provided

**Commenter(s):** Organization Resources Counselors, Inc. (21).
16. Multi-Employer Citation Policy

Regulating Agency: Department of Labor/OSHA

Citation: OSHA Directive CPL 2-0.124, Multi-Employer Citation Policy, Effective Dec. 10, 1999

Authority: Occupational Safety and Health Act, 29 U.S.C.

Description of What Existing Guidance Does: The policy allows OSHA to issue citations to more than one employer, usually both the general contractor and independent subcontractor, for the same condition that violates an OSHA standard. This is based on a theory that the general contractor "controls," or has general supervisory authority over, the work site and is therefore responsible for all violations that occur there.

Commenter Description of Issue(s):

• Requires the general contractor (GC) to "police" the work site, based on an assumption that since the GC has the authority to require an independent subcontractor to comply with building plans and other specifications, the GC must also ensure that the subcontractor complies with OSHA standards.
• The Policy expands the common law liability of general contractors. This violates the OSH Act, which provides that employers are responsible for their own employees. In order to avoid a citation under this policy, a general contractor must engage in activities it would otherwise not be legally required to do. OSHA does not have the statutory authority to impose these requirements.

Small Business Impact: N/A

Commenter Proposed Solution(s):

• Propose OSHA immediately withdraw the Multi-Employer Citation guidance from publication and suspend enforcement of the policy.
• Propose OSHA seek statutory authority from Congress to adopt such a rule.
• Propose OSHA, if given the statutory authority, promulgate the rule in accordance with the notice and comment rulemaking procedures under the Administrative Procedures Act.

Estimate of Economic Impacts: The continued enforcement of this policy could lead to significant increases in the cost of construction for hiring additional safety personnel. This cost could be in the millions of dollars. However, since this policy has not undergone the scrutiny of the regulatory process, there are no data as to its specific costs and benefits. Additionally, OSHA enforcement of this policy has led to severe, duplicative penalties for a single violation of an OSHA regulation.

Commenter(s): National Association of Home Builders (48).
17. General Operating and Flight Rules; Inspections

Regulating Agency: DOT/Federal Aviation Administration

Citation: Guidance; FAA policy Order 8300.10, Chapter 83

Authority: 49 U.S.C. 106 (g)

Description of What Existing Guidance Does: FAA’s guidance provides compliance assistance for its rules governing the maintenance, and alterations of U.S. registered civil aircraft operating within or outside of the United States.

Commenter Description of Issue(s):

• The rules and guidance are outdated.
• The rules and guidance require small operators to obtain FAA re-approval of their Approved Aircraft Inspection Programs (AAIP) for minor, technical changes.
• The guidance mandates thorough instructions in the Instructions for Continuous Airworthiness (ICA) that are in conflict with the approval process required by the regulation.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Update the guidance to reflect the approval process required by the regulation.

Estimate of Economic Impacts: Administrative costs of reproduction and obtaining FAA approval are ongoing and are largely born by small businesses.

Commenter(s): Small Business Administration, Office of Advocacy (97).
18. **Marine Safety Manual**

**Regulating Agency:** Department of Transportation/U. S. Coast Guard

**Citation:** Marine Safety Manual, Chapter 1 section 1

**Authority:** 33 USC Section 1225

**Description of What Existing Regulation Does:** The USCG shares regulatory authority with RSPA for the shipment of Class 1 materials involved in movement of vessels and through waterfront facilities. The USCG enforces RSPA's hazardous materials regulations (HMR) in its area of jurisdiction through a "Marine Safety Manual" (MSM) that sets quantity-distance (Q/D) standards for establishing limits on the size of Class 1 shipments that may be handled at one time in a port. The manual provides guidance to Captains of the Port (COTP) on the management of hazardous materials.

**Commenter Description of Issue(s):**

- USCG is developing a risk based approach called SAFER. However, the protocol is several years away from being implemented. Coast Guard has no plans to issue guidance in the interim that will ameliorate the deficiencies in the Q/D approach.
- The regulations have never been established through a normal rulemaking process. The Manual states that the issuance of permits in handling explosives would consider a number of factors, not just Q/D tables. However, Coast Guard guidance on handling of explosives in ports focuses generally on separation distances.
- No other DOT administration applies a Q/D approach. Instead they utilize a risk-based approach. The USCG approach is equivalent to assuming that each explosive shipment will simultaneously explode without warning.
- The straight application of the MSM Q/D policy effectively closes all U. S. ports to the dockside loading or unloading of shipload bulk quantities of Class 1 materials. Only about a dozen ports accept smaller shipments (one to three containers of Class 1 freight).

**Small Business Impact:** No information provided.

**Commenter Proposed Solution(s):** Request that USCG be instructed to issue interim guidance that will acknowledge problems with Q/D policy and provide COTPs with information on best practices and applicable DOT safety rules while taking account of both public safety and other relevant considerations.

**Estimate of Economic Impacts:** Information has been provided by commenter on trends in commercial shipments of explosives and problems encountered at specific ports where dockside loading restrictions have been changed.

**Commenter(s):** Institute of Makers of Explosives (184).
19. Technical Advice Memorandums for Low Income Housing Tax Credit

Regulating Agency: Treasury/Internal Revenue Service

Citation: IRS Technical Advice Memorandums for Low Income Housing Tax Credit, Numbers: 200043015; 200043016; 200043017; 200044004; and 200044005, each dated July 14, 2000.

Authority: Internal Revenue Code, Section 42

Description of Guidance Document: IRS Technical Advice Memoranda set forth standards for determining what costs are usable in calculating the low-income tax credit.

Commenter Description of Issue(s): The IRS Technical Advice Memoranda are IRS legal opinions used during a particular tax audit. The IRS has requested that state housing finance agencies use these memoranda as a basis for issuing tax credits even though they technically apply to one taxpayer. Since they take aggressive positions aimed at reducing the amount of tax credits that can be issued in those specific situations, hundreds of other taxpayers are negatively impacted.

Commenter Proposed Solution(s): IRS should issue formal guidance to eliminate the confusing unofficial guidance that taxpayers currently must rely upon. Issues needing to be addressed are site preparation costs, reasonable development fees, professional fees relating to basis items and construction financing costs. The commenter believes that all of these costs should be included in computing the tax credit eligible amount.

Estimate of Economic Impacts: In the current situation, uncertainty results in a reduced level of financing being available to construct housing for low income tenants.

Commenter(s): National Association of Home Builders (48).
20. ADA/ABA Guidelines

Regulating Agency: Access Board

Citation: None provided.

Authority: Americans with Disabilities Act

Description of Guidance Document: These guidelines establish a “safe harbor” for employers to follow to avoid violation of the Americans with Disabilities Act. They provide guidelines on how to make public facilities, including hotels and medical offices/facilities, accessible to individuals with disabilities.

Commenter Description of Issue(s): The ADA requires that bathrooms be wheelchair accessible. The guidelines call for more than one wheelchair accessible bathroom per floor. This is a costly requirement.

Small Business Impact: None provided.

Commenter Proposed Solution(s): Allow for only one wheelchair accessible bathroom per floor.

Estimate of Economic Impacts: Each accessible bathroom costs $150 per month or $3600 (the commenter has 3 accessible bathrooms) per year.

Commenter(s): Dennis Costello (177).
21. EPA Index of Applicability Decisions—Region V Determination for New Flyer

Regulating Agency: Environmental Protection Agency

Citation: 66 FR 57453

Authority: Clean Air Act, 42 U.S.C. 7412(d) & (g)

Description of Guidance Document: Region V has determined that a new manufacturing facility that had limited its emissions by adopting a "synthetic minor" emissions cap in its permit in order to be exempt from the applicable National Emissions Standards for Hazardous Air Pollutants (NESHAP) rule could not modify its permit to expand its operations within five years of the initial permit date. EPA determined that modifications within five years of the initial permit application were evidence of "phased construction" and that the source would therefore have been in violation of the NESHAP standards for the period of the initial permit. EPA posted this determination in the Federal Register as a nationally applicable final action.

Commenter Description of Issue:

• The guidance has had the effect of preventing sources from taking a "synthetic minor" permit limit if they believe that they might want to expand operations in the near future.
• This eliminates the option of voluntarily limiting emissions rather than complying with the NESHAP technical standards.
• The guidance is counter to positions expressed by EPA headquarters personnel about the appropriate use of "synthetic minor" permit limits

Small Business Impact: None provided.

Commenter Proposed Solution:

• Do not allow EPA to post internet guidance as nationally applicable guidance.
• Require Regional EPA actions to be submitted to EPA Headquarters and OIRA for review.
• Require that EPA complete a rulemaking revising the NESHAP "general provisions" clarifying that this interpretation is incorrect.

Economic Impacts: None provided.

Commenter: National Environmental Development Association (15).
22. New Source Review

Regulating Agency: Environmental Protection Agency

Citation: Guidance on the Appropriate Injunctive Relief for Violations of Major New Source Review Requirements (November 17, 1998)


Description of Guidance Document: The Clean Air Act (CAA) provides for standards of performance for new stationary sources. EPA established a regulatory exclusion from the definition of modification under the new source review (NSR) program, providing that "[a] physical change or change in the method of operation shall not include: (a) Routine maintenance, repair and replacement . . . ." 40 C.F.R. § 52.21(b)(2)(iii)(a). The guidance provides for appropriate injunctive relief for violations of major NSR requirements.

Commenter Description of Issue:

• At the time the NSR regulations were promulgated, EPA did not provide any significant explanation of the exclusion.
• This guidance, which was not subject to notice and comment, has been interpreted as narrowing the "routine maintenance" exclusion to frequent, traditional, and comparatively inexpensive repairs to maintain existing equipment. This more aggressive posture was reflected in the proceedings against utilities beginning in November 1999. The new, narrower exclusion has effectively modified a regulation without notice and comment rulemaking.

Small Business Impact: None provided.

Commenter Proposed Solution: Adopt a new exclusion from the definition of modification by regulation.

Economic Impacts: The enforcement memorandum has been used to force utilities to spend hundreds of millions of dollars to meet new performance standards.

Commenter: U.S. Chamber of Commerce (32).
23. “Once in, Always in” Policy

Regulating Agency: Environmental Protection Agency

Citation: www.epa.gov/ttncaaa1/t3/memoranda/pteguid.wpd

Authority: Clean Air Act, 42 U.S.C. 7412(d)

Description of Guidance Document: A 1995 EPA policy determination states that a source must be either an area or major source at the time of the compliance date for its NESHAP. Once a source has become a major source, it will always be regulated as a major source despite changes to its process or production that might reduce its potential to emit.

Commenter Description of Issue:

• Policy removes the incentive for sources to reduce their emissions through pollution prevention, product reformulation, or other means in order to become “area sources” and no longer be subject to technology-based standards.
• Requires sources to maintain cost-intensive record-keeping and monitoring requirements even though the source no longer emits sufficient hazardous air pollutants to qualify as a “major source.”

Small Business Impact: None provided.

Commenter Proposed Solution: Require EPA to promulgate a rule reversing this interpretation.

Estimate of Economic Impacts: None provided.

Commenter: National Environmental Development Association (15).
24. EPA Guidance on Improving Air Quality Through Land Use Activities

Regulating Agency: EPA/OAR

Citation: http://www.epa.gov/otaq/transp/landguid.htm

Authority: CAA Section 131 (42 U.S.C.A. Sect 7431)

Description of Guidance Document: The guidance describes the options that local, State, and regional air quality agencies, in cooperation with other interested citizens and groups, can use to account for the air quality benefits of certain land use activities in the air quality planning process (development of State Implementation Plans).

Commenter Description of Issue(s):

- EPA's Guidance policy on land use is de facto regulation since it enables states to adopt restrictions on local land use in order to receive Federal air quality credits form EPA needed to demonstrate compliance with the CAA.
- If a state adopted regulatory restrictions on land use under their SIP, as allowed under EPA's guidance, those land use restrictions would be federally enforceable as required under the CAA. EPA lacks authority to issue a regulation or guidance that creates a regulatory mechanism that could infringe or transfer authority over local land use authority from local governments to the state or Federal government.
- "Credible" science does not exist to demonstrate the link between land use restrictions and air quality.
- The public has not had opportunity to participate in the development of the policy or the opportunity to provide contrary information, consider possible alternatives, assess unintended consequences, and judge the objectivity, quality, and reliability of the information used to develop EPA's guidance.

Small Business Impact: None provided.

Commenter Proposed Solution(s): EPA should take one of the following three actions.

- Withdraw the guidance from publication and seek statutory authority from Congress to develop regulations in this area.
- Withdraw the guidance from publication and seek public comment on whether they have the statutory authority to issue guidance in this area.
- Withdraw the guidance from publication and publish it for notice and comment in its current form.

Estimate of Economic Impacts: None provided.

Commenter(s): National Association of Home Builders (48).
25. Improving Air Quality Using Economic Incentive Programs

Regulating Agency: EPA

Citation: None provided.

Authority: Clean Air Act

Description of Guidance Document: EPA’s guidance document outlines economic incentive programs that States may incorporate in their State Implementation Plans. The guidance outlines four main incentive programs: emission trading programs, financial mechanism programs, clean air investment funds, and public information programs. The key principles that must be incorporated in the economic incentive program include: integrity, equity (equal protection for all segments of the population), and environmental benefits (such as reducing emissions faster than traditional regulatory approaches).

Commenter Description of Issue(s):

• EPA's approach is too prescriptive, and will actually hinder, rather than encourage, the development of innovative state programs.
• EPA’s three fundamental principles that must apply to all EIPs -- integrity, equity, and environmental benefit -- inappropriately trump objectives of cost-effectiveness, efficiency, flexibility, and innovation.
• The “environmental benefit principle” would prevent states from developing innovative cost-effective programs if they cannot demonstrate that the new program is not just equivalent to, but more environmentally beneficial than traditional programs.
• Emission fees and trading programs offer cost-effective alternatives to traditional command-and-control approaches largely because they permit facilities for which the cost of reducing emissions is high to compensate those for which the costs are lower. The “equity principle” may prevent high-control-cost facilities from taking advantage of such opportunities and thus halt any viable efforts at cost-effective programs.

Commenter Proposed Solution(s): EPA should remove from the guidance the three fundamental principles which are overly prescriptive and may hinder the development of flexible programs that will benefit all communities.

Estimate of Economic Impacts: Restricting lower-cost environmental solutions may make facilities located near communities of concern more likely to fail. The economic loss to the community will reduce available jobs and taxes. Case studies have demonstrated that economic growth in low-income communities improves public health more than pollution control efforts.

Commenter(s): Mercatus Center (George Mason University) (73).
26. TRI Reporting Forms and Instructions

Regulating Agency: EPA/Office of Environmental Information


Authority: Emergency Planning and Community Right-to-Know Act, Sec 313

Description of Guidance Document: This document provides forms and instructions for reporting toxic chemical releases under the Toxic Release Inventory.

Commenter Description of Issue(s):

• Earlier TRI guidance (issued in 1989) stated that materials sent off-site for recycling or reuse should be treated the same as products distributed for commerce and not reported on TRI forms as “waste.” Beginning in 1991, this interpretation was changed and materials sent off-site for recycling and reuse were required to be reported as waste sent off-site for “disposal, treatment, energy recovery or recycling.” This revision was accomplished by simply changing the instructions to the form, not through notice and comment rule making. This significantly increases the amount of toxic chemicals reported as being sent off-site as waste, even though this material will be reused for beneficial purposes and not released to the environment. (IPC)

• Commenter believes removal of the following information from Section 7A of the Form R (On-Site Waste Treatment Methods and Efficiency) would significantly reduce burden without reducing or compromising the information necessary for communities to assess potential impacts from nearby facilities: waste stream code, influent concentration range, and basis of estimate. (ACC)

Small Business Impact: None provided.

Commenter Proposed Solution(s):

• Change the instructions to exclude materials sent off-site for recycling or re-use from the definition of waste sent off-site (IPC).
• Revise the Form R and instructions to remove waste stream code, influent concentration range and basis for estimate (ACC).

Estimate of Economic Impacts: None provided.

Commenter(s): IPC -- Associated Connecting Electronic Industries (43), American Chemistry Council (12).
27. TRI Reporting Questions and Answers and Other Guidance

Regulating Agency: EPA/Office of Environmental Information


Authority: Emergency Planning and Community Right-to-Know Act, Sec 313

Description of Guidance Document: This document provides detailed guidance in question and answer format using illustrative examples for industrial facilities to use in reporting releases and other waste management activities to the Toxic Release Inventory. Other documents provide guidance for specific industry sectors, specific aspects of TRI compliance (e.g., reporting of PBTs), etc.

Commenter Description of Issue(s):

- Commenter is concerned about Qs 114, 137, and 162, which suggests that facilities must now “double count” intermediary compounds produced during manufacturing processes in making threshold determinations. Under EPCRA 313, reporting requirements are tied to whether a facility “manufactures or processes” more than 25,000 lbs of a listed chemical, or “otherwise uses” more than 10,000 lbs. (Note: For so called “persistent, bioaccumulative, toxic” (PBT) chemicals, EPA recently lowered these reporting thresholds by rule to either 10 or 100 lbs, depending on the specific chemical.) According to commenter, EPA’s earlier 1989 guidance indicated that if, for example, some amount of chromium was transformed into several different compounds during a series of electroplating baths, that chromium only needed to be counted once for the reporting threshold computation. The 1998 guidance, in contrast, indicates that the chromium should be counted separately each time it is converted into a new compound, and the quantities at each processing stage summed, to determine if the reporting threshold is exceeded. This results in repeated counting of the same underlying chromium and causes many more facilities to be subject to reporting requirements. (IPC)

- Commenter is also concerned that Qs 193, 354, 375, and 421 continue to refer to the out-of-date 25,000 and 10,000 lb thresholds for reporting of lead and lead compounds. (IPC)

- Guidance is frequently used to change previous interpretations, thus bypassing notice and comment rule making and imposing substantial burden on regulated entities to keep up-to-date with latest guidance version. Examples from 1998 Qs and As include:
  - Q 189 revises interpretation of motor vehicle exemption to state that refueling facilities must now count chemicals in gasoline towards the processing threshold;
  - Q 246 revises interpretation that ammonia in human waste is exempt and instead states that it should be considered “manufactured as a byproduct”;
  - Q 588 states that metal scrap sent off-site to be melted down and re-used must be included in the facility’s processing threshold determination, in contrast to earlier guidance;
  - Q 164 states that petroleum piped into and then out of a storage tank must now be counted towards the facility’s processing threshold;
  - Q 285 states that chemical byproducts in motor vehicle exhaust must now be counted towards the facility’s manufacturing threshold;
  - Qs 31 and 33 state that all hours worked by employees off-site must be counted towards the 10,000 hour (10 employee) threshold. Some of these changes were highlighted by EPA when it released the new guidance, others were not. Commenter states that this makes compliance a “moving target.” (API)

- Too many issues are inadequately considered during rule-makings (costs, impacts, technical feasibility) and then left to be addressed through guidance. (API)

- Guidance is often of poor quality and would not pass data quality guidelines (e.g., inadequate citations for sources of info, use of out-dated data, lack of data quality criteria). (API)

- Commenter notes that TRI guidance is currently contained in 28 separate documents, many of which are changed every year.
Small Business Impact: None provided.

Commenter Proposed Solution(s):

- Promptly revise the guidance or issue supplemental guidance that removes the requirement for double counting of intermediate compounds. (IPC)
- Update threshold references for lead and lead compounds. (IPC)
- Minimize changes to existing guidance documents, notice all changes in the Federal Register, and allow sufficient time for review and comment by the public before revisions to guidance are finalized. (API)
- Do not make changes that have the potential to expand reporting requirements through guidance; these should only be made through notice and comment rulemaking. (API)
- Date all guidance documents, clearly indicate which are final, and only expect facilities to rely on final guidance, not proposals or drafts. (API)
- Include draft guidance in notice and comment process during rule making. In economic analysis for rules, factor into compliance costs the time needed to review and keep current of changes in guidance. (API)
- Establish data quality criteria for data presented in guidance. (API)

Estimate of Economic Impacts: No quantitative estimate provided. Qualitative assertion that multiple counting of intermediate compounds “has the effect of radically expanding the universe of regulated entities.” Commenter IPC also notes that many facilities lack the scientific expertise to determine what intermediate compounds are created (and subsequently destroyed) during their processes. Some of these “reaction intermediaries” exist for only a few seconds before being transformed into something else. Commenter API notes that one of the key problems with “regulation by guidance” is that no analyses of costs and benefits are performed.

Commenter(s): IPC -- Associated Connecting Electronic Industries (43), American Petroleum Institute (22).
28. **Waterborne Disease Report and Education Campaign**

**Regulating Agency:** EPA/Office of Drinking Water and Ground Water and Centers for Disease Control

**Citation:** N/A

**Authority:** Safe Drinking Water Act, Sec 1458(d)

**Description of What Activity Will Do:** The 1996 SDWA amendments direct EPA and CDC to undertake a joint study of waterborne disease occurrence in at least 5 US cities and prepare a report on the findings of the study, along with an estimate of national waterborne disease occurrence. They further direct EPA and CDC to establish a national training and education program to inform both health care providers and the general public about waterborne diseases and their symptoms.

**Commenter Description of Issue(s):**

- Statute set a deadline of Aug 2001 for issuance of the report but it has not yet been completed.
- Commenter believes report and training/education program could provide significant public health benefits.

**Small Business Impact:** None provided.

**Commenter Proposed Solution(s):**

- Complete the report.
- Implement an aggressive waterborne disease education effort as soon as possible.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Center for Progressive Regulation (70).
29. **Food Quality Protection Act (FQPA) Policy Papers**

**Regulating Agency:** EPA/OPPTS

**Citation:** Federal Register (multiple notices)

**Authority:** Food Quality Protection Act (FQPA)

**Description of Guidance Document:** EPA issues science policy papers describing how the Agency will handle science issues that are key to the implementation of the FQPA, such as its cumulative risk policy and FQPA Safety Factor policy. EPA also issues guidance documents outlining pesticide tolerance data requirements.

**Commenter Description of Issue(s):**

- EPA's policies and data requirements drive the standards by which EPA is to review product registrations and are therefore more appropriate as rules than guidance.
- EPA policies are never final - EPA says such policies are continually evolving and these policies change as EPA sees fit, creating a moving target.
- Public input on changing policies is usually after-the-fact and large numbers of pesticide registration are reviewed and determinations are made based on ad hoc policy guidelines. The resulting restrictions from these "evolving" policies are permanent.
- Use of policy guidance does not provide public scrutiny of the complex science that is used in setting such polices or making re-registration decisions. If the scientific basis for a "policy" is found to be wanting and subsequently changed by EPA, it is too late to review any pesticide decisions made under the erroneous regime.

**Small Business Impact:** None provided.

**Commenter Proposed Solution(s):** EPA’s FQPA policies and decisions should be subject to the APA through rule-making procedures.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Farm Bureau Federation (24).
30. Integrated Risk Information System

Regulating Agency: EPA/ORD

Citation: http://epa.gov/iris/

Authority: None provided.

Description of Guidance Document: The Integrated Risk Information System (IRIS) is an electronic data base containing information on human health effects that may result from exposure to chemicals in the environment. Specifically, the database contains descriptive and quantitative information on reference doses for chronic noncarcinogenic health effects and hazard identification, slope factors and unit risks for carcinogenic effects. Federal and state officials use this information for regulatory purposes. EPA's current IRIS value for formaldehyde's potential carcinogenicity was established in 1987.

Commenter Description of Issue(s):

- Much of the IRIS information is outdated and/or poorly characterized and much of it is developed using outdated scientific methods.
- IRIS data don't comport with the Safe Drinking Water Act standards referenced in the OMB data quality guidelines. This standard requires the presentation of risk information to be "comprehensive" and "to specify peer-reviewed studies known to the agency that support [or] are directly relevant to...any estimate of [risk] effects."
- Since 1987, when EPA's current IRIS value for formaldehyde was published, an enormous amount of research has occurred.
- Organizations including OECD, WHO, Health Canada and the German MAK Commission have found that formaldehyde is unlikely to be carcinogenic at low doses.
- At environmentally relevant doses, the best available estimates of risk are orders of magnitude below the current IRIS value.
- Continued use of the 1987 value in the large number of ongoing regulatory proceedings that address formaldehyde will result in a serious misallocation of resources.

Small Business Impact: None provided.

Commenter Proposed Solution(s): EPA should expeditiously complete its update of the formaldehyde risk assessment. In addition, EPA should implement recommendations contained in the ACC September 18, 2001 comprehensive reform proposal including:

- Use of a rigorous peer review process that is open/transparent, external, independent, balanced and fully documented.
- Making reviews of information in IRIS open to public comment.

Estimate of Economic Impacts: None provided.

Commenter(s): American Chemistry Council (12); Michael H. Levin (179).
31. Interim Guidance for Investigating Title VI Administrative Complaints Challenging Permits

Regulating Agency: EPA

Citation: http://www.epa.gov/civilrights/docs/interim.pdf (February 5, 1998)

Authority: Executive Order 12898

Description of Guidance Document: The Interim Guidance seeks to prevent industrial development in communities based upon their racial or economic make-up. To implement this program, EPA compels states, which issue a vast majority of EPA permits, to deny or revoke operating permits in areas with large percentages of minority or lower income residents.

Commenter Description of Issue(s):

• The Interim Guidance allows administrative complaints to be brought against a state or local government at any stage of the permitting process, thus creating almost total uncertainty for any facility that is located in a community that has racial or low-income characteristics.

• Because the Interim Guidance applies to all state and local governments and EPA is able to suspend, annul or terminate Federal funding for all environmental programs administered by the state or local government for failure to follow the Interim Guidance, EPA imposes conditions in environmental permits that are in addition to conditions imposed by the substantive environmental laws. EPA has no statutory authority to implement this program.

• The Interim Guidance included a request for public comment, but was published and operative prior to any formal public input.

Small Business Impact: None provided.

Commenter Proposed Solution(s): EPA should immediately withdraw the Interim Guidance. EPA should further cease any efforts to finalize the draft Revised Guidance. If the agency believes that environmental justice principles, in addition to substantive environmental laws, should be applied to the permitting process, EPA should propose regulations under the procedures set forth in the Administrative Procedure Act.

Estimate of Economic Impacts: EPA's actions contradict efforts designed to encourage businesses to locate in inner cities and underdeveloped areas, costing residents of such communities badly needed job opportunities.

Commenter(s): U.S. Chamber of Commerce (32).
32. Calculation of the Economic Benefit of Noncompliance in EPA’s Civil Penalty Enforcement Cases

Regulating Agency: EPA

Citation: None provided.

Authority: None provided.

Description of Guidance Document: Provides guidance on calculating the economic gain from noncompliance with environmental regulations.

Commenter Description of Issue(s):

• EPA’s civil penalty policy requires that penalties capture the economic gain a violator derives from noncompliance. An approach that based penalties on the social cost of a violation, rather than the private gain, as envisioned in the law and economics literature, would be more likely to induce the optimal level of deterrence. The economic benefit approach can encourage precautionary measures that are not in the public interest.

• Though EPA’s policy of capturing economic gains embodies serious flaws from a social welfare perspective, its economic benefit model does have the advantage of being objective and easy to apply. This notice proposed several changes that will result in improvements to the economic benefit model.

• The notice also proposed to develop guidance to expand EPA’s approach to estimating private economic benefit to include “illegal competitive advantage.” We caution that some of the scenarios EPA presents under this heading reflect benefits that are already captured by EPA’s existing model. Further, they do not really reflect “competitive advantage” in the standard use of that term because they do not depend on, or necessarily affect, competition.

Small Business Impact: None provided.

Commenter Proposed Solution:

• Ideally, EPA should shift from an approach of capturing economic gain to one based on the social cost of the violation.

• If it continues to rely on an economic benefit approach, the model could be improved by using a risk-free rate to bring all cash flows to the penalty payment date on the recognition that the cash flows in question do not exhibit systematic risks (which would command a higher rate of return).

• We encourage EPA to use a different term for the type of benefits it referred to in the notice as “illegal competitive advantage” and to limit consideration of them to ex ante rather than ex post private gains, as it does in the avoided cost methodology.

Estimate of Economic Impacts: A penalty that reflected the environmental damage caused by the violation, not the avoided cost to the violator, could ameliorate some of the rigidity of more traditional regulations, and provide net social benefits.

Commenter: Mercatus Center (73).
33. TRI Lead Reporting Guidance

Regulating Agency: EPA/Office of Environmental Information


Authority: Emergency Planning and Community Right-to-Know Act, Sec 313(g)(2)

Description of Guidance Document: This document provides detailed guidance for industrial facilities to use in reporting releases and other waste management activities for lead and lead compounds to the Toxic Release Inventory under the new 100 lb reporting threshold.

Commenter Description of Issue(s):

• Guidance states that, "When expressing release and other waste management quantities of lead and lead compounds on a Form R, the level of precision one should use is one-tenth (0.1) of a pound." (p 1-11) Commenter believes this level of precision is overly burdensome, in conflict with legislative intent (which requires reporting to be based only on "reasonably available information"), results in facilities expending significantly increased effort in preparing TRI reports, and increases facility vulnerability to EPA enforcement and/or citizen suits if reports are not accurate to this level of precision.

• Earlier in the same paragraph from which commenter quotes, Guidance states, "When estimating releases and other waste management quantities of a listed chemical for purposes of reporting, facilities should base these determinations at a level of precision supported by available data and the estimation techniques used in the determinations." This is consistent with information provided during OMB review, when EPA clarified on several occasions that reporting to one-tenth of a pound would only be required if the level of precision in the underlying data supported it. The intent of specifying one-tenth of a pound precision was only to prevent facilities from rounding off to a lesser level of precision if data supporting one-tenth of a pound was "readily available." However, the Guidance is not as clear as it could be on this point.

Small Business Impact: None provided.

Commenter Proposed Solution(s):

• Revise the guidance or issue supplemental guidance providing simplified compliance requirements “that are in accord with the legislative intent of TRI.”

Estimate of Economic Impacts: No quantitative estimate provided. Qualitative assertion that reporting to this level of precision increases facility burden and may lead facilities to conduct analytical testing for concentrations of lead, to the required precision, in other materials.

Commenter(s): IPC -- Associated Connecting Electronic Industries (43).
34. **Pesticide Registration Notices**

**Regulating Agency:** EPA/OPPTS

**Citation:** Federal Register (multiple notices)

**Authority:** FIFRA

**Description of Guidance Document:** EPA issues pesticide registration notices that contain decisions about pesticide cancellations, restrictions, and procedures. These notices cover a variety of topics such as product labeling requirements and data requirements. Public comment is permitted under these PR notices, but they bypass public notice and comment procedures required by the Administrative Procedures Act (APA).

**Commenter Description of Issue(s):**

- EPA's PR Notices have the force and effect of regulation, but they bypass public notice and comment procedures required by the APA.
- PR Notices do not permit the same level of public scrutiny as proposed regulations, nor do they fully allow for public scrutiny into the science behind pesticide decisions.
- Use of PR Notices does not allow the same level of administrative or judicial scrutiny as proposed regulations and provide no judicially reviewable standard.
- End users are harmed by the process. Registrants who decide to discontinue a product because EPA has used unscrutinized and flawed data and procedures affect product availability for farmers and ranchers.

**Small Business Impact:** None provided.

**Commenter Proposed Solution(s):** EPA should convert its PR notice procedures into regulatory rulemaking subject to the APA.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Farm Bureau Federation (24).
35. Site-Specific Risk Assessments in Resource Conservation and Recovery Act (RCRA) Permits

Regulating Agency: EPA/OSWER

Citation: [www.epa.gov/epaoswer/hazwaste/combust/risk.htm](http://www.epa.gov/epaoswer/hazwaste/combust/risk.htm); [www.epa.gov/epaoswer/hazwaster/combust.ecorisk.htm](http://www.epa.gov/epaoswer/hazwaster/combust.ecorisk.htm); [www.epa.gov/epaoswer/hazwaste/combust/burn.pdf](http://www.epa.gov/epaoswer/hazwaste/combust/burn.pdf)

Authority: RCRA, 42 U.S.C. 6901 et seq.

Description of Guidance Document: EPA has issued guidance documents describing how to conduct site-specific risk assessments in cases where the permitting authority requires a risk assessment as a permit condition for facilities that combust hazardous wastes. These guidance documents have been issued as clarifications of generic regulatory language that allows the permitting authority to request information as necessary to protect human health and the environment.

Commenter Description of Issue:

- Guidance requires performance of indirect exposure and ecological risk assessments, even though neither the statute nor the regulations discuss such assessments.
- Risk assessment requirements are contained in a series of documents making it difficult to identify the exact requirements that a permit applicant must satisfy.
- Current guidance provides no thresholds for permit denial or for requiring greater emissions controls.

Small Business Impact: None provided.

Commenter Proposed Solution:

- Repeal all guidance requiring site-specific risk assessments.
- EPA should assess the need for such risk assessments and, if justified, promulgate a rule to require such risk assessments.

Economic Impact: An average of $500,000 per facility.

Commenter: Cement Kiln Recycling Coalition (28); U.S. Chamber of Commerce (32).
36. EPA’s Cancer Risk Assessment Guidance

Regulating Agency: EPA

Citation: [http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf](http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf)

Authority: N/A

Description of Guidance Document: EPA’s Cancer Risk Assessment Guidance establishes a framework for developing risk assessments of carcinogens. The Guidance includes as a default assumption a linear no-threshold model relating dose to cancer incidence. Alternative models can be used for risk assessment where empirical evidence supports an alternative (non-linear) mechanism relating dose to cancer incidence.

Commenter Description of Issue(s): Almost all of the regulatory standards promulgated by EPA are based on the one-hit or multiple-hit theory of cancer causation that leads to the linear no-threshold risk model. Linear extrapolation of the target theory from mutations to cancers was never justified. EPA’s approach is simply wrong.

Small Business Impact: None provided.

Commenter Proposed Solution(s): EPA should adopt a non-linear multi-hit model to replace its current default model.

Estimate of Economic Impacts: None provided.

Commenter: George E. Parris, Ph.D. (149).
37. **RCRA Spent Catalyst Policy**

**Regulating Agency:** EPA/OSWER

**Citation:** Letter to Keith Begseid from Elizabeth Cotsworth, [http://yosemite.epa.gov/osw/rcra.nsf/documents/36FCE39649B91C2F8256936006F6BBF](http://yosemite.epa.gov/osw/rcra.nsf/documents/36FCE39649B91C2F8256936006F6BBF)

**Authority:** 40 C.F.R 261.32

**Description of Guidance Document:** Clarifies that spent catalysts are defined as spent hydrotreating and hydrorefining wastes and are therefore regulated as hazardous wastes under RCRA.

**Commenter Description of the Issue:** EPA issued a letter to one company official who requested an interpretation of the regulatory status of these catalysts. EPA then published the letter on its website and presented the letter as an enforceable determination.

**Small Business Impact:** None provided.

**Commenter Proposed Solution:** Require FR publication of letters establishing an agency interpretation. Subject guidance that has rule-like effects to notice and comment rulemaking.

**Estimate of Economic Impacts:** None provided.

**Commenters:** U.S. Chamber of Commerce (32).
38. Superfund Indirect Cost Guidance

Regulating Agency: EPA/OSWER

Citation: 65 FR 35339

Authority: Federal Financial Management Improvement Act of 1966 (Title VIII, Public Law 104-208) and CERCLA section 113(a)

Description of Guidance Document: This guidance provides methodology for calculating indirect costs of superfund cleanups. Indirect costs of cleanup are then charged to potentially responsible parties as part of the total costs of cleanup.

Commenter Description of Issues:

- Includes costs that are not recoverable under CERCLA.
- Fails to satisfy government cost accounting principles.
- Was originally attempted as a rulemaking with a proposed rule published in April 1997 (62 FR 22423) but was then issued as guidance rather than as a final rule.

Small Business Impact: None provided.

Commenter Proposed Solution:

- Revise guidance to include only costs recoverable under CERCLA.
- Resolve underlying problems with EPA’s system of accounting for superfund costs.
- Subject this guidance to public notice and comment.

Estimate of Economic Impact: $600-$700 million for recovery of past costs, $100 million annually for future indirect costs.

Commenter: American Chemistry Council (12).
39. **Ecoregional Nutrient Criteria Documents**

**Regulating Agency:** EPA/Office of Water

**Citation:** Ambient Water Quality Recommendations..., 66 FR 1671-1674, Jan 9, 2001; and Ambient Water Quality Recommendations..., 67 FR 9269-9270, Feb 28, 2002.

**Authority:** Clean Water Act, Sec 304(a)

**Description of Guidance Document:** These documents provide recommended ambient water quality criteria for nitrogen, phosphorous, chlorophyll and turbidity for 26 nutrient ecoregions, and serve as guidance for States to adopt into their water quality standards. States are not required to adopt the EPA developed criteria, however, many States do so in practice.

**Commenter Description of Issue(s):**

- Commenter believes the published ecoregional nutrient criteria violate OMB’s Information Quality Guidelines, in particular the transparency and reproducibility standards for influential information. Commenter claims that EPA did not provide adequate notice and opportunity for comment on criteria, that EPA did not provide data on which criteria are based until nine months after they were published, and that it is impossible to reproduce the criteria from the data and methodological descriptions provided by EPA to date.
- Commenter further believes the methodology for developing the criteria is fundamentally flawed because it is based on statistical modeling and does not attempt to link nutrient levels to in-stream effects and designated uses.

**Small Business Impact:** None provided.

**Commenter Proposed Solution(s):**

- Withdraw the 26 ecoregional nutrient criteria, subject them to an open public review process, and suspend the schedule for States to adopt them into water quality standards.

**Estimate of Economic Impacts:** Commenter estimates that more stringent, water quality based effluent limits on construction operators to comply with nutrient criteria would add $1,200 to $2,000 to the price of an average new home, which would reduce new home sales among low-income households by 24,000 to 40,000 units per year.

**Commenter(s):** National Association of Home Builders (48).
40. **Submetering Water Systems**

**Regulating Agency:** EPA/Office of Ground Water and Drinking Water

**Citation:** Memorandum on Submetering Water Systems, Cynthia Dougherty, Dir, OGWDW, to Water Division Directors, Regions I - X, Mar 13, 1999; Memorandum on Submetering & Consecutive Water Systems, Beverly Banister, Acting Dir, Water Management Division, Region IV, Jun 1, 2000.

**Authority:** Safe Drinking Water Act, Sec 1411(g)

**Description of Guidance Document:** These memos interpret the term “selling” under the SDWA as applying to submetering of individual tenants by owners of multifamily dwellings. Submetering means installing separate water meters on each apartment and billing each tenant for their actual water use rather than including a fixed water charge in the rent that is unrelated to use. The effect of this interpretation is to subject multifamily dwellings with more than 15 units to regulation as “public water systems” under the SDWA if they engage in submetering.

**Commenter Description of Issue(s):**

- A number of studies have shown that submetering significantly reduces water usage by providing tenants an incentive for water conservation. EPA does not dispute this finding, and in fact presents it on its own website.
- Multifamily dwellings that practice submetering do not store or treat water and there are no associated adverse health impacts resulting from submetering.
- The effect of EPA’s current interpretation of the term “selling” is to impose substantial regulatory burden on owners that engage in submetering and thus to discourage the practice. It has also caused disputes with several States that have attempted to define “selling” as not including submetering.

**Small Business Impact:** None provided.

**Commenter Proposed Solution(s):**

- Issue new guidance that would interpret the term “selling” as not including submetering by multifamily dwellings that do not store or treat water.
- Alternately, initiate notice and comment rule making on ways to promote water conservation by facilitating submetering.

**Estimate of Economic Impacts:** Commenter estimates that there are 15 million multifamily dwellings that provide housing for 35 million residents. Currently, only a small percentage practice submetering, partly because of the adverse regulatory consequences. Studies have shown that submetering can reduce water usage by 25 to 40 percent.

**Commenter(s):** National Association of Home Builders (48).
41. Drinking Water Affordability

Regulating Agency: EPA/Office of Ground Water and Drinking Water

Citation: National Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act (Final Draft Report), USEPA, Aug 19, 1998.

Authority: Safe Drinking Water Act, Sec 1412(b)(15)(C)

Description of Guidance Document: Under the 1996 amendments to the SDWA, “small system variances” may be issued to systems serving less than 10,000 persons for standards associated with certain regulated contaminants. If EPA determines that there is no nationally “affordable” treatment technology for systems of the appropriate size category that can achieve compliance with the standard, and if the State subsequently determines based on a site-specific analysis that the particular system cannot afford to comply with the standard, the system may instead install a less protective “variance technology” provided both the State and EPA determine that the alternate technology is adequately protective of public health. However, small system variances are not allowed if EPA determines that “affordable” compliance technologies are available. The Act further directs EPA to publish criteria for making these national “affordability” determinations. EPA has adopted a methodology that first calculates an “affordability threshold,” defined as 2.5 percent of median household income (MHI) for systems in a particular size category, and then subtracts the average water bill for systems in that size category to arrive at an “expenditure margin” that represents the average amount that households served by that size system have available for compliance with new drinking water standards. If the average cost, as estimated by EPA, for systems in that size category to comply with a new standard is less than this expenditure margin, compliance is deemed affordable and no small system variances are authorized. The referenced guidance document uses this methodology to calculate an expenditure margin of approximately $500 per household for all small system size categories. To date, no drinking water standards have had estimated average compliance costs exceeding this figure, and no small system variances have been authorized.

Commenter Description of Issue(s):

• Commenter believes use of 2.5 percent of MHI (which has now risen to about $1,000) as an affordability threshold is inappropriate because it fails to address the situation of low income rural communities.
• Commenter believes this is an “environmental justice” issue.
• Commenter disagrees with EPA’s conclusion that drinking water bills of this magnitude would not require low-income households to trade-off health care or other “essentials” to pay for drinking water. Commenter claims that numerous studies (no specific references provided) have shown the opposite.

Small Business Impact: None provided.

Commenter Proposed Solution(s): Revise national affordability criteria to allow small system variances for contaminants such as arsenic.

Estimate of Economic Impacts: Commenter states that expenditures on the order of $1,000 per year for drinking water could force low-income households to make serious trade-offs that affect their health and well-being, including foregoing food and medical care.

Commenter(s): National Rural Water Association (44).
42. **Clean Water Act Jurisdiction ("SWANCC Decision")**

**Regulating Agency:** EPA/Office of Water and Army Corps of Engineers

**Citation:** *Supreme Court Ruling Concerning CWA Jurisdiction over Isolated Waters*, Memo from Gary Guzy, Gen Counsel, USEPA and Robert Anderson, Chief Counsel, USACE, to regional, division, and district personnel, Jan 18, 2001.

**Authority:** Clean Water Act, Sec 404

**Description of Guidance Document:** The Clean Water Act generally prohibits discharges into “navigable waters” without a permit issued either by the Corps under Sec 404, or by EPA under Sec 402. The Act defines navigable waters as “water of the US, including the territorial seas.” In a recent decision (*Solid Waste Agency of Northern Cook County v. US Army Corps of Engineers*, No 99-1178, Jan 9, 2001), the Supreme Court held that the Corps had exceeded its authority under the Clean Water Act by asserting jurisdiction over a series of isolated, non-navigable intrastate ponds based on their potential use as resting places by migratory birds (this basis for asserting jurisdiction was known as the “migratory bird rule”). Shortly after the decision was issued, the General Counsels of EPA and the Corps published a memo interpreting the Court’s decision and its potential applicability to other situations. There have also been a number of lower court cases that have attempted to apply the Court’s reasoning to other situations and not all of these attempts have reached similar conclusions.

**Commenter Description of Issue(s):**

- Commenter believes that guidance memo is intended to “circumvent the Court’s ruling” and asserts that the Corps “has declared that it is essentially enforcing the [migratory bird] rule despite the Court’s ruling.” (ARTBA)

- Commenter is concerned that agencies may seek to limit the application of the Court’s ruling. (ARTBA)

**Commenter Proposed Solution(s):** OMB should “monitor” how this decision is interpreted by the agencies. (ARTBA)

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Road and Transportation Builders Assn (1).
43. **Policy Statement on Mandatory Binding Arbitration as a Condition of Employment**

**Regulating Agency:** Equal Employment Opportunity Commission

**Citation:** Federal Register, July 10, 1997


**Description of Guidance Document:** EEOC in this document opposes the enforcement of arbitration agreements, stating that in some cases they are inconsistent with the civil rights laws. EEOC maintains that requiring employees to agree to arbitration as a condition of employment deprives them of a statutory right to bring their claims to court.

**Commenter Description of Issue(s):**

- EEOC's policy statement is in direct opposition to the Supreme Court's decisions in Gilmer v. Interstate/Johnson Lane Corp (500 U.S. 20 [1991]) and Circuit City v. Adams (532 U.S. 105 [2001]).
- The Supreme Court in EEOC v. Waffle House (122 S.Ct. 754 [2002]) found that EEOC is not bound by a charging party's agreement to arbitrate employment-related claims. This illustrates that there are roles in employment discrimination law enforcement for both the EEOC and private arbitration agreements.

**Commenter Proposed Solution(s):** Rescind the policy document.

**Estimate of Economic Impacts:** The cost of defending against an unwarranted charge or lawsuit by the EEOC.

**Commenter(s):** Equal Employment Advisory Council (2).
44. Fair Credit Reporting Opinion Letters – Workplace Investigations

Regulating Agency: FTC

Citation: 16 CFR 600


Description of Guidance Document: FTC has determined that organizations that regularly investigate workplace misconduct for employers, such as private investigators, consultants or law firms, are consumer reporting agencies under the Fair Credit Reporting Act (FCRA). Consequently, investigations conducted by these entities must comply with FCRA’s notice and disclosure requirements. These include notice to the employee of the investigation, the employee's consent prior to the investigation, providing the employee with the nature and scope of the proposed investigation, a copy of the full investigative report (if the employee requests it) and notice to the employee of his or her rights under FCRA prior to taking any enforcement action.

Commenter Description of Issue(s):

- Makes it impossible to conduct an investigation while complying with these requirements.
- Employers and investigators face unlimited liability (including punitive damages) for any compliance mistake.
- Letters deter employers from using experienced and objective outside organizations to investigate suspected workplace misconduct.
- The results conflict with advice of courts and administrative agencies, both of which have encouraged employers to use outside organizations to perform workplace investigations.

Small Business Impact: While letters affect all employers, they are particularly damaging to small and medium size companies which often do not have resources to conduct their own workplace investigations.

Commenter Proposed Solution(s): Rescind the opinion letters and any similar FTC guidance and letters.

Estimate of Economic Impacts: The changes would eliminate the potential of unnecessary litigation stemming from the FTC’s current interpretation of FCRA, thus reducing costly litigation. The change would permit employers to gain needed information in order to deter workplace problems such as harassment, violence and theft which cost employers, employees and the general public the loss of peace of mind and money.

Commenter(s): U. S. Chamber of Commerce (32); Olgetree and Deakins (33); CNF, Inc. (59); Gill Studios (61); Brent Bradford (65); Equal Employment Advisory Council (2).
45. **OMB Analytic Guidance**

**Regulating Agency:** Office of Management and Budget

**Citation:** N/A

**Authority:** N/A

**Description of Guidance Document:** OMB issued guidelines in 1996 and again in 2000 to aid the agencies in developing analyses of the benefits and cost of their economically significant regulations.

**Commenter Description of Issues:** Aside from the issues identified in its draft report, OMB should also review its analytic guidance with respect to the role of stakeholders, value of information analysis, characterization of annualized costs and benefits, and standardization of procedures for estimating costs and benefits.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** OMB should not substitute guideline improvement with guideline enforcement, which continues to be insufficient. OMB should return *any* economically significant regulation to an agency if the accompanying economic analysis fails to comport with the fundamental principles of Executive Order 12866.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** American Chemistry Council (12).
46. Performance of Commercial Activities

Regulating Agency: Office of Management and Budget

Citation: OMB Circular No. A-76


Description of What Existing/Proposed Regulation Does: OMB Circular No. A-76 sets forth the procedures for determining whether the private sector or in-house Government personnel should perform commercial activities. It also provides policy for how and when a Federal agency competes a commercial activity with the private sector.

Commenter Description of Issue(s):

• The A-76 competitive process is costly, long, does not accurately reflect the government's cost of doing business, and gives Federal employees an unfair competitive advantage.
• Competition has proven to provide significant cost savings regardless of who wins, as well as increase innovation, efficiencies and quality of service. A new commercial activity policy is needed, especially as the Federal government continues to face budgetary constraints, a decreasing Federal workforce and reevaluates our nation's priorities post 9-11.
• An equal, transparent, consistent competitive process is necessary to ensure the performance of commercial activities is conducted as efficiently and cost effectively as possible. Such a process will also encourage businesses to enter and remain in the Federal market, particularly small businesses that generally do not have the resources to engage in lengthy competitions.

Small Business Impact: Yes.

Commenter Proposed Solution(s): Rescind OMB Circular A-76 and adopt a framework for public-private competitions similar to the process detailed in the Federal Acquisition Regulation (FAR).

Estimate of Economic Impacts: Requiring a FAR-type process for public-private competitions will significantly reduce the time and money required to conduct competitions as currently under A-76. It will allow the Federal government the authority to purchase best value products and services in a timely fashion, as it encourages competition.

Commenter(s): U.S. Chamber of Commerce (32).
47. **Cost Accounting Standards for Educational Institutions**

**Regulating Agency:** Office of Management and Budget

**Citation:** 48 CFR Part 9903, 9905 and OMB Circular A-21

**Authority:** 41 USC

**Description of What Existing/Proposed Regulation Does:** The government Cost Principles for Educational Institutions are set forth in OMB Circular A-21. The circular establishes principles for determining costs applicable to federally funded grants, contracts and other agreements with educational institutions.

**Commenter Description of Issue(s):**

- The CAS standards are complex and confusing. Review and approval of the university materials has stalled, due to lack of funds and lack of personnel trained to deal with CAS rules outside of the Defense Contract Audit Agency.
- To date, only a handful of universities have received official agency endorsement of their disclosure statement. The great majority of disclosure statements from universities are pending.
- The majority of universities are uncertain if their disclosure statements have been approved, and if so, how to proceed when changes in their procedures may require revised disclosures.

**Small Business Impact:** No.

**Commenter Proposed Solution(s):** None provided.

**Estimate of Economic Impacts:** None provided.

**Commenter(s):** Katharina Phillips, Council on Governmental Relations (146).
48. Credit Union Participation in SBA Lending Programs

Regulating Agency: Small Business Administration

Citation: 13 CFR 120.410

Authority: None provided.

Description: SBA requires financial institutions participating in its 7(a) loan guarantee program to be open to the public. SBA's current interpretation of that phrase, dating back about a decade, excludes credit unions that are not community-based.

Commenter Description of Issue(s): SBA's policy is an impediment to increased lending to small businesses, particularly since credit unions tend to be willing to make smaller loans than other financial institutions.

Small Business Impact: None provided.

Commenter Proposed Solution(s): SBA should reinstate its previous policy that held credit unions are eligible to participate in SBA lending programs, including those without a community charter.

Estimate of Economic Impacts: None provided.

Commenter(s): Credit Union National Association (52).
49. **Wetlands Delineation Guidance Documents**

**Regulating Agency:** U.S. Army Corps of Engineers

**Citation:** 1987 Wetlands Delineation Manual

**Authority:** Clean Water Act, Sec 404

**Description of Guidance Document:** The Clean Water Act generally prohibits discharges of dredge or fill into “navigable waters,” including wetlands, without a permit issued by the Corps under Sec 404. The term “navigable waters” has been interpreted to include all wetlands adjacent to navigable waters or to tributaries of the navigable waters, including intermittent and ephemeral tributaries. The wetlands delineation manual describes methodologies for delineating the boundaries of wetlands subject to the Sec 404 permitting requirements.

**Commenter Description of Issue(s):**

- Current broad definition of “wetlands” (mostly established through guidance that circumvents APA) imposes significant costs on farmers and ranchers. Of particular concern is extension of term to cover areas that are rarely “wet” which commenter refers to as “dry wetlands.” (AFBF)
- Commenter is concerned that wetlands regulation has gotten out-of-hand and impeded real estate development. (R. Marling)

**Commenter Proposed Solution(s):**

- The following items and issues should be addressed through rule making (AFBF):
  - 1987 Wetlands Delineation Manual;
  - Definitional criteria for a jurisdictional wetland, including hydrology duration, hydrology location, hydric soils, and hydrophytic vegetation:
  - Definitions of the terms “navigable waters,” “waters of the US,” “adjacency,” “tributary;”
  - Definition of regulated activities within jurisdictional wetlands
  - Mitigation requirements

**Estimate of Economic Impacts:** No quantitative estimate provided. Commenter AFBF states that broad assertion of jurisdiction over agricultural “dry wetlands” has resulted in decreased property values, shifted tax burdens, inability of farmers to obtain credit, and inability of farmers to physically expand many types of farming operations.

**Commenter(s):** American Farm Bureau Federation (24), Robt Marling (142).