TACD

TRANS ATLANTIC CONSUMER DIALOGUE
DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

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POSITION PAPER AND RESOLUTION ON
HORIZONTAL REGULATORY INITIATIVES IN EU-U.S. REGULATORY COOPERATION

INTRODUCTION

Regulatory reform or "Better Regulation" is an important public policy issue in the EU and in the U.S.. As consumer advocates, we want to see better regulation also (we do not favour "worse regulation") but we need to clarify what is meant in this context by "better". For TACD, better regulation is something done in a balanced and integrated way, and which provides an opportunity to improve, and certainly not lower, the levels of environmental protection, consumer protection and health standards protection. As the regulatory process changes proposed in the name of "Batter Regulation," "Smarter Regulation," and "Administrative Cost Reduction" have developed on each side of the Atlantic, they have distorted regulatory policy in both the EU and U.S. in ways that require urgent resolution. We do not wish to see these flaws exported and amplified as part of the process of regulatory cooperation. The purpose of regulatory cooperation between the EU and U.S. is to improve, in the most effective way, the health, safety and economic well-being of consumers on both sides of the Atlantic.

Regulatory process changes in the U.S., such as impact assessments and reductions in information collection, are slowly being imported into European regulatory policy and have been the subject, under the heading of "horizontal regulatory dialogue," of discussions in the EU-U.S. Roadmap for Regulatory Cooperation. This TACD briefing paper traces these trends, identifies their potential impacts on consumers and the public interest, and offers recommendations for protecting consumers from these potential harms.

REGULATORY PROCESS CHANGES IN THE U.S.

In the United States, Congress passes laws, but federal agencies are given a great deal of power to implement those laws through regulation. As the administrative state expanded significantly in the 1930s and 1940s in response to the Great Depression and World War II, many parties recognized the need for a more democratic procedure for establishing the details of binding federal regulation. Thus, in 1946 the Administrative Procedure Act (APA) was born.[1] The APA established minimal procedural conditions of rulemaking for all federal agencies, including guarantees of transparency, formal notice to the public via a publication called the *Federal Register*, and an opportunity for all interested parties to participate in rulemaking. The APA also sets up a process for federal courts to directly review federal agency decisions.

In the aftermath of the enactment in the 1960s and 1970s of historic protective legislation for consumers, workers, and the environment, including the Clean Air Act, the Clean Water Act, the Coal Mine Health and Safety Act, the Consumer Product Safety Act, the National Traffic and Motor Vehicle Safety Act, and the Occupational Safety and Health Act, business interests mounted a long-term campaign to persuade policymakers that regulatory policy decisions are so irrational that the regulatory process should be changed in order to supply the supposedly missing rationality. Bolstered by industry-funded and ideologically-driven scholarship purporting to demonstrate that small businesses bear an unjustifiably disproportionate compliance cost burden[2], that regulatory costs overwhelm the attendant benefits[3], and that regulations divert resources away from more effective life-saving measures[4] (all of which has been subsequently exposed as irremediably flawed or otherwise countered[5]), this campaign has succeeded in freighting the simple process of the APA with burdensome additions such as the following:

- Centralized political review of major regulations and other policies by the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget (OMB). Although OIRA has never been statutorily charged with protecting public safety or public health, the White House simply declared by executive order that OIRA should have the power to review regulations before they are published in the *Federal Register* and take effect.[6]
- Economistic analytical requirements adding layers of cost-benefit analysis (comparisons of monetized costs and monetized benefits) and cost-effectiveness analysis (ratios of cost estimates per unit of benefit, such as costs per "Quality Adjusted Life Year" saved) as preconditions of developing regulations. Although some agencies are charged by statute with considering economic analysis in order to determine whether a regulation is technically feasible, the historic protective authorities of the 1960s and 1970s nonetheless charged the agencies with considering health, safety, and the public interest as paramount. Presidential executive orders requiring impact assessments and regulatory reviews by OIRA have changed that balance, and now economic impact assessment is *de facto*, if not *de jure*, a major factor in guiding agencies selecting among regulatory alternatives.
- Limitations on information gathering through the Paperwork Reduction Act, which establishes percentage goals of paperwork "burden hour" reductions and requires OIRA approval of information collections that pose the same questions to 10 or more persons (i.e., most standardized information collections undertaken by the U.S. federal government). There are no exceptions for information needed to protect the public or data useful for assessing agency performance. Although studies have routinely documented that the bulk of paperwork burden is created by U.S. tax authorities, OIRA has nonetheless consistently focused its reviews on information collections proposed by health, safety, consumer, and environmental agencies.
- Special access for special interests, as OIRA's centralized regulatory review function and relative lack of transparency has made that office especially attractive for industry interests seeking to weaken or stall regulations, and as the Small Business Regulatory Enforcement Fairness Act not only gave small businesses special privileges in enforcement proceedings but also gave them special access to review pending regulations before the rest of the public, including representatives of consumers and the public interest.
- Hurdles to dissemination of scientific and other information such as OMB's peer review guidelines, which mandates new pre-dissemination levels of review for many

kinds of federal information, and a new executive order and bulletin on agency publication of general policy statements, interpretations, and other guidance documents.

- Opportunities to challenge government findings, such as the Data Quality Act, which creates new procedures for industry to challenge factual assertions in government documents, and several final and pending policies requiring agencies to create catalogues of activities such as scientific assessments which regulated industry would have an incentive to challenge.

RESULTS OF REGULATORY PROCESS DISTORTIONS

These post-APA distortions of the regulatory process have resulted in an almost complete lack of significant regulation in the last 35 years and in substantial harm to consumers and the public interest that belie the good government rhetoric advanced to justify them:

- Paralysis by analysis: Agencies are so legendarily slow to pass needed protections that the terms "ossification" and "paralysis by analysis" are ubiquitous in administrative law commentary. As has repeatedly been observed, the average time from 1974 to 1992 for Federal Trade Commission final rules to reach finality after their initial proposal was 63 months.[7] Likewise, the Occupational Safety and Health Administration has slowed significantly over the years as new burdens have been added.[8]

- Industry bias in the rulemaking process: Centralizing regulatory review in a single political office has been widely viewed as creating a "one-stop shop" for industry interests seeking to roll back or weaken regulation and in recent years industry has had a great deal of success with these efforts to the detriment of consumers.[9]

  Beyond centralized review, the special privileges accorded by post-APA statutes to small business are attractive to larger enterprises, who then advocate for legal definitions of "small business" capacious enough to cover most U.S. business concerns or use small business allies in coordinated litigation and policy campaigns that they fund.

- Politicization of science: Efforts are underway, from the Data Quality Act to the more recently proposed OMB guidelines on risk assessment, to replace expert assessments based on the weight of the evidence with what has been called the "corpuscular" approach, in which every single study that could be incorporated in a review is picked apart and subjected to industry's tactic of "manufacturing uncertainty." White House politicization of science has reached such a fever pitch in recent years that over 60 leading scientists formally protested recent threats to scientific integrity.[10]

- Regulatory underkill: Agencies have dramatically slowed their production of major regulations.[11] The Department of Labor's Occupational Health and Safety Administration, once the bête noir of industry, has now become the black hole of government: it has failed to produce any new major rules protecting workers since 2002, and the only reason it has a potentially major new protection against hexavalent chromium currently on the agency agenda is that a federal court demanded the development of a standard.[12] Delay of needed protections costs the public and has, on occasion, been deadly.[13]

- Information gaps: The regulatory process accretions to the APA have raised significantly the demand for information as a precondition for action, but there are many gaps in the corpus of needed information about recognized hazards, particularly in the area of chemical toxicity. Industry's strong disincentive to produce information needed to *fill* the

gap is complemented by policies that prevent regulators from *bridging* the gap with approaches that require less precision.[14] Meanwhile, it is becoming apparent that the Paperwork Reduction Act has become an obstacle to the ability of federal agencies to gather the information they need from the public.[15] In short, while industry will produce distorted data on the cost of regulation, there are few (and diminishing) federal funds to produce independent data on the benefits of regulation, and independent scientists and public interest groups lack the funds for long-term studies of environmental and other hazards.

PARALLEL DEVELOPMENTS

These burdens on regulatory and science policy have been evolving in the U.S. throughout the last 30 years. Similar process burdens are now rapidly replicating themselves in a variety of ways in Europe as well, under the banners of "Smart Regulation," "Better Regulation," "Better Governance," and "Administrative Cost Reduction."

- Centralized political review: France has moved to create its own version of OMB, creating a Better Regulation Office in the Ministry of Finance, Economy and Industry,[16] while the UK has likewise created a Better Regulation Executive in the Cabinet Office[17] and Ireland has created a regulatory reform office in the Department of the Taoiseach.[18]

- Paralysis by analysis: The UK and Ireland are among the European nations that have recently required regulatory impact assessments emphasizing market failure and cost-benefit analysis.[19]

- Reducing information collection: The Netherlands has led the way in a European parallel to the U.S. Paperwork Reduction Act, with its Administrative Cost reduction program that inspired an international working group on the Standard Cost Model.[20]

These regulatory process and information policy changes are relatively new, most dating back no earlier than the mid to late 1990s; analysis of their effects on consumer protections and other public interest policies is still developing. Just the same, consumer groups and other public interest watchdogs have begun to see harmful effects on public policy, such as the following:

- An implicit assumption that "better" means "less," rather than more effective, regulation.

- An unjustified assumption, based on little or no hard evidence, that self-regulation is "better" than legislative measures.

- A tendency to overstress economic and other easily measurable factors in impact assessments, to the detriment of the wider public good.

- An underestimation of the harder to measure potentially bad consequences of failing to regulate in an appropriate and timely manner.

- A tendency to raise the burden of proving the case for regulation or to impose procedural or other obstacles to effective regulation and enforcement.

- A trend of compromises within the legislative process reducing the "enforceability" of new regulatory measures.

- An inherent imbalance in the process of consultation and public discourse, in favor of business and to the detriment of the wider and more diffuse public interest.

- A corresponding imbalance in the evidence base for policy-making, heightened by misdirected policies on the funding of research, with the result that there is much consumer research but little *consumer oriented* research.

There is a growing concern that these new analytical requirements and process burdens undermine the Precautionary Principle and put consumers at risk. For example, a National Consumer Council report observes that impact assessment methodologies in the UK are distorted and "may lead to inaccurate assessment of the consumer detriment and faulty regulatory decisions."[21]

Meanwhile, this trend is being incorporated into European Commission policy. The EC recently adopted guidelines to systematize impact assessments[22] (combining both cost-benefit analysis and risk assessment) and recently announced a 25% "administrative costs" reduction goal[23] (paralleling the U.S. Paperwork Reduction Act).[24]

EU-U.S. HORIZONTAL REGULATORY PROCESS DIALOGUE

Members of the TACD support a process of regulatory cooperation based on open, transparent multi-stakeholder discussions with an objective of improving regulation by achieving best practices. However, this is not the current reality.[25] There is a clear danger that the flaws in the regulatory regimes on each side of the Atlantic will be exported and amplified through the process of regulatory cooperation.

In particular, importation of U.S. ideas for regulatory process changes that tilt the playing field in favor of industry and away from consumers may accelerate, as regulatory process issues have become the subject of high-level talks between European and U.S. leaders. The Transatlantic Economic Partnership announced Guidelines on Regulatory Cooperation and Transparency Implementation Roadmap (1 April 2002),[26] which counseled "using the same or similar assumptions and methodology as those used by" TEP counterparts in impact assessments.[27] Subsequent EU-U.S. dialogues on regulatory cooperation and transparency have increasingly incorporated regulatory process issues under the heading of "horizontal initiatives," evolving from a general topic list[28] to an organized "informal dialogue" between the White House's OMB and EC officials and expert exchange program[29] that has now undertaken a comparison of impact assessment approaches and has held two meetings to discuss "good regulatory practices."[30] This dialogue specifically contemplates being applied to "ongoing sectoral dialogues" about specific issues of concern to consumers.

OMB has published a version of the working paper that has resulted from the OMB/EC comparisons of analytical methods, which concludes with this note:

> Hence, one may conclude that while many similarities exist, there are significant differences, particularly as regards the legal and institutional framework, the resulting different stages at which [regulatory impact assessments (RIAs)] are produced, and the difference in purpose they serve in the two systems. Carrying out one *ex-ante* RIA that can be shared by U.S. regulators and the Commission at this moment in time may be challenging. Sharing the same sources of information, making sure the basis of each

> analytical approach is sound, and building on each analysis based on a better understanding of the other's system are likely to produce better real results in the area of regulatory cooperation.[31]

The paper evinces continuing interest in the prospect of harmonizing impact assessment methodologies so that EC and U.S. regulators can rely on the same assessment, which at present is so "challenging" that incremental approaches, such as "[s]haring the same sources of information," may be more immediately on the horizon for the horizontal regulatory dialogue.

TACD CONCERNS

Government has an obligation to protect the public and the environment. The public uses government institutions to pool its collective resources into an organized form that can counter the larger forces that isolated individuals cannot otherwise surmount. Independent science and information are vital to the fulfillment of that responsibility and to democratic accountability. Reforms of the regulatory process and science/information policy must serve these ideals, not detract from them.

While TACD has in the past recommended that the European Commission examine the U.S. APA as a model for transparent regulatory rulemaking, we have warned against the policies that generate paralysis such as the Paperwork Reduction Act and the Small Business Regulatory Enforcement Fairness Act. The U.S. experience with these post-APA regulatory process distortions now being advocated in Europe is very troubling. It has resulted in weaker protections for consumers, the environment, and the public interest, and it has stalled agencies to such a degree that few new protective regulations have been promulgated in the last 35 years and certain agencies are now completely unresponsive to democratic claims on them. The regulatory burdens advocated by industry that have been added to the original APA have succeeded in stalling or derailing hundreds of important policy responses to documented hazards and emerging threats. Thus, for example, the United States has no approval process for genetically modified foods, but instead looks at them under a patchwork of decades-old statutes that never considered the possibility of genetic engineering. In contrast, the European Union has moved ahead to develop a series of new directives to appropriately deal with this new technology.

The European embrace of the Precautionary Principle in its rulemaking processes has made it the envy of consumer advocates in the U.S., and consumers on both sides of the Atlantic have reason to fear that the Precautionary Principle is at grave risk of becoming an empty shibboleth should U.S.-style regulatory process changes become the norm in Europe. As Brussels becomes the world's leading proponent of new consumer and environmental regulations, it has also become the target of the same forces that have worked in the United States to slow down and derail regulatory processes. Major U.S. industries are setting up lobbying operations in Brussels, and the United States has appointed an ambassador to Brussels who is well-known for his energetic spearheading of anti-regulatory lawsuits, the development of anti-regulatory lobbying groups, and other similar activities.

TACD is very concerned that U.S. experiences with these post-APA regulatory process distortions not be replicated in Europe, and that new developments arising in European and Canadian systems (such as the Canada GD-R's requirement of intensive analysis of all existing regulations, even proven safeguards) likewise not be duplicated in the U.S. or elsewhere in Europe.

TACD RECOMMENDATIONS

1. The EC and EU member states should not adopt centralized political review and control of regulations, regulatory impact assessments, or information collections, in the mode of OMB's Office of Information and Regulatory Affairs. Primary responsibility for implementing legislation and developing regulations to protect the public should continue to reside with the agencies charged with those responsibilities, which have the resources and expertise to exercise them most wisely.

2. TACD calls on participants in the EU-U.S. horizontal regulatory dialogue not to pursue the goal outlined in the initial April 2002 TEP Guidelines on Regulatory Cooperation and Transparency Implementation Roadmap of harmonizing impact assessment methodologies and assumptions used in impact assessments. Although the EC has developed its own impact assessment requirements and guidelines, it would be contrary to the Precautionary Principle for the EC to adopt proposals such as the pending OMB bulletin on risk assessment methodologies, which would eliminate precautionary methods such as use of worst-case assumptions (like environmental risk assessments that pinpoint exposure levels based on the most exposed person rather than the average exposure). Additionally, it has been documented that U.S. economic impact assessments routinely overestimate regulatory costs and underestimate regulatory benefits.[32] (Although OIRA has tried to disprove the empirical observations with a skewed study of its own, it has been subsequently discredited.[33]) Simply adopting skewed U.S. impact assessment assumptions would skew European assessments in a manner that would essentially create a transatlantic policy reward to the lobbying efforts of U.S. industry.

3. Information resource management must be a two-way street, so that calls for "administrative cost reduction" or "paperwork reduction" are balanced against an imperative that no such policy will threaten the quality, quantity, or utility of information needed to protect the public. Any such initiatives should avoid arbitrary reductions in time spent complying with information collection requirements, avoid centralized political review and control of information collection, and instead focus on electronic reporting and the use of sensors and other modern technologies that enable us to gather needed information more efficiently.

4. Too many of the U.S. initiatives, such as the OMB peer review guidelines and the draft guidelines for risk assessment, establish onerous requirements for government assessments that do not apply to industry assessments, such as scientific studies offered in support of licensing or other applications. Additionally, some U.S. policies (such as the Small Business Regulatory Enforcement Fairness Act) grant business interests a seat at the table for policy development that consumer and labor representatives do not enjoy. The EU-U.S. dialogue should counsel the U.S. on correcting these imbalances in its policies, and the EC and EU member states should not replicate those imbalances in their own policies.

5. The Precautionary Principle should apply in cases when the scientific evidence is not conclusive enough to determine a level of protection but there is a necessity to take measures for the purposes of protecting public health, safety, or the environment. The TACD once again calls on the U.S. to incorporate the Precautionary Principle in regulatory decisions involved in consumer health and safety and the environment. The U.S. and the EU should include the Precautionary Principle as an agenda item in the EU-U.S. horizontal regulatory dialogue.

Endnotes:

[1] *See generally* 5 U.S.C. § 551 *et seq*.

[2] *See, e.g.*, W. Mark Crain & Thomas D. Hopkins, *The Impact of Regulatory Costs on Small Firms* (Oct. 2001), *available at* www.sba.gov/advo/research/rs207tot.pdf.

[3] *See, e.g.*, Robert Hahn, *Regulatory Reform: What Do the Government's Numbers Tell Us?*, *in* RISKS, COSTS AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION 208 (Robert W. Hahn ed., 1996); John F. Morrall III, *A Review of the Record*, 10 REGULATION 25 (1986).

[4] *See* Tammy O. Tengs & John Graham, *The Opportunity Costs of Haphazard Social Investments in Life-Saving*, *in* RISKS, COSTS AND LIVES SAVED, *supra*, at 172.

[5] *See, e.g.*, Winston Harrington, *Grading Estimates of the Costs and Benefits of Federal Regulation: A Review of Reviews* (Resources for the Future Discussion Paper No. 06-39, 2006), *available at* www.rff.org/Documents/RFF-DP-06-39.pdf; Richard W. Parker, *The Empirical Roots of the Regulatory Reform Movement: A Critical Appraisal*, 58 ADMIN. L. REV. 359 (2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=916541; Genevieve Smith, OMB Watch, *Regulation and Competitiveness* (2006), *available at* www.ombwatch.org/regs/compete/regandcompetitiveness.pdf; Richard W. Parker, *Grading the Government*, 70 U. CHI. L. REV. 1345 (2003); Lisa Heinzerling, *Five-Hundred Life-Saving Interventions and Their Misuse in the Debate over Regulatory Reform*, 13 RISK 151 (2002); Lisa Heinzerling & Frank Ackerman, *The Humbugs of the Anti-Regulatory Movement*, 87 CORNELL L. REV. 648 (2002); Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981 (1998).

[6] The first executive order in the series was the Reagan administration's Exec. Order No. 12,291 (1981), which gave OIRA power to review all regulations. The Clinton administration declined the opportunity to eliminate this process and instead modified it with Exec. Order No. 12,866 (1993), which left in place the OIRA review mandate but limited its scope to "significant regulations" (a category flexible enough that it accommodates any regulation OIRA decides it wants to review). This order was most recently modified by President Bush's Exec. Order No. 13,422, which extends this review power to cover not just regulations but also significant "guidance," a new term covering a wide range of policies and interpretations. This order is so new that its complete scope is yet to be determined.

[7] *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1389 n.22 (1992).

[8] *See id*. at 1387-88 ("[OSHA] in 1972 spent about six months from inception to publication of the final rule on its first occupational health standard for asbestos. Two of its next three health standards, a generic rule for fourteen carcinogens and a standards for vinyl chloride, took about one year, and nine months, respectively. The next three standards, for cotton dust, acrylonitrile, and arsenic, each took over three-and-one-half years. These last three standards were promulgated during the relatively activist Carter Administration when OSHA was anxious to write new rules to protect workers. Today, OSHA health standards rarely take less than five years to promulgate.").

[9] In the wake of the Ford/Firestone rollover deaths, Congress mandated a series of reforms, among them that NHTSA must require automakers to develop tire pressure monitoring systems to warn drivers whenever a tire becomes dangerously underinflated. OIRA intervened, forcing NHTSA to issue standards that would mandate an inadequate system that would fail to alert drivers in all underinflation situations. OIRA's interference has resulted in unnecessary delays and litigation to force NHTSA to comply with the law. An estimated 10,635 injuries and 79 deaths would be averted each year by a Tire Pressure Monitoring Rule developed in compliance with the law. (*See* Joan Claybrook, Letter to John Graham, Administrator of OMB-OIRA, Mar. 11, 2002, *available at* www.publiccitizen.org/documents/Tire_pressure_Letter_to_Graham_final.pdf.)

OIRA thwarted an Environmental Protection Agency effort to protect soil and drinking water from excessive levels of manganese — an industrial by-product linked to numerous health problems, including respiratory problems, sexual dysfunction, psychological disturbance, as well as a condition similar to Parkinson's. Acceding to demands from the steel industry, OIRA ordered EPA to remove manganese from a final rule listing substances as hazardous wastes. (*See* OMB Watch, *OMB Weakens Hazardous Waste Rule*, OMB WATCHER, Nov. 6, 2002, *available at* www.ombwatch.org/article/articleview/1173/1/416?TopicID=1.)

[10] *See* Union of Concerned Scientists, *Scientific Integrity in Policy Making*, *available at* www.ucsusa.org/scientific_integrity/interference/reports-scientific-integrity-in-policy-making.html.

[11] *See* J. Robert Shull & Genevieve Smith, OMB Watch, *The Bush Regulatory Record: A Pattern of Failure* 22 Fig.4 (Sept. 2004), *available at* www.ombwatch.org/regs/2004/patternoffailure/finalreport.pdf.

[12] *See id*. at 51.

[13] For example, the current administration withdrew many proposals for new or updated protections off of agency agendas once it took office. Among the items withdrawn from the agenda of the Mine Safety and Health Administration were proposals to create new regulations for life-saving escape routes and to improve the devices that help trapped miners breathe — the need for which was tragically proven anew by the January 2006 Sago mine disaster, which killed 12 miners. *See, e.g.*, Robert Shull & Gary Bass, OMB Watch, *Statement on Sago Mine Disaster*, Jan. 6, 2006, *available at* www.ombwatch.org/article/articleview/3224/1/317?TopicID=5.

[14] *See* John S. Applegate & Katherine Baer, *Strategies for Closing the Chemical Data Gap* (CPR White Paper No. 602, Apr. 2006), *available at* http://progressiveregulation.org/articles/Closing_Data_Gaps_602.pdf.
[15] *See* Harrington, *supra* note 5, at 35-36.
[16] *See* Jonathan B. Weiner, *Better Regulation in Europe* (Duke L.S. Leg. Studs. Res. Paper No. 130, Oct. 2006), at 22.
[17] *See id*. at 21.
[18] *See id*. at 21-22.
[19] *See id*.
[20] *See* Wiener, *supra* note 16, at 22.
[21] *See* Jill Johnstone & Alena Kozakova, National Consumer Council, *Imperfect Markets*.
[22] The guidelines were issued in 2002, *see* European Commission, Communication from the Commission on Impact Assessment, COM(2002) 276 final, 5 June 2002, *available at* http://trade.ec.europa.eu/doclib/docs/2005/february/tradoc_121479.pdf, and they were updated in 2005 and 2006, *see* European Commission, *Impact Assessment Guidelines with March 2006 update*, SEC(2005) 791, 15 June 2005, *available at* http://ec.europa.eu/governance/impact/docs/key_docs/sec_2005_0791_en.pdf.
[23] *See* Günter Verheugen, EC Vice-Pres. for Enterprise & Indus., *Better Regulation for Jobs and Growth*, Address to Former Members Dinner, European Parliament Former Members Assoc'n, 10 May 2006, *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/287&format=PDF&aged=1&language=EN&guiLanguage=en, at 3.
[24] Key documents on these and related initiatives are available at http://ec.europa.eu/governance/impact/key_en.htm.
[25] TACD has repeatedly identified flaws of regulatory cooperation activities as they are currently conducted. Among the issues that trouble consumer groups are the following:

- Through formal and informal contacts, the process of regulatory cooperation is not transparent and focuses too much on the concerns of industries subject to regulation, to the detriment of wider public issues.
- Indeed, the relative lack of transparency is difficult to reconcile with, and at worse even bypasses, the rules on transparency at "domestic" level on each side of the Atlantic.
- The process of regulatory cooperation can operate to "kill" potential regulatory initiatives prematurely before they are discussed on a wider level.
- There is also a tendency to present as "objective" and "scientific" assumptions and conclusions that contain in fact a high degree of political or ideological content – in relation to impact assessments, for example.

[26] Available at www.ustr.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/TEP_Guidelines_on_Regulatory_Cooperation_Transparency_Implementation_Roadmap.html.
[27] *Id*. § IV.11(b).
[28] *See* 2004 Roadmap for EU-U.S. Regulatory Cooperation and Transparency, 6 Feb. 2004, § II.
[29] *See* 2005 Roadmap for U.S.-EU Regulatory Cooperation, § I.
[30] *See* 2006 Joint Report on the Roadmap for EU-US Regulatory Cooperation, Annex 2 to Progress Report on Economic Initiative, June 2006, § II.
[31] U.S. Office of Management and Budget, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* 88, *available at* www.whitehouse.gov/omb/inforeg/2006_cb/2006_cb_final_report.pdf.
[32] *See* Ruth Ruttenberg & Assocs., Public Citizen, *Not Too Costly After All:An Examination of the Inflated Cost-Estimates of Health, Safety, and Environmental Protections*, Feb. 2004, *available at* www.citizen.org/documents/ACF187.pdf.
[33] *See* Frank Ackerman, *The Unbearable Lightness of Regulatory Costs*, *available at* http://ideas.repec.org/p/dae/daepap/06-02.html.