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U.S. Response to APEC-OECD Integrated Checklist on Regulatory Reform

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Submitted by: US



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U.S. RESPONSE TO APEC-OECD INTEGRATED CHECKLIST ON REGULATORY REFORM

A. Horizontal Criteria Concerning Regulatory Reform

A1. To what extent is there an integrated policy for regulatory reform that sets out principles dealing with regulatory, competition and market openness policies?

Executive Order (E.O.) 12866 of September 30, 1993, "Regulatory Planning and Review," established basic principles governing Federal rulemaking. These principles call on agencies to demonstrate the need for a proposed action (e.g., a market failure) and its consequences. In deciding whether and how to regulate, E.O. 12866 requires agencies to assess the costs and benefits of available regulatory alternatives (including the alternative of not regulating). Specifically, E.O. 12866 states that, "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits..." E.O. 12866 further states that, "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."

A major tool that the U.S. has used to improve existing rules is the solicitation of public reform nominations under the Regulatory Right to Know Act (Section 624 of the Treasury and General Government Appropriations Act, 2001, 31 U.S.C. § 1105 note, Pub. L. No. 106-554, 114 Stat. 2763A-161 - 162). Pursuant to this Act, the U.S. Office of Management and Budget (OMB), which is part of the Executive Office of the President, has initiated three public nomination processes to undertake reform of existing regulations.

- In 2001, OMB requested public nominations of rules that should be rescinded or modified; 71 nominations were received from 33 commenters. OMB and the agencies identified 17 actionable reforms.
- In 2002, OMB again requested public nominations of reforms of rules and also sought nominations for reform of guidance documents and paperwork requirements. OMB received 316 nominations from more than 1,700 commenters. OMB and the agencies identified 55 high priority reforms.
- In 2004, OMB called for reform nominations on the manufacturing sector, because it continues to be one of the most heavily regulated sectors of the U.S. economy. This call solicited specific suggestions for reforms to regulations, guidance documents or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty and increasing flexibility, especially for small businesses. OMB received 189 reform nominations from 41 commenters; OMB identified 76 priority reforms.

A2. How strongly do political leaders and senior officials express support for regulatory reform to both the public and officials, including the explicit fostering of competition and open markets? How is this support translated in practice into reform and how have businesspeople, consumers and other interested groups reacted to these actions and to the reforms in concrete terms?

Within OMB, the Office of Information and Regulatory Affairs (OIRA) is leading the U.S. reform effort with respect to the development and reform of regulations. To ensure an adequate consideration of regulatory impacts on small businesses, competition, and market openness, OIRA consults with other U.S. agencies with expertise in these areas. OIRA, for example, often seeks the views of the Small Business Administration (SBA) and the SBA Chief Counsel for Advocacy. OIRA does this for two reasons. First, E.O. 12866 directs each agency to “tailor its regulations to impose the least burden on ... businesses of different sizes.” Second, the Regulatory Flexibility Act (RFA) (5 U.S.C. § 601-612) sets forth the regulatory principle that Federal agencies endeavor, consistent with applicable statutes, to fit regulatory requirements to the scale of entities subject to the regulation, and designates the SBA Chief Counsel for Advocacy as the official responsible for overseeing agency compliance with that Act.

When reviewing draft regulations that may affect competition, OIRA coordinates with U.S. Department of Justice’s Antitrust Division (DOJ Antitrust) and the Federal Trade Commission (FTC). Similarly, if a draft regulation raises international trade issues, OIRA involves the Office of the U.S. Trade Representative and the U.S. Department of Commerce to ensure that it is not unnecessarily trade restrictive.

OIRA has also worked closely with the various agencies to decide which regulatory reforms to pursue. The U.S. Small Business Administration and, in the case of the 2004 manufacturing reform nominations, the U.S. Department of Commerce, have also participated in this effort. The criteria by which nominations were reviewed included whether the agency believed that a case could be made that the benefits of the regulatory reform exceeded the costs. Of course, OIRA and the agencies also took into consideration agency resources and competing priorities. With respect to the fostering of competition, DOJ Antitrust and the FTC have the U.S. Government (USG) lead. With respect to open trade, USTR has the USG lead.

A3. What are the accountability mechanisms that assure the effective implementation of regulatory, competition and market openness policies?

Since a key goal of U.S. regulatory policy is to maximize the net benefits of new regulations, accountability requires an accounting of their costs and benefits. Accordingly, for over 20 years, the U.S. has been measuring and reporting the aggregate costs and benefits of major Federal rules. Pursuant to the Regulatory Right to Know Act, OMB reports annually to Congress on the costs and benefits of these rules.

The U.S. approach to regulatory reform also relies on transparency and targeted deliverables to ensure accountability. Working together, for example, OMB and the agencies have developed milestones and deadlines for all future actions on the agreed-upon manufacturing regulatory reforms. These range from performing a priority investigation and reporting to OMB in order to determine appropriate next steps, to issuing modernized regulations. OMB reports annually to Congress on agency progress in achieving milestones and completing reforms.

Agencies have made significant progress in meeting milestones and accomplishing the needed reforms. According to the most recent information provided to OMB, the agencies have now completed 38 of the 76 priority reforms from 2004.

A4. To what extent do regulation, competition and market openness policies avoid discrimination between like goods, services, or service suppliers in like circumstances, whether foreign or domestic? If elements of discrimination exist, what is their rationale? What consideration has been given to eliminating or minimising them?

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, the U.S. OMB's guidance on developing regulatory analyses, OMB Circular No. A-4, *Guidelines for the Conduct of Regulatory Analysis*, puts an increased burden of proof on agencies to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;
- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety or (b) to manage the use of common property resources.

OMB reviews draft agency regulations to ensure that agencies have adequately demonstrated that these types of regulations are necessary for the specific situation (or are legally compelled by statute).

In addition, U.S. law seeks to protect small firms from disproportionate or undue regulatory burdens. The RFA requires agencies to consider the impact of their rules on small entities and examine significant alternatives that minimize small entity impacts. For rules that impose significant impacts on a substantial number of small businesses, agencies must prepare a regulatory flexibility analysis.

A5. To what extent has regulatory reform, including policies dealing with regulatory quality, competition and market openness, been encouraged and co-ordinated at all levels of government (e.g. Federal, state, local, supranational)?

Within the Federal government, OIRA reviews agency draft regulations under E.O. 12866—including those actions that reform existing regulations—to ensure that these regulations are consistent with the President's policies and priorities. Executive Order 12866 requires OIRA to ensure adequate interagency review of draft rules, so that draft rules are coordinated with relevant agencies to avoid inconsistent, incompatible or duplicative policies. For regulations that

raise foreign trade or other international issues, the interagency review process includes agencies such as the Office of the U.S. Trade Representative, the U.S. Department of State, and the U.S. Department of Commerce.

When new regulations are developed, Federal agencies must also coordinate with State, local, and tribal governments.

- **Unfunded Mandates Reform Act:** Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. § 1501 note; Pub. L. No. 104-4) requires that each agency, before promulgating any proposed or final rule that may result in expenditures of more than \$100,000,000 (adjusted for inflation) in any year by State, local, and tribal governments, or by the private sector, must conduct a detailed cost-benefit analysis and select the least costly, most cost-effective or least burdensome alternative. Each agency must also seek input from State, local, and tribal government. OIRA monitors agency compliance with Title II, provides Congressional Budget Office (part of the U.S. Congress) with periodic submissions of agency analytical statements for covered regulations, and publishes an annual report on agency compliance with Title II.
- **Executive Order 13132 of August 4, 1999:** This presidential order seeks to ensure that the fundamental principles of federalism guide the agencies in the formulation and implementation of policies. In initiating regulatory actions that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government,” agencies must follow specific procedures for intergovernmental consultation and consider more flexible issuance of government waivers. Each agency must have a designated federalism official that certifies the agency has met the requirements of the E.O. for each affected rulemaking. OIRA monitors agency compliance with the Order as part of its review of agency draft regulations.

A6. Are the policies, laws, regulations, practices, procedures and decision making transparent, consistent, comprehensible and accessible to users both inside and outside government, and to domestic as well as foreign parties? And is effectiveness regularly assessed?

The Administrative Procedure Act (APA) (5 U.S.C. ch. 5) provides the foundation for regulatory transparency and accountability in the United States. The APA requires that agencies go through a notice and comment process open to all members of the public, both foreign and domestic. Agencies must publish proposed rules in the *Federal Register* and solicit public comment. All proposed rules currently open to public comment are also centrally located on one Federal website (www.regulations.gov). The public can use this site to send their comments electronically to agencies on Federal regulations published for comment in the *Federal Register*. Agencies consider the public comments, and publish the final rule in the *Federal Register*, including an announcement of when the rule will take effect and a response to the public’s comments on the proposal.

Existing regulations are codified and centrally located in the *Code of Federal Regulations*, which is updated annually and is widely available, including on the internet. The public is informed of future regulatory actions through the required agency regulatory plans and agendas that are published each year in the *Federal Register*. These plans and agendas alert the public of the most important regulatory actions the agency anticipates taking in the coming year.

The U.S. acknowledges the need for transparency and accountability in the development of guidance documents—those subregulatory documents that provide implementation or policy advice. As the scope and complexity of regulatory programs have grown, agencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs. OMB recently issued a proposed bulletin on good guidance practices and solicited public comment.

A7. Are the reform of regulation, the establishment of appropriate regulatory authorities, and the introduction of competition coherent in timing and sequencing?

With regard to existing regulations, the U.S. recognizes that many rules now in place provide important benefits to the American people. Therefore, OMB have pursued a targeted, public-generated process of reviewing existing rules.

For the regulatory reforms that the U.S. is currently pursuing (see answer to Question A1), OMB has worked with the agencies to identify milestones in achieving the reforms identified through this process. Any regulatory action resulting from this process is subject to the standard U.S. regulatory procedures, including public comment periods and OIRA review (as discussed in question B1). Progress made on these reforms is reported annually to the Congress.

A8. To what extent are there effective inter-ministerial mechanisms for managing and coordinating regulatory reform and integrating competition and market openness considerations into regulatory management systems?

OMB works closely with the various regulatory agencies when deciding to go forward with particular regulatory reforms. Most reforms must be adopted through a process that entails opportunity for public participation, such as notice and comment rulemaking, and thus will be subject to the same regulatory analysis (and interagency coordination) requirements under E.O. 12866 that apply to the development of any new regulation. This includes OIRA review of the draft regulation and coordination with relevant agencies to avoid inconsistent, incompatible or duplicative policies.

A9. Do the authorities responsible for the quality of regulation and the openness of markets to foreign firms and the competition authorities have adequate human and technical resources, to fulfill their responsibilities in a timely manner?

Yes: OIRA (for regulatory reforms and review), USTR (for opening foreign markets), and DOJ Antitrust and FTC (for competition) have adequate resources.

A10. Are there training and capacity building programmes for rule-makers and regulators to ensure that they are aware of high quality regulatory, competition and market openness considerations?

In the U.S., there are a myriad of avenues for regulatory officials to obtain training and build networks. Many of these opportunities are presented within agencies themselves or through private sector courses and forums.

The Federal government also offers opportunities for training and capacity building. For example, the U.S. Office of Personnel Management offers a course on regulatory policy for Federal regulatory officials. Additionally, following the release of its most recent guidance on regulatory analysis, OMB's Circular No. A-4, *Guidelines for the Conduct of Regulatory Analysis*, OMB provided extensive training on regulatory analysis to agency officials in 2004 and 2005.

A11. Does the legal framework have in place or strive to establish credible mechanisms to ensure the fundamental due process rights of persons subject to the law, in particular concerning the appeal system.

In the U.S., agency rulemaking is authorized by primary legislation passed by Congress, and agency rulemaking is subject to judicial review by the courts. Agency proposed rules are subject to the requisite notice and comment procedures discussed above (see answer to Question A6). Under the Administrative Procedure Act, the final rule must be based on the rulemaking record, must be a "logical outgrowth" of the proposed rule, and must respond to the public comments on the proposal. Otherwise, a court could overturn the regulation if it is challenged. Affected parties can also bring suit against the agency issuing the rule to have the courts reverse or remand the rule back to the agency because the agency violated the statute that authorized the rule or the U.S. Constitution. The information in the public record, and the agencies' use of this information, is often used by the courts in resolving legal challenges to regulations.

B. Regulatory Policy

B1. To what extent are capacities created that ensure consistent and coherent application of principles of quality regulation?

In the U.S., responsibility for review and coordination of Federal regulations is centralized within OMB. The scope of OMB's regulatory oversight is broad, covering agriculture, energy, transportation, information technology, housing, manufacturing, immigration, food safety, health care, public health, occupational safety and health, environmental protection and criminal justice.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the Federal office that reviews draft regulations. OIRA's review of draft rules is guided by E.O. 12866, "Regulatory Planning and Review," which was issued on September 30, 1993. This document directs agencies to follow certain principles in rulemaking, including consideration of alternatives to the rulemaking and analysis of the rule's effects on society, both its benefits and costs.

In addition, OMB has long provided guidance on regulatory analysis and the assessment of costs and benefits. The latest such guidance is OMB's Circular No. A-4, Guidelines for the Conduct of Regulatory Analysis, which OMB released in September 2003 (<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>). OMB developed the guidelines in collaboration with the President's Council of Economic Advisors, and revised the proposed guidelines based on public comments, peer review, and interagency review.

OIRA's review of agency draft regulations ensures that agencies, to the extent permitted by law, comply with key regulatory principles and that agency rules reflect the President's policies. OIRA also serves to ensure adequate interagency review of draft rules, so that draft rules are coordinated with relevant agencies to avoid inconsistent, incompatible or duplicative policies.

B2. Are the legal basis and the economic and social impacts of drafts of new regulations reviewed? What performance measurements are being envisaged for reviewing the economic and social impacts of new regulations?

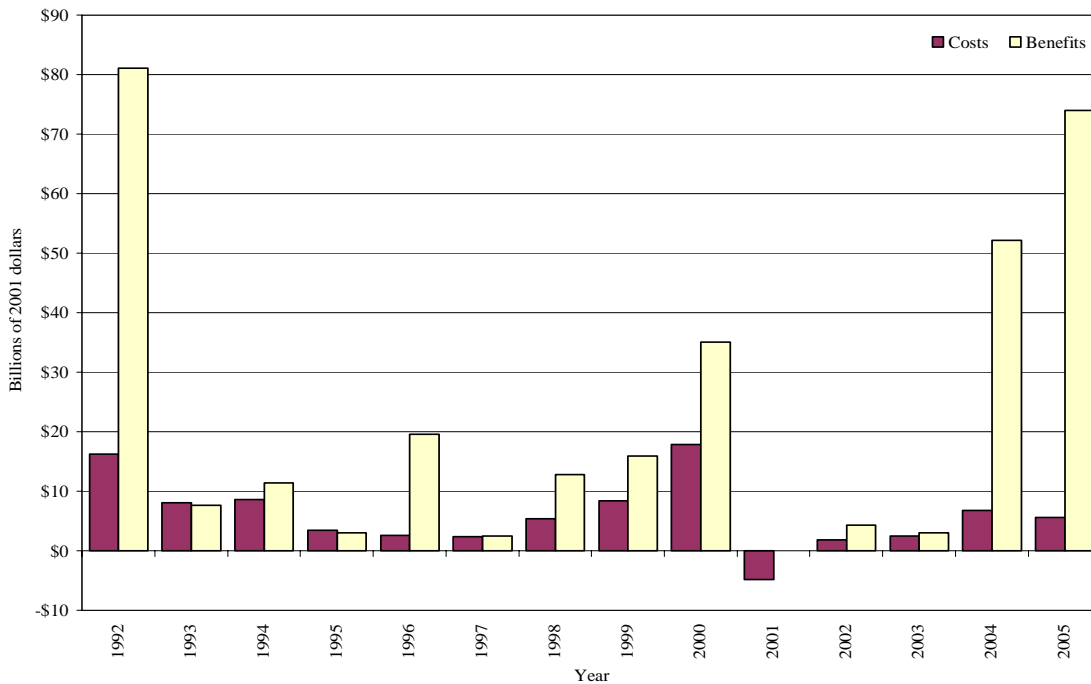
As one of its regulatory principles, E.O. 12866 states that when developing a regulation, agencies "shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Both economic and social impacts are considered during this assessment.

The principal mechanism for monitoring a rulemaking agency's compliance with E.O. 12866 and OMB Circular No. A-4 is OIRA's review of agency draft regulations before publication. Once a proposed rule is published, the agency's assessment of costs and benefits is available to the public for comment. Additionally, certain "major" rules, generally those expected to have an annual effect on the economy of \$100 or more, are subject to additional external oversight as a result of the Congressional Review Act (5 U.S.C. ch. 8). This law directs Federal agencies to submit all final rules to the U.S. Congress before they take effect, and the Act provides an

expedited process by which Congress can consider and pass legislation to overturn a newly issued regulation.

In terms of performance measurement, the U.S. has been measuring and reporting the aggregate costs and benefits of major rules for over 20 years. The figure below indicates the net benefits of major regulations from 1992 through September 2005. The figure shows that in no year were costs significantly greater than benefits, even though benefits are likely understated (in the figure) relative to the cost estimates since some rules had estimated monetized costs but not estimated monetized benefits. Moreover, the figure shows that the Bush Administration issued regulations with net benefits over its first 56 months at a yearly average rate that is 280 percent greater than the rate of net benefits produced by the regulations issued during the previous Administration.

Costs and Benefits of Major Rules (1992-2005)



B3. Are the legal basis and the economic and social impacts of existing regulations reviewed, and if so, what use is made of performance measurements?

While the USG has succeeded generally in ensuring that, when possible, the estimated future impacts of new regulations are quantified and monetized, OMB have recognized the need to improve the *ex post* (retrospective) assessment of the impacts imposed by existing regulations.

However, one way that the U.S. has examined the performance of existing regulations is through the Program Assessment Rating Tool (PART), a policy tool used by OMB to evaluate the

relative effectiveness of agency programs. The PART is based on the principle that Federal programs should achieve results, and that their performance must be appropriately measured and deficiencies addressed. It is a questionnaire of approximately 30 questions. In conjunction with OMB, the agency completes the questionnaire, assessing the program against a set of criteria and providing recommendations to improve program results. For regulatory programs, OMB considers: 1) the extent of affected stakeholders' involvement in the development of the regulation; 2) the quality of analyses performed during formulation of the regulation, including compliance with OMB guidelines; 3) consistency of the regulations with other existing agency regulations; and 4) the regulation's effectiveness in achieving the stated policy goal.

Results of PART evaluations are publicly available on the website www.expectmore.gov/. These evaluations often inform OMB and agency decisions on resource allocation among Federal programs.

B4. To what extent are rules, regulatory institutions, and the regulatory management process itself transparent, clear and predictable to users both inside and outside the government?

The APA provides the foundation for regulatory transparency and accountability in the United States. The APA requires that agencies go through a notice and comment process open to all members of the affected public outside the Federal government. As a general matter, agencies must publish proposed rules in the *Federal Register* and solicit public comment. Agencies consider the public comments, and publish the final rule in the *Federal Register*, making sure that the final regulation is a "logical outgrowth" of the proposal. The information in the public record and agencies' use of this information is often used by the courts in resolving any challenges to regulations brought by the affected public.

Additionally, there are numerous mechanisms that create transparency by allowing the public to "track" the status of a regulatory action. Federal agencies are required by E.O. 12866 to annually publish a plan of the most important regulatory actions that they expect to take in the coming year in the *Federal Register*. When a draft rule is sent from the agency to OIRA for review, OIRA publicly discloses that review has been initiated and outside parties may provide written comments or request a meeting with OIRA. All such outside interaction is also publicly disclosed. Once rules are finalized and take effect, they are codified and centrally located in the Code of Federal Regulations, which is updated annually and is widely available, including on the internet.

B5. Are there effective public consultation mechanisms and procedures including prior notification open to regulated parties and other stakeholders, non-governmental organisations, the private sector, advisory bodies, accreditation bodies, standards-development organisations and other governments?

In the U.S., there are numerous opportunities for affected stakeholders to participate in the design and implementation of new regulations. As previously mentioned, the APA generally

requires agencies to publish notice and comment for all proposed rules in the *Federal Register*. All proposed rules currently open to public comment are also centrally located on one Federal website (www.regulations.gov/). The public can use this site to send their comments electronically to agencies on Federal regulations published for comment in the *Federal Register*.

The Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. § 601 note; Pub. L. No. 104-121) requires that the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) receive input from affected small businesses before proposed rules are published. If the U.S. Small Business Administration's Office of Advocacy recommends small-entity representatives be consulted on the rule and its effects, the agency then convenes a Small Business Advocacy Review Panel. The interagency panel reviews the draft proposed rule and the related analyses prepared by the agency, and submits a panel report to the agency that provides recommendations for regulatory alternatives.

In addition, stakeholders can request to meet with OIRA during review of a draft rule. OIRA's policy is to meet with any party interested in discussing issues, whether they are from State or local governments, small business or other business or industry interests, or from the environmental, health or safety communities. OIRA makes publicly available all substantive communications with any party concerning regulations under review. After a rule is published, OIRA will also make publicly available certain documents exchanged between OIRA and the rulemaking agency during the review period.

B6. To what extent are clear and transparent methodologies and criteria used to analyze the regulatory impact when developing new regulations and reviewing existing regulations?

Executive Order 12866 and OMB Circular A-4 set forth the analytic requirements for new regulations. Regulations that are expected to have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, are considered to be "economically significant" and are subject to the Regulatory Impact Analysis (RIA) requirement in E.O. 12866.

OIRA's review of draft regulations is the principle mechanism for determining whether the agency has appropriately characterized costs and benefits and that the RIA requirements are met. This often involves a consideration of various possible alternatives to identify the most cost-effective option. Under E.O. 12866, OIRA can return a draft rule to the agency for reconsideration. Returning a rule means that OIRA has concluded that the draft is not consistent with the principles of E.O. 12866 and that further agency effort is needed. In such cases, agencies may, and frequently do, conduct further work on the draft and resubmit it for OMB consideration. During the first year of the Bush Administration, OIRA returned more than 20 draft rules to agencies for reconsideration—more than the number of the returns in the entire eight years of the Clinton Administration. Agencies learned that OIRA cares about analysis and, as a result, returns are much less frequent.

B7. How are alternatives to regulation assessed?

OMB Circular A-4 directs agencies to consider alternatives to Federal regulation, including antitrust enforcement, consumer-initiated litigation in the product liability system, or regulation at the State or local level. OMB's review of agency draft rules includes an assessment of regulatory alternatives, as well as a consideration of whether regulation at the Federal level is the best way to solve the problem.

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. Under E.O. 12866, Federal agencies should only promulgate regulations that are "required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people." If the regulatory intervention results from a statutory or judicial directive, the agency must describe the specific authority for their action, the extent of discretion available to them, and the regulatory instruments they could potentially use.

B8. To what extent have measures been taken to assure compliance with and enforcement of regulations?

The U.S. regulatory enforcement and compliance mechanisms are largely decentralized, with statutory authority to regulate delegated by Congress to Federal agencies. The agencies that design and implement regulations in a specific area often have the best programmatic knowledge and expertise to ensure compliance is effectively and efficiently achieved. Agencies monitor compliance with regulations and often consider improvements to their regulatory programs as a result of program data that demonstrate areas with high enforcement costs.

The U.S. attempts to provide incentives for compliance with regulations, rather than focusing exclusively on enforcement. For example, OMB Circular A-4 encourages agencies to consider performance standards over design standards when formulating new regulations. Performance standards allow for flexibility in achieving compliance and can significantly lower the cost of compliance for regulated entities. In addition, regulatory reliance on market-based systems (such as cap-and-trade programs) can encourage private sector innovation and also result in the achievement of regulatory objectives more quickly and with less lost (and can even yield greater benefits than through traditional forms of regulation).