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The U.S. Chamber of Commerce and its transatlantic joint venture partner BUSINESSEUROPE work collaboratively on transatlantic issues in support of the recently created Transatlantic Economic Council (TEC). We are the two largest business federations and we represent companies of every size, sector, and region in the transatlantic economy. Our member companies are responsible for the strength of the U.S. and European economies that today makes up greater than 50 percent of the world's gross domestic product. In light of this strong relationship, our members would greatly benefit from increased economic integration and the elimination of market-distorting, divergent and incompatible regulations.

The U.S. Chamber and BUSINESSEUROPE endorse the work of the High-Level Regulatory Forum and recognize its importance to the TEC. Nothing within the TEC's agenda has the potential to create jobs and spur economic growth more than a framework for regulatory cooperation. While the TEC may not harmonize every existing regulation, it can and should, through the High Level Regulatory Forum, ensure that the methodologies used to promulgate future regulations are aligned to minimize any market-distorting impact that regulations might have on the global commerce, international trade, or investment.

The Chamber and BUSINESSEUROPE appreciate the opportunity to comment on the *Joint Draft Report for Comment – Review of the application of EU and U.S. regulatory impact assessment guidelines on the analysis of impacts on international trade and investment* (report) issued by the Office of Management and Budget (OMB) and the Secretariat General of the European Commission. We applaud both OMB and the Secretariat General's office for issuing the joint report and requesting stakeholder input. The following comments are those of the U.S. Chamber of Commerce; BUSINESSEUROPE is also submitting comments, but under separate cover.

I. Introduction

There is a clear need to reduce the divergence of U.S. and EU regulations in order to ensure the mutual protection of consumers and the environment and enhance the economic prosperity of both sides of the Atlantic. Improved methodologies for assessing the adverse impact of regulations on business and industry—where due consideration is given to the concerns of all stakeholders—will help to mitigate obstacles to trade, investment, and economic growth.

A necessary first step toward reducing divergence is to recognize that the EU and U.S. economies are inextricably bound together in a single transatlantic market. As such, any adverse regulatory impacts harm business as a whole, not just "trade" between nations. A climate conducive to global commerce will only be fostered by ensuring that both U.S .and EU regulatory structures are based on similar core principles reflecting the shared values of our societies.

Once the core principles have been agreed to and form the bedrock of both U.S. and EU regulatory systems, then focus can be given to the methodologies and how impacts are assessed and addressed. This means employing methodologies that assess potential regulatory impacts to international trade, investment, and economic growth—and provide the other side with the time, opportunity, and forum to comment on those impacts.

As the report correctly notes, current U.S. and EU assessment methodologies differ, often significantly. Nevertheless, the Chamber provides both general comments and specific comments in an effort to resolve those differences and, ultimately, to reduce regulatory divergence in the transatlantic market.

II. Core Principles for U.S./EU Regulation

There are certain core principles that should be incorporated into, and would provide the foundation for, a comprehensive regulatory system. In the transatlantic market, if both the U.S. and EU recognize and incorporate these core principles into their respective regulatory frameworks, the frequency and degree of divergence among regulations should be significantly reduced:

a. Transparency

The Chamber views transparency as an essential element of any regulatory process. Transparency entails the regulator making available to the public in a timely fashion all relevant information that serves as the basis of a regulatory decision. Transparency enhances the confidence of interested stakeholders, and strengthens the legitimacy of the regulatory process and outcome. Consequently, all regulatory rules and policies, and the analyses behind those rules and policies, should be a matter of public record.

Transparency is also a key component of good government because it reduces the probability that interested stakeholders, especially those adversely affected by a regulatory decision, will believe that decisions are biased or discriminatory. When regulatory decisions, including the underlying analyses and evidence that guided them, are clearly presented on the public record, the reasons for a regulatory decision will be apparent. Transparency makes all parties—the regulator and the regulated—better actors.

In the U.S., a myriad of laws, executive orders, circulars, and bulletins ensure transparency remains part of the regulatory process. Federal agencies are required to publish in the Federal Register, not just the proposed rule, but the supporting justification for the rule and the entire analytical process behind it.

At the international level, the Organization for Economic Co-operation and Development (OECD) has made great strides in promoting regulatory transparency among its member nations, particularly with the rise of the governance agenda. Transparency initiatives now form a major part of the regulatory policies of many OECD countries, with the majority of OECD member nations having issued government-wide transparency policies.

Despite the existence of such policies, however, and the fact that many OECD members are also EU member countries, much of the EU regulatory process does not lend itself to transparent rule-making. As such, the Chamber recommends that greater efforts to incorporate transparency into the EU regulatory process be made.

b. Stakeholder Involvement

Perhaps the most important part of any regulatory process is ensuring that the public has the opportunity to participate in the policymaking process. This

participation allows the public to have a voice in the making of the laws and rules that regulate them. Public participation protects citizens from arbitrary decisions by agencies by enabling citizens to effectively engage in the rulemaking process.

In the U.S., the Administrative Procedure Act guarantees that interested stakeholders will have a voice in the regulatory process. The EU has a number of "better regulation" procedures and guidelines, but no effective equivalent to the APA. Recognizing that the U.S. and EU have become each other's most important stakeholders, both sides must agree that the other will have an opportunity, method, and forum for participating constructively in the regulatory process.

c. Sound Science

Reliable data should the backbone of every rule and regulation. It is axiomatic that the better the data, the better the regulation. Therefore, efforts to improve the underlying science or data are ultimately efforts to improve the quality and effectiveness of regulation.

Sound science is a term-of-art typically used to contrast "junk" science, or analysis that is not based on credible, verifiable evidence. Sound science is also peer-reviewed science—where methods and conclusions are critically examined and verified by other scientists. Requiring thorough and consistent peer review of important scientific and technical information early in the information development process is critical to ensuring sound science. Peer review is also fundamental to making certain that the data underpinning regulatory decisions are based on credible evidence and rigorous technical analysis.

In the U.S., OMB's Final Information Quality Bulletin for Peer Review enhances the practice of peer review of government scientific documents and helps ensure the quality of published information. Similarly, the EU has issued principles and guidelines on the Collection and Use of Expertise. Nevertheless, both the U.S. and EU must do a better job of incorporating sound science into their analytical processes in order to effectively reduce regulatory divergence.

d. Data Quality

Any decision based on inaccurate or incomplete data is inherently flawed. That is why it is important to ensure that regulatory decisions are based on good quality data.

In the U.S., the Information Quality Act (IQA) compels federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of disseminated information. In other words, agencies must do their best to make sure the data they use is right. The IQA also establishes a system whereby interested parties can seek correction of erroneous, disseminated information.

The Chamber has been a strong proponent of the IQA because, by utilizing sound data, we can be assured that regulators are focusing our resources on the problems that need to be addressed, and that their decisions are based on good quality information. The IQA could be greatly improved by making agency decisions under the IQA judicially reviewable.

The EU should likewise mandate that its regulators use the highest quality data available in crafting rules or regulations. Poor quality data will result in ineffective regulations, and ultimately detracts from the credibility of the rule-makers. Data quality must be a core principle of any regulatory framework, and the U.S. and EU can incorporate this principle by agreeing: (1) to a uniform definition of data quality; and (2) to set up a joint technical review body that would constantly work to improve data collection and management, as well as provide expert judgment on what constitutes quality data should any disagreements arise.

e. Cost-Benefit Analysis

Cost-benefit analysis is a policy-making tool used by federal agencies to assess the expected costs and benefits of a proposed regulation. In the U.S., federal agencies are mandated by executive order to conduct cost-benefit analyses for proposed major rules.

Agencies currently use *ex ante* studies to conduct cost-benefit analyses. *Ex ante* studies are pre-regulation forecasts of what the agency predicts will happen once a rule takes effect. Unfortunately, *ex ante* studies are an inadequate form of economic modeling for assessing the costs and benefits of regulations because they do not present the public with a reasonable and true account of the costs of regulatory impacts. For example, e*x ante* studies do not account for rules originally deemed to be minor by an agency but which later end up having major impacts. As a result, projected costs and benefits of new regulations are often inaccurate and end up costing businesses significant time and money in regulatory compliance costs.

The Chamber also recommends using *ex post* validation studies, which would require agencies to assess the actual costs and benefits of a regulation after it has gone into effect, and therefore would more accurately identify the true regulatory burden on the public. Validation studies will also help demonstrate whether initial agency forecasts were sound, thereby engendering greater public confidence in the regulatory process.

The Chamber believes some form of cost-benefit analysis must be part of both the U.S. and EU regulatory process. A rule or regulation that imposes significant costs on economic activity —with little or no corresponding benefit—only serves to harm transatlantic commerce.

III. Specific Comments

The Joint Paper also requested specific feedback on four discrete topics.

1. **Both sides value the timely announcement of planned legislative and regulatory initiatives, and of transparency concerning upcoming corresponding impact assessments. In this context it is desirable to establish ways to indicate whether a planned regulatory or legislative initiative, might have an impact on transatlantic commerce, or might otherwise be of interest to U.S., EU third countries.**

More important than the process by which you determine impacts is ensuring that stakeholders have the ability to assess the underlying reasons (social, political, technical, etc.) for a particular regulation. Nevertheless, improving methodologies for assessing international impacts is critical to reducing regulatory divergence.

One possible improvement would be the creation of a single, publicly accessible Web site that posts all proposed rules and regulations by either the U.S. or EU. Such transparency will greatly enhance stakeholder involvement. In the U.S., an electronic version of the Unified Agenda—used by many agencies to satisfy the requirement that proposed rules be published and publicly available—provides similar transparency and works as an early barometer of regulatory considerations.

Also, the U.S. Department of Transportation (DOT) has an electronic database that identifies and categorizes regulatory impacts to key trading partners, including the EU. This database is unique to DOT when it should be standard across all government agencies, and it could serve as a model for both the U.S. and EU. Such a

searchable database would greatly enhance our ability to identify and assess transatlantic market impacts.

2. **Both sides underline the importance of having their impact assessment methodologies and procedures incorporated into a transparent set of rules or guidelines that are accessible to the public, accompanied by a rigorous system of quality control. In this context it is crucial to have public consultation and notice and comment mechanisms in place that give the authorities, businesses, and citizens of the, EU, U.S. and third countries the opportunity to voice solicited or unsolicited comments on planned initiatives, and to reflect their input in impact assessment and impact analysis reports.**

Both sides should have sufficient time, opportunity, and ability to respond to proposed regulations. The EU has as guidance a timeline of six weeks for comment. However, since it is merely guidance and not a requirement, the Commission has in several instances decided to go against its own guidance and offer much shorter windows of opportunity to comment. This effectively limits the opportunity for substantive public input into the regulatory process, and runs contrary to good governance principles.

Additionally, the EU's comitology system, through which implementing measures of existing legislation are approved by regulatory committees of national experts working with the Commission, could also be improved by requiring impact assessment and stakeholder consultation. This would also provide another avenue for mitigating adverse impacts on third countries, trade and investment.

Equally important, both sides should have recourse to redress their objections. It is easy to conceive, for example, of a situation where either the U.S. or EU disagrees with the other's decision regarding the impact of a regulation. The EU may see a U.S. regulation as having an adverse impact on EU businesses. If the U.S. disagrees and moves forward, shouldn't the EU have the opportunity to redress such a decision?

3. **Both sides are committed to make their proposed policies and accompanying impact assessments public, which will allow the other side to respond if it expects international trade and investment issues to be significant. The results of relevant underlying technical analysis and data should generally be published or otherwise made available.**

Agreed. All policies and assessments must be publicly available. Likewise, all peer reviewed scientific information and technical analyses that form the basis of the assessments should be required to meet the same levels of transparency. In fact, both the U.S. and the EU should release cost-benefit analyses/impact assessments for comment in advance of releasing proposed regulations for comment.

4. **As regards methodologies concerning the impact on trade and investment *per se*, both sides have identified possible elements for consideration in their respective rules and guidelines for impact assessment. In particular, if preliminary analysis suggests that a proposal might significantly affect international trade and investment, guidance should be provided on the type of analysis that would be useful to make decision makers aware of the international impacts. This could include:**

    - **an analysis demonstrating the need for any proposed regulation that might directly impede international trade or investment,**
    - **an analysis of the degree in which different groups (foreign and domestic businesses and consumers) are affected by such a proposal or**
    - **a recommendation that existing international standards or regulatory approaches, if applicable, should be analyzed as an explicit regulatory alternative.**

Neither the U.S. nor the EU methodologies for assessing the international impact of regulations is adequate.

The U.S. ostensibly requires agencies to consider impacts "beyond the borders of the United States," and suggests that rules acting as non-tariff barriers be "carefully evaluated." [1] In practice, however, agencies typically assess just the domestic impact of regulations and there is little enforcement of agency mandates to consider international impacts. Moreover, agencies are given little guidance on how specifically to determine whether a rule will act as a non-tariff barrier to commerce, what kind of analysis should be conducted, or when a rule is likely to hinder trade and investment.

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1 OMB Circular A-4

The EU methodology is likewise inadequate. Due to its unique, multi-state structure, the EU does provide—through its Impact Assessment Guidelines—technical guidance on what and how to assess impacts on global commerce. Nevertheless, impact assessments are imperfect vehicles, relying on causal chain analysis as a tool of assessment. Furthermore, the Impact Assessment Board has no institutional authority to enforce a methodology or stop a bad regulation, and therefore provides no real check on the system. While the U.S. system provides for numerous checks—from OIRA, to the Congress, to the courts—they have been slow to enforce mandates to consider international impacts.

IV. Additional Approaches

In addition to the general recommendations stated above, the Chamber notes that there are additional steps that need to be taken to ensure that U.S. and EU regulators properly consider the international impacts of regulations.

a. Paradigm Shift in the Mindset of Regulators

Regulators by nature have had a historically domestic mindset. In the U.S., regulatory agencies were created decades ago to regulate a marketplace that had minimal ties to the rest of the world. Today's global markets have changed all of that; yet regulators continue to remain narrowly focused on domestic markets.

The extraterritorial impact of domestic regulations is often overlooked or hardly understood. Part of the reason for this is that regulators do not believe that their responsibilities include trade facilitation. If, however, a regulator is arguably required to achieve its regulatory objective in the least market-distorting manner possible, it must take into account trade and investment.

The report does highlight several examples of where regulators took into account potential impacts to trade and investment. Yet these isolated examples are not representative of the vast majority of regulations. Rather than allowing regulators to operate in an ad hoc fashion, a systematic process is needed whereby regulators will be required to consider international impacts as a matter of course.

A paradigm shift from a domestic focus to a more international focus needs to occur to transform the regulatory practices on either side of the Atlantic. Regulators need to apply regulatory best practices like transparency and stakeholder input along

with risk and economic based methodologies in a consistent manner that takes into account international trade and investment.

The Chamber believes that a first step in such a paradigm shift would be for both the U.S. and the EU to issue a memorandum on regulatory consideration of trade and investment across the Commission and the U.S. government. As part of the memorandum, the EU's Impact Assessment Board should require impact assessments to have a specific portion of the assessment dedicated to the examination of international best practices in a regulatory area as well as an articulation of the international considerations taken by the Commission. Likewise, OMB should underscore with U.S. agencies the importance of its Circular A-4 on Regulatory Analysis issued in 2003 that raises consideration of regulations as potential non-tariff barriers. U.S. agencies should explicitly indicate any international trade and investment impacts as part of its cost-benefit analysis as well as identify any international regulatory best practices considered. Finally, the scope of OMB Circular A-4 should be expanded beyond imported goods to include services.

OMB readily admits in the draft report that Circular A-4 does not offer any guidance as to how regulators are to consider international trade and investment effects. As such, it would be helpful for both the Impact Assessment Board and OMB to issue a better definition of what constitutes trade and investment. Too often trade and investment are narrowly defined as what is exported or imported. Improved definitions will hopefully lead to a greater understanding by regulators of the impact their decisions have on global commerce.

b. Binding International Agreement

Looking forward, the Chamber believes that a legally binding agreement on regulatory cooperation ("ARC") signed between the U.S. and the EU would permanently set in place many of the components that we are advocating in these comments. The ARC would also provide much needed political oversight, a clear mandate, and the funding necessary to achieve effective regulatory cooperation between the two continents. Finally, we believe that the U.S.-EU ARC would have beneficial "halo" effects on other important commercial relationships, and provide compelling model for international regulatory cooperation.

Past efforts to bring about regulatory cooperation between the U.S. and the EU have been largely informal, non-binding dialogues – mostly focused on existing regulations. The Chamber believes that a new approach is needed. Rather than

focusing on existing regulations, the rule-making processes within the transatlantic market need to be the focus of a new legally binding regulatory cooperation agreement.

With an ARC in place, U.S. and EU rule-makers would operate under a common set of regulatory principles and core beliefs. The ARC would include: 1) a commitment to require rule-makers to assess the cost/impact of forthcoming regulations on transatlantic commerce; 2) a requirement to minimize divergence of future regulations by adopting each others best practices and where there are disagreements in regulatory approaches, a requirement for regulators to state the justification for the divergence; 3) an agreement on the methodology of cost/impact assessment, particularly the compilation, quality, and processing of data for regulatory purposes; 4) an agreement on key principles of transparency and a process that includes the opportunity for regulatory agencies and industries on both sides of the Atlantic to comment; and 5) some post-implementation review.

We believe the ARC would bridge differences and prevent costly divergences across the Atlantic. We project that the ARC would translate into significant cost savings and new commercial opportunities benefiting the global economy and the transatlantic consumers.

V. Conclusion

In summation, the Chamber recommends the following: (1) that the U.S. and EU use comparable standards to propose and justify regulations, and (2) that each consider the impacts of regulations to the other side. By incorporating the core principles discussed in these comments into the regulatory process, both the U.S. and EU will reduce the frequency and degree of divergence among their rules and regulations. Such efforts will ultimately promote transatlantic commerce, while simultaneously setting the stage for an improved—and unfettered—global marketplace.

The U.S. Chamber thanks you for the opportunity to comment on this report, applauds the work of the High-Level Regulatory Forum.

Below is a summary of specific recommendations made in these comments:

- Both the U.S. and the EU regulatory systems should allow stakeholders to challenge the underlying rationale (social, political, technical, etc.) for a

particular regulation, not simply comment on the impacts of a potential regulation.

- Both the U.S. and EU should make greater efforts with regard to transparency and generate more opportunities for stakeholder input early in the regulatory process. The EU also needs to heed its own guidance when it comes to the suggested six week comment period and would benefit from making the comment period mandatory. Finally, the transparency of the comitology process needs to be addressed.

- In the U.S., agency decisions under the IQA should be made judicially reviewable. The EU should likewise mandate that its regulators use the highest quality data in crafting rules or regulations. The U.S. and the EU should work together to develop joint criteria in support of data quality.

- Promote the use of *ex post* validation studies, which would require agencies to assess the actual costs and benefits of a regulation after it has gone into effect, and therefore would be a good first step in accurately identifying the true regulatory burden on the public. The High-Level Regulatory Forum might take this on as a pilot project.

- Creating a single, searchable, publicly accessible Web site that posts all proposed rules and regulations by either the U.S. or EU.

- Both sides need to find a better mechanism in the regulatory process to provide recourse to redress any transatlantic objections.

- Both the U.S. and the EU should release its cost-benefit analysis/impact assessment for comment in advance of releasing proposed regulations for comment.

- The U.S. and EU should provide greater guidance to regulators on what it means to account for impacts on trade and investment.

- The EU's Impact Assessment Board should require impact assessments to have a specific portion of the assessment dedicated to international considerations, including examination of international best practices.

- OMB should underscore with U.S. agencies the potential of regulations to act as non-tariff barriers. U.S. agencies should indicate any international trade and investment impacts in a special section of its cost-benefit analysis and also address international best practices.

- The scope of OMB Circular A-4 should also be expanded beyond imported goods to explicitly include services.

- The Impact Assessment Board and OMB should issue a definition of what constitutes trade and investment.

- Looking forward, the Chamber believes that a legally binding agreement on regulatory cooperation between the U.S. and the EU would permanently set in place many of the components that we are advocating in these comments.

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