

APRIL 2002

**GUIDELINES ON
REGULATORY COOPERATION AND TRANSPARENCY**

I. INTRODUCTION

1. At the London Summit of May 1998, the European Union and the United States launched the Transatlantic Economic Partnership (TEP). The TEP Action Plan, in its section on bilateral actions in the area of technical barriers to trade in goods, calls on both sides to take actions to address technical barriers to trade in goods, including improving the dialogue between U.S. and EU regulators.

The Action Plan further calls on both sides to identify and implement jointly defined general government Guidelines for effective regulatory co-operation and for improving access to each other's regulatory procedures, including the opportunity for all interested parties to have meaningful input in regulatory procedures and receive reasonable consideration of their views.

2. In a Joint Statement on Regulatory Cooperation of December 1997, both sides called for enhanced cooperation, whenever possible, in the areas of consultation in the early stages of drafting regulations, greater reliance on each other's technical resources and expertise, and harmonization of regulatory requirements or mutual recognition. The statement notes that the goal of this cooperation will be to maintain a high level of protection for health, safety, consumers and the environment and to ensure the integrity of the regulatory processes as both sides seek to improve effective market access.

3. The Joint U.S.-EU Statement on Early Warning and Problem Prevention Principles and Mechanisms, adopted at the Bonn Summit in June 1999, notes that early warning is intended to help each side to take the other side's interests into account at an early stage when formulating policy, legislative or regulatory decisions, and that the bedrock of early warning is transparency. Regulatory cooperation should also contribute to this objective.

II. OBJECTIVES

4. The objectives of these Guidelines are to improve cooperation between regulators and to promote transparency to the public in establishing and amending regulations, and, in particular, to:

(a) Improve the planning and developing of regulatory proposals, leverage resources for regulations development, improve the quality and level of technical regulations, pursue, as appropriate, harmonized, equivalent or compatible solutions, and take appropriate steps to minimize or, where appropriate, eliminate unnecessary divergence in regulations through a

more systematic dialogue between regulators, involving increased cooperation at all phases of the regulations development process;

(b) Obtain an increased predictability in the development and establishment of regulations by identifying and exchanging regulatory objectives, instruments and time-tables;

(c) Grant the opportunity for regulators of each to provide the other with meaningful input on regulatory matters, and the possibility to obtain reasonable consideration of such input;

(d) Promote public participation through disclosure of and access to supporting documents, particularly the timely release of the supporting rationales, analyses and data for regulatory proposals, and a timely opportunity for all interested parties, both domestic and non-domestic, to provide meaningful comments concerning regulatory proposals, including supporting materials;

(e) Obtain from each other and interested parties the benefit of the expertise, perspectives and ideas for alternative approaches, and of a fuller identification of unintended effects and practical problems associated with regulatory proposals, thereby promoting the adoption of technical regulations that are more performance-oriented and cost-effective and have fewer adverse effects;

(f) Provide public explanations for technical regulations, including the technical information and major regulatory alternatives considered, the analyses performed, the potential impacts on consumers, regulated parties, and others identified, the criteria applied to guide decision-making, and the consideration given to the public comments; and

(g) Create greater public understanding of the purpose and effect of regulatory proposals, greater public confidence in the fairness and openness of the regulations development process, and greater public acceptance of the technical regulations adopted, thereby enhancing the development and implementation of regulations, and contributing to a stable and sustainable foundation for long-term economic and social growth and development.

Taking these steps will help minimize and resolve trade frictions, and facilitate trade in goods.

5. These Guidelines should be implemented in ways that:

(a) Contribute to achieving high levels of protection for health, safety, consumers and environment;

(b) Are fully consistent with any applicable domestic legal requirements, including rules and policies on transparency of government activities to the public at large, and preserve the integrity of the domestic regulations development process; and

(c) Are fully consistent with any applicable international rights and obligations, including those of the World Trade Organization, in particular under the Agreement on Technical Barriers to Trade.

6. The Guidelines are intended to make a contribution to on-going discussions in multilateral institutions on the process of regulations development.

III. FIELD OF APPLICATION

7. This document sets forth the Guidelines which regulators of the U.S. Federal Government and the services of the European Commission intend to apply on a voluntary basis as broadly as possible.

8. The regulatory activity concerned is the planning and development of technical regulations relating to goods in the field of application of the WTO/TBT Agreement, including the development of technical regulations for submission as legislative proposals with the exception of regulatory processes relating to agricultural products.

9. The Guidelines should apply to future technical regulations, and amendments to existing technical regulations. Regulatory cooperation in accordance with the Guidelines should apply to those regulations and amendments that regulators of either side believe may have significant trade effects, benefits or other impacts.

IV. OPERATIONAL ELEMENTS OF REGULATORY COOPERATION

Consultation and Exchange of Information

10. Regulators should consult with their counterparts and exchange as much information as possible in order to achieve the above objectives. Such consultation and exchange should occur throughout the regulations development process, beginning as early as possible in that process. Dialogues may be informal, and could take place in actual meetings, or remotely, using electronic or other forms of communication, and be made on a bilateral or multilateral basis.

Regulators may share non-public information to the extent such information may be shared with foreign governments in accordance with applicable rules.

Identification and Selection of Problems to be Addressed through Regulation

11. Regulators should:

(a) Data collection. Examine the appropriateness and possibility of collecting the same or similar data about the nature, extent and frequency of problems potentially warranting regulatory action as those collected by their counterparts where it would expedite making statistically significant judgments about those problems. The possibility and appropriateness of collecting complementary data about the nature, extent and frequency of those problems

to be addressed by a particular regulatory action should also be examined. Periodically conduct comparisons of data collection practices.

(b) Analysis of data and of problem causality. Examine the possibility and appropriateness of using the same or similar assumptions and methodology as those used by their counterparts for analyzing the data and determining the magnitude and causes of specific problems potentially warranting regulatory action. Periodically compare analytical assumptions and methodologies.

Periodically compare judgments with those of their counterparts about the existing or anticipated problems, their relative magnitude, and their causes, as well as possible regulatory solutions.

(c) Priority setting. Compare the data, analyses and criteria used in selecting rulemaking priorities with those used by their counterparts. Periodically compare bases for selecting rulemaking priorities.

Monitoring of Forthcoming Rulemaking Projects

12. To enable monitoring of forthcoming rulemaking projects, regulators should:

(a) Periodically exchange information of ongoing or planned rulemaking proceedings in their areas of responsibility. Such information should include annual work programs listing the new technical regulations, and the amendments to existing technical regulations, that are likely to be proposed or adopted in the next year; and

(b) Upon request by their counterparts concerning a specific proposal, supplement the annual work programs, to the extent possible, with information regarding regulatory approaches under consideration, including potential benefits, costs and other impacts for all parties, domestic and non-domestic, where assessed and available.

Research

13. Regulators should examine areas in which plans for pre and post-normative R&D to support rule-making and implementation could be periodically exchanged and compared.

Cooperative research agendas should aid in reducing duplicative research; generating more information at less cost; gathering the best technical data; establishing a common scientific basis; addressing the most pressing regulatory problems in a more consistent and more performance-oriented manner; and thus minimizing unnecessary differences in new regulatory requirements, while more effectively improving health, safety and environmental protection.

Selection of Regulatory Approaches

14. Regulators should, early in the regulations development process, exchange information with counterparts about contemplated approaches to regulatory requirements, including conformity assessment procedures, in order to:

- (a) Examine the possibilities for greater convergence on how to state the objectives of regulations and to define the scope of regulations. The interface between regulations and voluntary standards should also be addressed in the context;
- (b) Compare methods and assumptions used in analyzing regulatory proposals, including, where appropriate, analysis of technical and economic practicability, and benefits of any major alternative regulatory requirements and approaches considered. Such information exchange should also include a comparison of the potential cost-effectiveness of the regulatory proposal to that of major alternative regulatory requirements and approaches considered.

Rule-making

15. Regulators should exchange information about contemplated regulatory requirements and examine opportunities to minimize unnecessary divergences in technical regulations through means such as achieving harmonized or compatible solutions or to consider the use of mutual recognition, as may be appropriate, in specific cases.

Post-implementation review of technical regulations

16. If post implementation reviews of regulations are carried out, regulators should:

- (a) Compare methods and assumptions used in such reviews. Reviews may include *inter alia* an examination of the effectiveness of the technical regulation in achieving its stated objectives, its burdensomeness, and its compatibility with other technical regulations.
- (b) Where applicable, make summaries of the results of post-implementation reviews available to regulators of the other side.

V. OPERATIONAL ELEMENTS OF TRANSPARENCY

17. The planning and development of technical regulations is an issue that concerns the public, whether domestic or foreign. Transparency is necessary to ensure that these concerns are properly understood and taken into account in this process.

Regulators should apply, in accordance with relevant rules, the following elements of transparency in technical regulations planning and development:

- (a) Provide information about current and future activities to develop regulations, and opportunities for public participation;
- (b) Consult with the public, including interested stakeholders, domestic and foreign, in an early and broad manner;
- (c) As part of the development process for technical regulations:
 - (i) Provide timely announcement to the public about regulations at an early appropriate stage in their development when amendments to the regulation can still be introduced and public comments taken into account;
 - (ii) Invite the public to submit comments on the regulation, accompanying explanations, and supporting documents, and specify a reasonable period of time for the submission of comments;
 - (iii) Further aid public commenters by:
 - A) Providing a public explanation of the reasoning underlying the regulation. The elements of this explanation would ideally include the need for the regulation, its aims, its anticipated impacts (quantified where possible), its economic and technical feasibility, and alternative regulatory options; and
 - B) Identifying the relevant research, data, and analysis relied upon by the regulators in developing the regulation and facilitating public access to that material. Any limitations to public access should be clearly defined.
- (d) Respond in an adequate and timely manner to public questions and recommendations;
- (e) Take public comments into account in the development of technical regulations and address them in an explanation of the reasoning underlying the final action. This explanation would ideally address each significant issue raised by the comments, the rationale of the final action, and a summary of any significant changes to the regulation; and
- (f) Make increased use of the Internet to provide access to documents, research, data, and analysis, and regulatory explanations.

VI. PROCEDURAL ASPECTS OF THE GUIDELINES

18. The implementation and functioning of these Guidelines, and progress on identified regulatory projects, will be reviewed on an ongoing basis by the TEP/TBT Working Group.
19. Both sides will work jointly to identify areas for further improvements in the existing regulatory cooperation, and areas in which regulatory cooperation could be further expanded or established *ex novo*.
20. Both sides will continue efforts to identify means to improve operational transparency in their respective regulatory systems. Both sides will review ways to improve access of interested parties, domestic and foreign, to each other's regulatory procedures and will continue to consult with those parties on operational transparency.
21. Both sides will encourage conformity assessment bodies and standards development organizations to follow the Guidelines relating to transparency, where relevant, when such bodies interpret regulations.
22. Both sides will endeavor to identify specific regulatory proposals for the initial application of the Guidelines.