

August 24, 2004

Ms. Dorothy Dwoskin
Assistant U.S. Trade Representative for WTO & Multilateral Affairs
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

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

Dear Ms. Dwoskin:

We write with regard to the document titled "Comments of the United States on Notification G/TBT/N/EEC/52 Regarding European Commission Regulation COM(2003) 644," as submitted to the Technical Barriers to Trade Committee on June 21, 2004. (The comments are available on the web site for the U.S. Mission to the EU, at <http://www.useu.be/Categories/Environment/June2204USREACHComments.html>.) The Comments address "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" (Comments, Paragraph 1).

While we disagree strongly with many of the assertions made in the Comments, this letter focuses on Paragraphs 37 and 38, which read, in relevant part, as follows:

37. ... 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.

Environmental Defense was extremely active in the creation of both the OECD SIDS program starting in the late 1980s and the U.S. HPV Chemical Challenge Program a decade later. In addition, we have also closely monitored the progress of and actively

participated in both programs since their creation. For example, we provided technical comments on the great majority of proposed test plans submitted under the HPV Challenge (see listings for individual chemicals at <http://www.epa.gov/chemrtk/viewsrch.htm>). We also published two detailed reports on implementation of the Challenge.¹ In addition, members of our staff have consistently participated in policy meetings and chemical assessment reviews under the OECD SIDS program.

In our view, the concerns raised in paragraphs 37 and 38 of the U.S. comments are not only irrelevant under the Technical Barriers to Trade Agreement, but also are simply not credible based on our extensive experience with the U.S. HPV and OECD SIDS Programs, for the reasons discussed below.

1. With regard to paragraph 37's claim that REACH "could undercut progress achieved to date" in the OECD SIDS and U.S. HPV programs, the OECD SIDS program and the U.S. HPV program are designed to ensure that at least basic toxicity data are publicly available. Under the programs, data from growing numbers of chemicals are in fact publicly available. The only way that REACH could "undercut" that progress would be if REACH somehow caused the data to be de-published. Needless to say, REACH has no such provisions.

Moreover, data that have been and will be generated under the U.S. HPV and OECD SIDS programs are totally consistent with and acceptable under REACH (though in some cases REACH requires additional data as well). Hence, these data will be directly applicable in meeting the REACH requirements. Significantly, all of the available means being used under these programs to provide data are also allowed or encouraged under REACH: not only new testing, but also use of pre-existing data (as long as it meets data-quality criteria), use of valid structure-activity relationship (SAR) analysis techniques, read-across from data on related chemicals, and formation of chemical categories.

2. With regard to the concern raised in paragraph 38 that REACH's "robust summary" submission requirement for registrations could somehow undercut the U.S. HPV or OECD SIDS program:

a. This issue has already recently been raised by the chemical industry in the context of the U.S. HPV and OECD SIDS as well as REACH, with ready agreement expressed on the part of EU representatives that a) it is already the express intent of REACH to ensure that companies that invest in developing data to be submitted under REACH are adequately compensated, and b) to the extent

¹ *Facing the Challenge: A Status Report on the U.S. HPV Challenge Program* (available at www.environmentaldefense.org/go/hpvchallenge) and *Orphan Chemicals in the HPV Challenge: A Status Report* (available at www.environmentaldefense.org/go/hpvorphans).

further clarifying language is needed, it will be added. Thus, to the extent this argument has any merit, it is already being addressed.

b. Moreover, under the U.S. HPV and OECD SIDS programs, companies for years have been routinely relying on and even directly submitting robust summaries of data developed under one program to satisfy the requirements of the other program. Often, the submitting company or consortium is not the one that generated the data in the first place. Yet no concern has been raised by the industry with regard to this practice in these ongoing programs.

c. Industry representatives have asserted that 95% or more of the robust summaries due under the U.S. HPV Challenge have already been submitted; large numbers of such robust summaries have also been submitted by companies under the OECD program. These summaries have been submitted over the course of a number of years by industry without any conditions placed on their use by other companies. Indeed, both programs have already made the summaries publicly available for unfettered use, and we are not aware of any objections raised by industry; rather, they have embraced public access to such summaries as the primary means of demonstrating to the public that hazard data exist on their high-volume chemicals.

d. In addition, REACH already contains cost-compensation provisions for vertebrate-animal data (which are the most expensive to generate) in registrations less than a decade old, so – in contrast to the U.S. HPV and OECD programs, which contain no compensation or cost-sharing requirements whatsoever – REACH actually helps spread the cost of data generation. See REACH Article 25.

Finally, two other observations warrant inclusion. First, both the U.S. HPV program and the OECD SIDS program seek to develop and make public the data elements specified in the Screening Information Data Set. As that name makes clear, SIDS provides a limited set of hazard-based *screening data*; it does not supply adequate data for a full risk-based analysis. By contrast, REACH contains provisions under which more extensive toxicity and use and exposure data sufficient to determine safety or magnitude of risk are to be developed.

Second, the U.S. HPV and OECD program apply *only* to “high volume” chemicals – those produced in quantities exceeding one million pounds annually in the U.S., and 1000 metric tons annually in at least two OECD member countries, respectively. While the high-volume criterion formed a useful starting point, there is no scientific justification for asserting that data are not needed for lower-volume chemicals. Certainly, it makes no sense to regard the high-volume thresholds as a permanent *de minimis* threshold. By contrast, REACH requires eventual registration of all compounds produced in quantities

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above one metric ton annually per producer, though with reduced data requirements for those produced in quantities between one and ten metric tons.

Not only does REACH provide for more-extensive data on a wider array of chemicals, it also provides for both evaluation of those data and for action with regard to chemicals that are found to be toxic. Neither the OECD SIDS program nor the U.S. HPV program has comparable features.

These common-sense objectives deserve the support – and emulation – of the U.S. government, rather than continued attempts to undercut REACH's adoption. We note with dismay that most concerns raised by the U.S. government regarding REACH continue to be comprised of assertions that are either unsubstantiated generalities or factually erroneous (or both). In light of the evident inability of existing U.S. laws to fill data gaps on the vast majority of chemicals in commerce (including those produced in Europe that are sold in the U.S.) or to take timely and appropriate action to protect public health and the environment even after a problem is identified, attempts by the U.S. government to derail REACH are a grave disservice to America's public health and environment.

Sincerely,

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cc:

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