U.S. Submits Comments on EC's Reach Proposal To WTO Committee
Date: June 21, 2004
http://www.useu.be/Categories/Evironment/June2204USREACHComments.html

Below are U.S. Government comments on the EU's REACH proposal that were submitted to the World Trade Organization's Technical Barriers to Trade Committee:

Comments of the United States on Notification G/TBT/N/EEC/52
Regarding European Commission Regulation COM(2003) 644

Introduction

1. The United States appreciates this opportunity to comment on the European Commission's proposed Regulation COM(2003) 644 of 29 October 2003, concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH), which was notified to WTO Members in G/TBT/N/EEC/52 of January 21, 2004 and G/TBT/N/EEC/52/Add.1 of March 10, 2004.

2. We applaud the European Commission (EC) for submitting a WTO TBT notification for its REACH proposal at this stage of the EU regulatory process -- i.e., before the EU Council adopts its common position. This represents a welcome step in providing a more meaningful opportunity for interested WTO Members to provide comments, consistent with the EU's transparency obligations under the TBT Agreement.

3. We urge the Commission to provide a meaningful consideration and response, not just for written comments from WTO Members, but for all substantive written comments it may receive from interested parties in response to this notification. The Commission's constructive Internet consultation on its May 2003 public draft regulation demonstrated clearly that there is strong global interest and concern about this particular draft EU regulation.

4. The United States remains keenly interested in the development of the EU's new, comprehensive regulatory framework for chemicals (REACH). As chemicals are used in some manner in the production or use of most manufactured products, and the full scope for implementation of the regulation is not clear, the current proposal could affect the majority of U.S. goods exported to the EU (over $150 billion in 2003). With the May 1, 2004 expansion of the EU to 25 countries, the potential impact on US-EU trade will be even greater.

5. The United States shares the EU's interest in ensuring robust protection of the environment and human health. Our societies demand that we achieve these objectives. 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.

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

7. We are concerned, however, that the European Commission's draft chemicals regulation still appears to adopt a particularly costly, burdensome, and complex approach, which could prove unworkable in its implementation, disrupt global trade, and adversely impact innovation. The proposal also appears to discount substantial resource constraints facing governments and industry.

8. In our view, despite a number of welcome modifications, the Commission's October 2003 proposal continues to raise fundamental questions about its workability -- and thus its ability to

effectively achieve its health and environmental policy objectives. Many U.S. concerns about the Commission's approach, as outlined in our detailed July 2003 comments, remain (see http://www.useu.be/Categories/Evironment/July1003USEUChemicalsComments.html). We note that some EU governments have articulated similar concerns about the workability and uncertain economic implications of the Commission's proposed REACH approach. We also note that many of the EU's trading partners continue to stress that the potential adverse consequences of REACH for global trade are enormous. Given the range of concerns expressed in Europe and around the world, it remains essential that the implications of the Commission's proposed regulation be accurately and fully assessed.

Key Elements of Concern

Unworkable Regulatory Approach

9. Despite a number of limited improvements to its proposed regulation, the Commission's October 2003 proposal retains an overly complex and expansive regulatory approach that continues to raise serious questions about the key issue the Commission has stressed in its consultation process - namely the workability of REACH. In our view, the Commission's revised proposal remains difficult, if not impossible, to implement in an efficient and cost-effective manner. An unworkable regulatory approach will not permit the EU to realize its intended health and environmental objectives.

10. While the Commission's proposal now simplifies regulatory treatment for selected chemicals, such as polymers (at least for the near-term) and certain intermediates, it continues to impose an administratively burdensome regulatory regime on thousands of chemical substances and uses that are unlikely to pose any significant risk to health or the environment.

11. We urge the EU to ensure that a robust, science-based regulatory approach is incorporated in REACH. A regulatory focus on substances that are likely to pose the highest risks to human health and the environment would simplify tasks, conserve government and industry resources, and allow the most significant potential benefits to be realized. For example, a more cost-effective approach would be to target substances with the lowest cost per risk reduction.

12. In this respect, we agreed with the concerns expressed by Prime Minister Blair, President Chirac, and Chancellor Schroeder in their September 2003 letter to European Commission President Prodi in which they stated that the Commission's proposed regulation was "too bureaucratic," "unnecessarily complicated," and "that it will as a result not be workable in practice." We believe these observations remain valid with respect to the current REACH proposal.

13. As the EU Council and European Parliament consider the Commission's proposal, we encourage EU authorities to introduce suggestions for alternative mechanisms and techniques that could better target EU resources, set priorities and yield a more cost-effective regulation.

14. Implementation of an overly expansive and complicated approach will prove problematic given resource constraints at the level of the Commission, as well as the Member States. Commission documentation of limited EU testing capacity, for example, underscores the importance of establishing a transparent mechanism for the broad acceptance of data from non-EU test labs and sources. Companies outside the EU will need clear guidance to ensure that data from non-EU labs and sources is widely accepted. Guidance will be particularly important for foreign firms conducting tests in countries which may not be covered by the OECD procedures for mutual acceptance of data.

15. We seek clarity on the conditions imposed on producers or importers for submitting registrations for substances contained in articles. For example, under Article 6 (General Obligation to Register Substances in Articles), how is "article type" defined? How is a producer or

importer to interpret the condition “intended to be released during normal and reasonably foreseeable conditions of use?” Likewise, how is a producer or importer to interpret that a substance is “likely to be released during normal and reasonable foreseeable conditions of use, even though this release is not an intended function of the article?” How does the Commission intend to ensure consistency in the interpretation of this Article by Member State customs authorities?

16. We also believe additional clarity is needed with regard to how the cost-sharing arrangements and consortia for registrations/testing would work.

17. The authorization process with its hazard-based approach continues to present a potentially large and complex challenge. Making authorization decisions on a company-specific basis for a significant number of chemicals and a myriad of uses is likely to be difficult and time-consuming. We encourage the EU to consider ways to reduce further the scope, simplify the task, and prioritize review to target chemicals of greatest concern, while relying on a science-based decision-making framework.

18. A question here is whether the authorization process can lead to generic exemptions (e.g., for certain uses) that would apply to all relevant parties, and which would presumably appear in Annex XIII. Although the “Explanatory Memorandum” that accompanies the proposal indicates Annex XIII (“List of Substances Subject to Authorization”) can be amended to include additional exemptions per the procedures of Article 130, how that process would work is unclear.

19. We note that under Article 57.8 (Granting of Authorizations), a holder of an authorization “shall ensure that the level of exposure is reduced to as low as is technically possible.” Given that it would be possible to reduce exposure to zero by not producing or using the substance at all, it is not clear how this condition is to be interpreted. As a practical matter, how is a holder of an authorization to comply with this provision? What role, if any, does control cost play in reducing levels of exposure?

20. The authorization process should be informed by the data 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.

21. In the authorization phase, manufacturers and/or importers/exporters would be required to produce information that shows that risks associated with requested uses are adequately controlled or, if the risk is not adequately controlled, whether the use of the substance is socially and economically important, as well as information on alternatives/substitutes. We would appreciate clarification on what constitutes “adequate control,” “economic importance,” and “social importance” -- and how the EU would intend to ensure consistency in the interpretation of these information requirements.

22. We question whether firms requesting authorizations would have access to data that would be critical to conducting effective analyses (e.g., on competitors’ potential alternatives, which often are treated as business confidential). We also question whether firms would have personnel with expertise sufficient to prepare the types of analysis, or with access to appropriate methodologies, that would be needed to provide the bases for public decision making.

23. We believe the authorization section does not result in sufficient information from companies to assess the proper balance of safety, risk, and availability of products (including substitutes/alternatives). For example in Annex XV, where information about socioeconomic analyses is offered, a list of elements that “may” be included in an authorization justification is provided. Furthermore, Annex XV does not suggest that consideration of human health and environmental risk information is included for authorization requests, which raises the question as to the role that risk will play in the authorization process.

Imposes Substantial Costs/Uncertain Benefits

24. The costs to implement REACH would be substantial, yet the Commission has not fully and transparently assessed the economic implications of its proposal. For example, the full impacts on downstream users and the recent entry of 10 new countries into the EU are still being examined as part of a new Commission impact assessment.

25. European studies conducted assessing the economic impacts of REACH on the French and German economies (MERCER and Arthur D. Little, respectively) have underscored substantial potential adverse effects on European economic growth and employment. We understand that other EU governments are now examining the practical implications of implementing REACH at the Member State level. We encourage EU governments to make such assessments public. It is important that these different studies are conducted and compared to get a more informed sense of the implications of the Commission's proposed regulatory approach for national and local government authorities throughout Europe.

Disrupts Global Trade

26. The EC's proposed regulatory approach could adversely impact production and transatlantic trade worth tens of billions of dollars in chemicals and downstream products. Among key sectors the Commission's impact assessment noted could be affected were textiles, pharmaceuticals, electronics, automobiles, and advanced materials. The Commission further noted that serious and very specific impacts could be experienced by users of specialty chemicals, such as makers of semiconductors.

27. Given the widespread use of chemicals as inputs in most manufactured products, the REACH proposal could impact the majority of U.S. goods exported to the EU. To illustrate the enormous potential scope of this regulation on products, the Commission-sponsored business impact assessment (Risk & Policy Analysts (RPA)) stated that 500,000 to 5 million different article types are on the EU market -- with an average of 10-50 substances per article. This proposal could impose burdensome analytic, reporting and administrative requirements on many downstream users.

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

29. Small manufacturers, who account for 95% of the EU's chemical firms and the majority of U.S. firms, would face a relatively larger burden in complying with REACH. We remain concerned about the ability of smaller companies, especially non-EU firms, to comprehend and comply with the administrative requirements of REACH. The proposal places all SMEs at a distinct disadvantage because most do not have the resources or the capital to meet REACH's administrative requirements.

30. Some EU and foreign manufacturers of chemicals and downstream products may simply exit the EU market, reducing competition in the marketplace. Finding ways to reduce regulatory and administrative burdens will be important in assuring continued SME access to this market.

31. We are also concerned about possible disruptions that REACH may impose on importers of chemicals. A typical distributor may import 1400 preparations from outside the EU. Based on the current proposal, such a firm would have to register each substance included in the 1400 preparations if its imports of the substance exceed one ton per year, which could create tremendous demands on the firm's resources. In addition, some of the information required under REACH may not be readily available to the importer, as the chemical producers may be unable or unwilling to provide the information.

32. The Commission's October 2003 impact assessment notes that various projected impacts of the REACH system for downstream users have differed widely. One key factor in estimating the cost of implementing REACH to downstream users is how many chemicals are likely to be withdrawn from the market.

33. While the EC's impact assessment suggests only 1-2% of substances will be withdrawn from the market as a result of REACH, other European studies (e.g., MERCER, Arthur D. Little) estimate substantially higher withdrawal rates (10% or more). Higher withdrawal rates could result in substantially higher costs for implementing REACH.

34. The EC impact assessment also notes that the consequences of the withdrawal of chemicals will be seen in reduced availability -- and possibly performance -- of chemical preparations available to downstream users. The typical chemical preparation may contain a mixture of between 5-500 basic substances, sourced from numerous suppliers. It is therefore likely that the withdrawal of particular substances will lead to the need to reformulate or replace a wider variety of preparations -- involving time and additional costs. The EC study notes, however, that "it is uncertain how widespread such occurrences will be in practice."

35. It is important that the Commission conduct a more in-depth assessment of the implications of REACH for downstream users and global supply chains. In this regard, we are encouraged that the EC is now conducting an improved extended impact assessment focused on the implications of REACH for downstream users.

Departs from Ongoing International Regulatory Cooperation

36. Given the considerable international implications of REACH, we remain concerned that the Commission proposal does not adequately recognize ongoing international efforts designed to assess risks posed by existing chemicals. Many of these programs show considerable promise in achieving their objectives. As we have urged in the past, the Commission approach should supplement, not supplant, these ongoing efforts.

37. We support multilateral efforts in the OECD to promote greater international regulatory cooperation and harmonization in the area of chemicals. We suggest that the Commission approach should be consistent with these international efforts and seek to complement activities that are underway at the national and international levels 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 U.S. High Production Volume (HPV) Chemicals Challenge Program.

38. We believe the proposal could negatively impact participation in the OECD SIDS program and the U.S. HPV Chemicals Challenge Program in view of the "robust summary" submission requirement for registrations. Registrants should be required to certify to the authority that they have appropriate access to studies underlying, and used for, the development of technical dossiers.

39. We note that the new emphasis on in-vitro testing is limited by the availability of testing procedures. The EU has recognized this, and is dedicating resources to develop alternative testing methods. However, these may not be available soon. Even when new test methods are developed, using these methods, prior to OECD acceptance, will present issues for compliance under the OECD procedures for "mutual acceptance of data". The process could result in situations where industry would need to do non-OECD tests to meet European requirements and OECD tests for other governments.

Adversely Impacts Innovation

40. Higher compliance costs likely will impact negatively innovation and hinder the introduction into the EU market of more effective and safer chemicals and downstream products.

41. The Commission's assessment of the business impacts (RPA report), for example, states that impacts on innovation are expected to be negative in that both financial resources and staff normally devoted to product development and innovation will instead be focused on addressing the potential for, and impacts of, the withdrawal of substances.

Creates Market Uncertainty

42. We remain concerned that 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.

43. For example, it is unclear which chemicals -- and which uses -- will be subject to restrictions in the EU once REACH is implemented. Uncertainty is twofold: it stems from the complex and unclear decision-making process involving Member State authorities, the Commission, and the new Chemicals Agency, as well as an unclear/imprecise 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.")

44. 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 EU in its efforts to create a regulation that targets chemicals of greatest concern, and would facilitate evaluation of the costs and benefits of the REACH system.

45. Depending on the specific activity under this draft regulation, the European Chemicals 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.

46. While the EC's October 2003 proposal better defines the responsibilities of the Chemicals Agency, we continue to question how the Member State authorities and the Agency will effectively coordinate their work. There remains a serious potential for needless duplication and a lack of consistency in implementation and enforcement of the regulation across Member States. A 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.

47. A stronger role and strong scientific credentials for the Chemicals Agency could help ensure more coherence and consistency in the implementation of REACH. To increase efficiency and consistency, we continue to believe that the Chemicals Agency should have more complete decision-making powers and accountability throughout the process -- particularly with respect to evaluations and authorizations.

48. We would appreciate further clarification concerning how authorization decisions will be made by the Commission, including how the Chemicals Agency's opinions (Article 61) will be taken into account, as well as what role Member State views might play in the authorization process.

49. In addition, we would appreciate further clarification concerning how the process for deciding on additional substances to be included in Annex XIII (Articles 54 and 56) will work in practice. For example, will there be any opportunity for the public (including NGOs and industry) to provide comments before a decision is taken to include a new substance in Annex XIII?

50. We would also appreciate clarification as to how regulatory actions (such as those referred to above) might be "underpinned by the precautionary principle" (Article 1.3). What scientific information or risk assessments will be required to support such regulatory actions?

51. Moreover, we have noted that the Commission has included an appeals process to address concerns of legal uncertainty. However, it appears that this appeals process (Article 87) is limited to decisions taken by the Chemicals Agency, and does not extend to decisions taken by the Commission, for example those related to Authorization (Article 57). We would appreciate clarification on the scope for appeals and whether any similar appeal process applies to the Commission's decisions.

52. The draft regulation requires 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 such 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. We would appreciate any further clarification that the Commission could provide on this issue, and whether there has been any consideration given to the impacts that such an approach might have on innovation within the EU.

53. Further, 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. Such a standard may not give submitting companies assurance that their confidential data will be protected. We would appreciate more detailed information on how the proposed REACH approach would treat confidential business information to ensure that legitimate commercial interests are protected.

54. We also are concerned that mechanisms for data sharing and mandatory consortia of companies not be imposed in a manner that may create anti-competitive results.

Concluding Remarks

55. While the Commission's October 2003 proposal does reflect limited improvements to its proposed regulation for REACH, in our view, the draft regulation still appears to adopt a particularly costly, burdensome, and complex approach, which could prove unworkable in its implementation, disrupt global trade, and adversely impact innovation. It fails to clarify how and on what basis key regulatory decisions will be taken.

56. To better achieve its objectives, we continue to strongly encourage the EU to: 1) reduce the scope of aspects of the regulation to better focus scarce resources on substances that are likely to pose the highest risks and ensure a robust, science-based regulation; 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, simplify, and enhance transparency concerning 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. As the EU Council and European Parliament consider and revise the Commission's proposed regulation, these European institutions should also ensure that the approach is fully consistent with the EU's WTO obligations.

57. Given the scope, far-reaching implications and global interest in this extensive regulation, we urge the Commission to provide for meaningful consideration of, and written response to, the substantive comments received. We also urge the Council and the Parliament to consider the comments the Commission receives from this WTO notification. As these bodies deliberate on the Commission's proposal, we encourage them to craft revisions that will improve the cost-

effectiveness of the regulation, while minimizing unnecessary adverse impacts on trade and employment.

58. We look forward to reviewing the Commission's improved impact assessment, which is due by the end of 2004, including its assessment of the full impacts on downstream users. 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.

59. We also request the Commission to keep the TBT Committee fully informed as this draft regulation continues to move forward through the EU's decision-making process, including providing updates concerning any changes that might be made to the regulation.