Comments of the United States on the
European Commission's Draft Chemicals Regulation

Introduction

As a major economic and political partner of the European Union (EU), the United States is keenly interested in the EU's development of a new, comprehensive regulatory framework for chemicals. As chemicals are used in some manner in the production or use of most products, the European Commission's proposal could affect the majority of U.S. goods exported to the EU ($143 billion in 2002). We therefore welcome the opportunity to provide comments on the European Commission's draft Chemicals Regulation to implement its REACH (Registration, Evaluation, and Authorization of Chemicals) framework.

The Commission's ongoing public comment period on this important regulation represents a constructive and noteworthy step. We are encouraged that the Commission is seeking public comments on its draft EU Chemicals Regulation and pleased that all interested parties, including non-EU stakeholders, have an opportunity to provide comments. In our experience, we have found that the regulatory process is improved by broadly applying public notice and comment procedures since it helps ensure that all relevant viewpoints and information are considered, resulting in more effective and practical regulation. We also look forward to reviewing the Commission's impact assessment when completed, as this too is an important tool in developing quality regulation.

As we noted in our extensive comments last year on the European Commission's "Better Regulations Package," the United States supports the Commission's objectives of improving the quality of EU regulations and making its regulatory process more transparent (see http://europa.eu.int/comm/secretariat_general/sgc/consultation/docs/cont_us.pdf). We look forward to a continued constructive dialogue with the European Commission as it finalizes its proposal.

Overview

The United States shares the EU's interest in ensuring robust protection of the environment and human health. These are objectives we achieve through our domestic regulation and through our active participation in activities to promote international regulatory cooperation and harmonization in the area of chemicals. We are also engaged in a constructive bilateral regulatory dialogue and technical exchange with the European Commission on approaches to the regulation of chemicals.

The United States also appreciates and supports the EU's interest in gaining information on chemicals currently in use, in facilitating the introduction of new, greener and safer chemicals, and striving to improve the EU-wide system for regulating chemicals.

We are concerned, however, that the European Commission's draft chemicals regulation appears to adopt a particularly costly, burdensome, and complex approach, which could prove unworkable in its implementation, adversely impact innovation and disrupt global trade. The proposal also appears to discount substantial and ongoing resource constraints facing governments and industry. In this respect, the Commission's proposed regulatory approach raises fundamental questions about its workability -- and thus its ability to effectively achieve its health and environmental policy objectives.

There are a number of key concerns that the United States has regarding the workability of the Commission's draft regulation. Among these concerns, we highlight the following: the proposal establishes a generally unworkable regulatory approach; departs from ongoing international regulatory cooperation efforts; imposes substantial costs with uncertain benefits; adversely impacts small and medium sized enterprises (SMEs); disrupts global trade; adversely impacts innovation; creates market uncertainties; provides unclear administrative coordination and consistency; and raises concerns regarding consortia and data sharing.

Given the broad scope and implications of the proposal, this draft EU regulation is of much interest and concern to many of the EU's trading partners. We also note that a number of European studies of the Commission's regulatory approach have forecasted substantial adverse impacts for European economies and employment (MERCER, Arthur D. Little). It is important that the implications –- both positive and negative -- of the Commission's regulation be accurately and fully assessed.

Key Elements of Concern

<u>Unworkable Regulatory Approach</u>

X The complex regulatory approach outlined in the Commission's draft regulation raises fundamental questions about its workability -- and thus its ability to effectively achieve its health and environmental policy objectives. In our view,

the Commission's proposal, while an improvement in some respects compared to the approach outlined in the White Paper, would be difficult, if not impossible, to implement in an efficient and effective way.

X As currently drafted, the Commission's proposal, even with its phase-in periods, would impose substantial costs up front, whereas benefits would be realized slowly due to the sheer enormity of the program.

X The Commission's proposal imposes a stringent regulatory regime on thousands of uses of chemical substances that pose little risk to health or the environment. Our assessment is that the proposal's focus on tens of thousands of chemicals, polymers, intermediates, and the inclusion of articles is overly broad and fails to focus on substances likely to pose the greatest risks to human health and the environment.

X Implementation of this overly broad approach will prove problematic given staffing and resource constraints. For example, the Commission (Orientation paper) estimated that EU testing capacity is sufficient to meet only 25-30% of the required testing under this proposal over the first ten years. Therefore, the implementation timeframe is overly optimistic and/or the expected costs of testing are substantially underestimated. This limitation on EU testing capacity also underscores the importance of establishing a transparent mechanism for the broad acceptance of data from non-EU test labs and sources. It also underscores the need to use a category approach to evaluate existing chemicals.

X We believe that resources should focus on chemicals and chemical uses likely to pose the greatest health and environmental risks. We support Commission consideration of alternatives to better target resources.

X In this respect, we suggest a more limited treatment of certain types of chemicals (e.g., certain polymers, intermediates, and chemicals that are constituents of articles) due to their low intrinsic hazard, low exposure potential, or adequate coverage under existing laws and regulations. For substances that are not excluded, the approach should focus on substances where there is a demonstrated potential for significant risk. Such a focus would simplify tasks, conserve government and industry resources, and allow the largest potential benefits to be realized quickly. We recognize and encourage the EU's

ongoing consideration of mechanisms that would yield a more cost-effective regulation.

X Reduced animal testing -- an outcome consistent with EU animal welfare objectives –- would be an additional benefit of a more focused approach.

X Regarding animal and other testing, it appears that the registration and pre-registration requirements, and the substance information exchange fora (SIEF) provisions may not ensure that certain data in the hands of lower production volume chemical producers would be made available to persons involved in SIEFs covering higher production volume producers. Because of the animal welfare concerns associated with requiring testing in areas where there are existing data, mechanisms could be investigated to provide authority to allow the collection of available hazard data in one step across all production volume triggers to avoid, for example, the need for persons in early tiers (e.g., a high volume producer) to conduct testing that already exists and that may be in the hands of a person in a later, lower production tier (or a processor).

X The authorization process with its hazard-based approach presents a potentially large and complex challenge. Attempting to make authorization decisions for a significant number of chemicals and a myriad of uses (application and user specific) is likely to be difficult and time-consuming. We encourage the Commission to consider ways to reduce further the scope and simplify the task.

X One such approach for authorizations could involve European authorities taking risk-based, Community-wide actions to allow, with appropriate controls, lower-risk uses of chemicals subject to authorization –- rather than requiring a separate authorization from each entity for each use. This approach could help focus the scope of the authorization process to more serious risk issues, while providing a consistent foundation for controlling lower risk exposures and uses on a EU-wide basis (and retaining the EU’s general provisions for “restrictions” of chemicals).

X The authorization process should be informed by the information developed under the registration and evaluation stages. The proposal’s procedures and timeframe for authorizations should permit data developed under

registration and evaluation to be considered by the authorities when making authorization decisions.

X We also note concerns about the overlap between this chemicals regulation and other existing EU regulations addressing chemicals in the use and disposal of articles, e.g., End-of-Life Vehicles (autos), Waste from Electrical and Electronic Equipment (WEEE), Restrictions on Hazardous Substances (RoHS). Rather than clarifying the EU's regulatory environment, this draft regulation appears to impose overlapping requirements and create additional market uncertainties in the treatment of articles.

Departs from Ongoing International Regulatory Cooperation

X In our view, the Commission proposal does not adequately recognize ongoing international efforts designed to address risks posed by existing chemicals. Many of these programs show considerable promise in achieving their objectives. The Commission approach should supplement, not supplant, these ongoing efforts.

X We continue to support multilateral efforts in the OECD to promote greater international regulatory cooperation and harmonization in the area of chemicals. We note that the Commission's approach in developing its proposal has departed from this ongoing OECD cooperation.

X We suggest that the Commission approach should be consistent with international efforts and seek to complement activities that are underway at the national and international level to address the testing needs and risks posed by existing chemicals. We are concerned that the Commission's proposal imposes an approach that could undercut progress achieved to date under these other programs, such as the OECD Screening Information Data Set (SIDS) program and the ICCA HPV initiative.

Imposes Substantial Costs/Uncertain Benefits

X The costs to implement the Commission's proposed regulation are substantial, yet the economic implications of this proposal have not been fully and transparently assessed. The Commission's own cost estimates for its proposal total 18-32 billion euros, and do not take into account effects on prices, international competitiveness and employment.

X European studies conducted assessing the economic impacts of REACH on the French and German economies (MERCER and Arthur D. Little, respectively) have underscored substantial adverse effects on European economic growth and employment.

X We also note that the costs of complying with REACH could negatively impact EU competitiveness and foreign investment. Contrary to the EU's Lisbon goals (creating the most competitive world economy by 2010), the draft regulation will actually impede EU economic growth and industrial competitiveness.

X Expected benefits under this regulation will be adversely affected if the regulation is not workable. The Commission-sponsored study (Risk & Policy Analysts (RPA)) quantifies projected health benefits based on the following assumptions: that all data will be developed and provided within the prescribed timeframe in the White Paper, that submitted information is sufficient to identify each specific chemical associated with certain occupational illnesses, that the relevant authorities evaluate the data as soon as it is submitted, and that risk management actions are implemented promptly and are completely (and, in some cases, instantaneously) effective. If these assumptions are not accurate, then the estimated benefits identified in the report could be inflated.

X We recommend that the Commission make changes to the policy to ensure its workability, and then undertake a new assessment of costs and benefits to reflect this revised proposal. As it stands, the assessments sponsored to date are based on heroic assumptions regarding implementation, and the estimates of costs and benefits are not reliable because of these assumptions.

<u>Adversely Impacts SMEs</u>

X Small manufacturers, who account for the majority of the EU chemicals and U.S. industry, would face a disproportionate burden in complying with REACH. Some EU and foreign manufacturers of chemicals and downstream products may simply exit the EU market, reducing efficiency and competition. Finding ways to reduce the regulatory burden will be important in assuring continued SME access to this market.

<u>Disrupts Global Trade</u>

X The proposed approach could adversely impact production and transatlantic trade in tens of billions of dollars in chemicals and downstream products -- from autos to textiles. Given the use of chemicals in most manufactured goods, the majority of U.S. exports of goods could be impacted by this proposal. We are concerned that the broader economic implications are not being adequately assessed.

X To illustrate the enormous potential scope of this regulation on articles, the Commission-sponsored business impact assessment (Risk & Policy Analysts (RPA)) states that 500,000 to 5 million different articles types are on the EU market -- with an average of 10-50 substances per article. This proposal would impose burdensome analytic, reporting and administrative requirements on downstream users -- especially for overseas manufacturers of articles.

X Downstream users of chemicals are especially concerned that this regulatory approach could significantly disrupt global supply chains. Manufacturers of chemicals for many applications may halt production where demand does not justify registration and testing costs.

X The Commission acknowledges that thousands of chemicals will be withdrawn from the market under its proposal. Product withdrawals are a key factor for analyzing impacts on downstream users in particular. Users stress that generally the withdrawal of specific chemicals will necessitate a re-formulation and redesign of products -- involving time and additional costs, and the possibility of new risks to human health and the environment.

Adversely Impacts Innovation

X High compliance costs likely will negatively impact innovation and hinder the introduction to the EU market of more effective and safer new chemicals and downstream products.

X We note that the Commission's assessment of the business impacts (RPA report) states that impacts on innovation are expected to be negative in that both money and expertise normally devoted to product development and innovation will instead be focused on addressing the potential for and impacts of the rationalization of substances. While the Commission proposal increases EU production triggers for the

testing of new chemicals, the shift to a pre-manufacture reporting regime with continued high up-front costs would likely mean that innovation and the introduction of new chemicals would occur increasingly outside the EU.

X Chemicals R&D work is an especially productive activity. This productivity likely will be reduced under the Commission's proposal as R&D resources are re-directed toward gathering and evaluating data on low-risk substances.

Creates Market Uncertainty

X The regulation does not provide sufficient information detailing how decisions will be taken regarding the regulatory treatment of various chemicals. This lack of clarity will likely create uncertainty in the market, affecting not only the chemicals industry but downstream users as well.

X For example, it is unclear which chemicals -- and which uses -- will be subject to restrictions, either through the evaluation process or during the authorization process. Uncertainty is twofold: it stems from the complex process involving member state authorities, the Commission, and the new agency in making such decisions, as well as an unclear regulatory standard (i.e., whether or not industry can "demonstrate that the risk from the use of a substance can be adequately controlled or that the socio-economic benefits outweigh the risk.")

X In addition, uncertainty is created by the proposal's unclear treatment of articles and the requirement to register substances in articles "if sufficient amounts of the substance are released to pose a risk to human health and/or the environment."

X The Commission should clarify the regulatory standard envisioned for chemicals. Such clarification would assist business decision-making related to innovation and overall supply chain management. Clarification would also assist the Commission in its efforts to create a regulation, which targets chemicals of greatest concern, and better define the costs and benefits of the REACH system.

Unclear Administrative Coordination and Consistency

X Depending on the specific activity under this draft regulation, the Central Agency, EU Member States, and/or the Commission are responsible for action. The administrative coordination for this regulation is complex, and not entirely transparent for stakeholders. Also, there appears to be the serious potential for a lack of centralization and consistency in implementation and enforcement of the regulation across Member States. This lack of consistency in regulatory implementation could undermine the integrity of a single EU-wide market, as well as the EU's health and environmental objectives.

Concerns Regarding Consortia and Data Sharing

X The draft regulation appears to require innovating companies who have submitted business confidential test data to the authorities in order to register a certain class of substance to disclose these data to their competitors under certain circumstances. In these circumstances, it is not clear that the innovating company has an opportunity to prevent this information from being disclosed. For instance, it appears that where the innovating company is unable to reach an agreement with its competitor to share test data, the Member State Competent Authority will itself disclose the data and require the innovating company to seek compensation from its competitor.

X Further, although the proposed regulation anticipates that the innovating company will be "compensated" for this apparent forced disclosure, it is not clear that this compensation is adequate. The regulation anticipates that the competitor will pay 50% of the "cost incurred" by the innovating company. However, this 50% may only amount to a fraction of the overall testing costs of the innovator -- which may include unfruitful testing of numerous products -- and does not compensate the innovating company for taking the risk of testing a new product.

X In addition, although the proposed regulation anticipates that companies submitting data can apply for confidential treatment of their data, the standards for what may be considered confidential may be unnecessarily exclusive. Notably excluded from the category of confidential information is "any information, which, if withheld, might lead to animal experiments being carried out". Such a standard may not give submitting companies much confidence that their confidential data will be protected.

- X Finally, it is unclear whether, if a company disagrees with a decision on confidentiality, there is a right of administrative or judicial appeal.

Concluding Remarks

As our comments have outlined, the Commission's draft regulation appears to adopt a particularly costly, burdensome, and complex approach, which could prove unworkable in its implementation, adversely impact innovation and disrupt global trade. To better achieve its objectives, we strongly encourage the Commission to: 1) reduce the scope of aspects of the regulation to better focus EU resources on substances that are likely to pose the highest risks; 2) develop an EU approach which supplements -- and does not supplant -– ongoing international cooperative efforts to effectively address the risks posed by existing chemicals; 3) clarify and simplify the process by which regulatory decisions will be made; and 4) ensure that the EU regulation's impacts – both positive and negative -- are fully and transparently assessed. The Commission should also ensure that its final proposal is fully consistent with the EU's international obligations.

Transparency is key to achieving a balanced, effective regulatory approach. Given the scope, far-reaching implications and global interest in this extensive regulation, we urge the Commission to provide sufficient time for a thorough and meaningful consideration of all public comments received, including an explanation for how comments were addressed in its final proposal. Following the comment period scheduled to conclude on July 10, it will be important that the Commission allow adequate time for making revisions to its proposal that will improve the effectiveness of the regulation in protecting health and the environment without imposing unnecessary costs on trade, employment and innovation.

Before finalizing its proposal, we urge the Commission to conduct an extended impact assessment, consistent with its Better Regulations initiative, including addressing the impacts on downstream users and future investment and innovation. The extensive impacts of this proposed regulation on EU and international stakeholders merit a full and comprehensive assessment, based on realistic assumptions as to how the program will be implemented.

We remain interested in cooperative engagement with the EU on this important issue.

Annex: Questions/Issues Relating to Selected Unclear Provisions

The following are a number of specific questions that relate to selected points of the draft regulation where the provisions are unclear as to how they are to be implemented and/or enforced.

1) Do certain provisions and definitions that apply to substances and preparations also apply to substances and preparations that are components of articles? See, for example, the definitions at points 2.11-2.13, 2.16, 2.17, and the obligations in points 4, 5, and 6. We do understand that registration is limited for substances in certain articles under point 64.

2) Regarding point 2.11, what is a consumer? Are persons that use articles to produce other articles (e.g., a computer manufacturer) considered to be downstream users of each of the substances that are components of each of the articles they use?

3) Regarding point 11 on information submitted for registration purposes, how are subject persons to define intended uses? For example, how specifically need a person describe the use?

4) The exemption from the registration requirement for certain polymers, while helpful in reducing lower-priority work, is likely to be confusing and complicated. Given the nature of polymers and the fact that the requirement is manufacturer-specific, it appears that it could result in perhaps an unanticipated number of registrations for a given polymer (e.g., made up of monomers A, B, C, and D). This could also be an area with ongoing registrations for a given polymer as market demands require forms of the polymer and production volumes change, accordingly. Enforcement will also be very difficult.

5) Regarding the point 20 registration and point 29 pre-registration requirements, and the development of point 30 on substance information exchange fora (SIEF), are there any concerns that certain data in the hands of lower production volume chemical producers would not be made available to persons involved in SIEFs covering higher production volume producers, especially in light of different registration timing but also the different data requirements for persons producing different amounts? Because of the intrinsic nature of hazard data and animal welfare concerns associated with requiring testing in areas where there are existing data, are there ways to obtain hazard data in one step across all production volume triggers to avoid, for example, the need for persons in early tiers (e.g., a

high volume producer) to conduct testing that already exists and that may be in the hands of a person in a later, lower production tier (or a processor)?

6) Under point 21, how will significant change in the annual or total quantities be determined by subject persons and judged by persons enforcing the provision?

7) Regarding point 31, when data have been paid for by several registrants, are subsequent registrants that use the data liable to pay each of the persons that has already contributed to the cost of the testing? Exactly how will the cost sharing mechanism work?

8) Regarding points 32-34, if a downstream user receives different information from different suppliers, can the downstream user pick and choose what information to rely on in deciding what its obligations are (e.g., under point 32.5)?

9) The criteria for authorizing uses of chemical is not clear. Point 48.2 indicates that an "authorization shall be granted if the risk to human health and the environment from the use of a substance arising from the intrinsic properties in Annex XIII is adequately controlled. What "adequately controlled" means is not apparent. Also no intrinsic properties are included in Annex XIII -- which is a currently blank listing of substances subject to authorization."

10) Also regarding authorization, point 48.8 states "notwithstanding any condition of an authorization, the holder shall ensure that the level of exposure is reduced to as low as is technically possible." How “as low as technically possible” will be interpreted is not clear, e.g., given that it would likely be possible to reduce exposure to zero by not producing or using the substance, will a person be out of compliance if there is any exposure associated with its activities? Irrespective of risk, such a provision is likely to be very costly and of questionable benefit.

11) How the point 64 "article exemption" (which exempts from the duty to register certain substances in articles) will be interpreted/applied is not clear. Will the production volume threshold apply for articles cumulatively by producer or importer or on an article-by-article basis? Also, how "release in sufficiently high amounts and in such a way to adversely affect human health or the environment" will be interpreted, applied, and/or enforced is unclear. The disposal practices for articles

will be particularly difficult to understand, especially for importers. The issues associated with the proposed approach for articles, while it represents an improvement over the approach proposed in the White Paper, are substantial such that its workability is questionable.

12) How certain aspects of the Annex IX "Rules for Adaptation of the Standard Testing Regime . . ." will be implemented is not clear. See especially Annex IX.3 on "Substance Tailored Exposure Driven Testing" which suggests that certain vertebrate animal testing may be omitted based on exposure scenarios documented in Chemical Safety Reports if adequately justified and documented. Will there be criteria developed to better define situations where testing can be omitted?