TACD

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BRIEFING PAPER ON REACH

Research in California and Sweden gained world-wide attention when scientists demonstrated that a widely-used flame retardant can be found at high levels in the breast milk of nursing mothers and that the chemical is building up in humans at a rate that is doubling every two to five years.[i] The chemical substance in flame retardant is polybrominated diphenyl ethers or PBDE. It is one of many chemical substances that are persistent in the environment, accumulate in human and animal tissue and has been demonstrated to cause health effects in laboratory animals. It is chemicals like these, which have been on the market since the 1970's and have gone largely unassessed by industry and unregulated by governments, that have prompted the European Union (EU) to propose a chemical policy overhaul.

THE REACH PROPOSAL: The proposed EU chemicals policy is called Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH). The primary goal of the program is to secure data on and appropriately regulate some 30,000 existing chemicals produced in excess of one ton (a portion of the estimated 100,000 on the European market) for which there is limited information with regard to toxicity and environmental effects. Under the program, registration will be required for old and new chemiclas. Registration is mandatory before a chemical is marketed or in order for existing chemicals to stay on the market, and chemicals of greatest concern will be subject to formal authorization procedures much like pharmaceuticals.[ii] The goals and principles of REACH have been supported by a wide array of consumer, public health and environmental groups in Europe including many members of TACD. TACD members in Europe have submitted comments to improve REACH in the consumer interest, while many TACD members in the U.S. have watched with dismay the coordinated U.S. industry and governmental effort to weaken the proposed policy.

Many U.S. consumer and environmental groups see benefits for U.S. consumers as global producers are encouraged to develop safer alternatives under REACH. Moreover, many U.S. groups are interested in strengthening U.S. law in this area to address the same problem – a lack of information and regulation regarding the tens of thousands of existing chemicals on the U.S. market about which little is known. The current regulatory structure for chemicals, the U.S. Toxic Substances Control Act (TSCA), was implemented almost 30 years ago and is far less effective at regulating potentially harmful substances already on the market than the proposed REACH model, due to the burdensome requirement that there be a chemical by chemical risk assessment performed before any action is taken to require toxicity testing or to regulate the chemical. If the goal is to protect the public and the environment from potentially hazardous chemicals, REACH provides significant advantages over TSCA. REACH still has to be discussed and adopted by the European Parliament and European Council. In this process, TACD is advocating for several improvements in order to ensure proper consumer protection in the final legislation included in the recommendations section below.

REACH: A SIGNIFICANT ADVANCE OVER U.S. CHEMICAL POLICY IN CONSUMER PROTECTION: A brief comparison of REACH to the TSCA follows.

REACH does not differentiate between new and existing chemicals. All chemicals produced in large amounts will be tested and apppropriately regulated with chemicals of highest concern requiring

formal authorizaton. TSCA merely requires premanufacture notice by industry and allows the U.S government to review new chemicals, but creates obstacles to acquiring information from companies for existing chemicals and makes regulation of existing chemicals all but impossible. TSCA thus leaves tens of thousands of existing chemicals (those on the market priort to TSCA's enactment in 1980) in the stream of commerce untested and unregulated.

REACH requires basic human and environmental toxicity data for both new and existing chemicals. Although there is a industry effort to limit the amount of data publicly available, REACH calls for making testing and other toxicity data publicly available and this database could be an important resource for consumers on both sides of the Atlantic. TSCA requires that all available data be presented for new chemicals, but only requires toxicity testing in rare instances and there is restricted public access to this data. With regard to existing chemicals, there are few data production or regulatory requirements. Thus, for the vast majority of chemicals on the U.S. .market, there is almost no information available about the hazards to public health or the environment.

REACH will require prior authorization for any use of inherently harmful chemicals, such as carcinogens, reproductive toxins, mutagens, and persistent, accumulative chemicals. The government is authorized to restrict or even ban such dangerous chemicals. TSCA ties the hands of regulators with regard to older chemicals which constitute more than 99% of what is on the market today by volume. EPA can only take action to restrict existing chemicals after EPA proves that the chemical presents an unreasonable risk, that its proposed regulation is the least burdensome option to reduce risk and that the benefits of regulation outweighs the cost.[iii] As a consequence, EPA has restricted less than 10 existing chemicals of an approximate 80,000 in 25 years.

REACH is based on the Precautionary Principle.[iv] As a consequence, industry is responsible for the testing and the safety of the chemicals it puts on the market in excess of one ton. In contrast, TSCA program for existing chemicals is the antithesis of precaution as it places the burden on underfunded government agencies utilizing taxpayer dollars to prove that existing chemicals are unsafe, before testing can be mandated or the chemicals can be restricted.

REACH is likely to prompt new innovation leading to safer, alternative substances resulting in less toxicity and health or environmental effects because one of the authorization criteria is whether there is any available information on alternative substances or technologies. TSCA does little to encourage manufacturers to pursue safer alternatives for existing chemicals.

With regard to protecting public health, safety and the environment, REACH provides significant advantages over current U.S. law. Yet, the legislation is not perfect and the most recently available draft of the legislation has been weakened from the initial draft.

U.S. EFFORTS TO COMBAT REACH: The EU began developing REACH in 1999, and the effort has been on the radar of U.S. officials for some time. A number of recent press reports and an investigative report prepared by the staff of the U.S. House of Representatives Committee on Government Reform demonstrate that U.S. government has made a vigorous attempt to defeat the REACH policy by coordinating with the U.S. chemical industry in a campaign targeting the European Commission and EU member states. In 2001, the U.S. Commerce Department advised U.S. industry to develop an official position and strategy as soon as possible to influence draft REACH text.[v] In 2002, the U.S. Trade Representative (USTR) circulated a "non-paper" arguing that the impending REACH policy raised significant concerns regarding compliance with the WTO's "least trade restrictive" requirement.[vi] In 2003, the Assistant USTR for Europe and the Mediterranean "tasked" the U.S. chemical industry with developing themes for the administration to utilize in protesting the REACH policy.[vii] Later that month, all 11 "themes" appeared in a diplomatic cable sent by U.S. Secretary of State Colin Powell to U.S. embassies in EU member states and candidate states, expressing alarm over the potential trade implications of the proposed policy and marshalling efforts to oppose the policy.[viii] More recently in August 2003, William Lash, U.S. Assistant Secretary of Commerce for Market Access and Compliance, suggested the transatlantic clash over REACH was poised to be "a big game; it will dwarf the [genetically modified food] dispute."[ix]

While the U.S.government has worked closely with industry to form its position on REACH it has failed to solicit or incorporate the wide variety of views held by other interested parties. TACD provides recommendations on how to diversify this consultation below.

EUROPEAN EFFORTS TO COMBAT REACH: The European chemical industry as well as several EU member states have actively advocated a weakened REACH or even a complete abandonment of a new chemicals legislation in the EU. The European Chemicals Industry Council (CEFIC), which is comprised of 40,000 chemicals companies, including Proctor & Gamble, Shell Chemicals and Dow Europe, produced a report in which it documented perceived burdens to business contained in the REACH proposal.[x] In particular, it criticizes the application of the Precautionary Principle and instead seeks a risk-based approach, wherein chemicals are first proven dangerous and then tested afterwards. Additionally, it thinks that the newly created European's Chemical Agency should have sole authority to initiate evaluation of substances. As it stands now, under REACH individual member states have the authority to initiate evaluations of substances.

In September, 2003, the political leaders from UK, Germany and France urged the EU Commission to fundamentally alter and weaken the REACH proposal in consideration of the potential burden on industry.[xi]

REACH AND THE PRECAUTIONARY PRINCIPLE: At the heart of this latest transatlantic trade dispute, however, is a broader debate between the U.S. and the EU governments over the Precautionary Principle, a legal concept that arose in the context of environmental law that has been increasingly cited by the EU as justification for innovative environmental, food safety and public health policies. In the environmental context, the 1992 Rio Declaration on the Environment and Development defines the principle in a provision which states, "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[xii] Proponents of the principle also argue that when science points to a potentially significant threat to public health or the environment, governments have an affirmative obligation to take action to avoid harm, that they should seek out and evaluate less harmful alternatives, and originators of products or new technologies should bear the burden of proving that their activity will not cause undue harm to human health or ecosystems.

The REACH program incorporates these principles, but does not for instance put as much emphasis on finding safer substitutes as some TACD members would like. Moreover, the REACH proposal will not ensure sufficient data for substances below 10 tonnes, and consequently consumers are not ensured approriate protection from potentially harmful substances in consumer articles. In contrast, REACH's critics argue that by basing its policy upon the Precautionary Principle (or in opponents terms, a "presumption of risk" rather than certain scientific evidence of risk), the policy is contrary to WTO provisions and jurisprudence which have been interpreted to require scientific proof of harm before regulatory action is taken,[xiii] and REACH opponents allege that many aspects of the regime conflict with a battery of obligations contained in several of the substantive agreements enforced by the WTO.[xiv]

The Precautionary Principle, although not always explicitly acknowledged as such, is already embedded in current health, safety and environmental laws and regulations in the U.S. as well as the EU. For instance, the U.S. Food Drug and Cosmetic Act prohibits use of a food additive or sale of a pharmaceutical until they are proven safe, and U.S. agencies have taken a variety of commonsense, precautionary actions over the years, for instance by banning blood donations by citizens who have lived in countries with Bovine Spongiform Encephalopathy (BSE) for more than three months before there was conclusive evidence that blood transfusions posed a problem. However, in the last decade the EU has outpaced the U.S. by developing a number of cutting-edge policies geared toward preventing harm, while U.S. regulators have largely maintained a 30-year-old regulatory status quo. Now, both industry and the U.S. government are concerned that a variety of EU regulations will take precedence as global models, as has been the case with the EU's effort to regulate genetically modified foods.[xv] The U.S. response to these precautionary policies has been to attempt to derail them, utilizing trade threats and other means. For instance, in 2003, the U.S. challenged elements of

the EU's genetically modified food regulatory regime in the WTO, an action that TACD has rigorously protested.

Not all governments will manage the same risks in the same way and will differ in how, when and to what degree they exercise precaution. In judging whether such policies pose a trade barrier, government's primary consideration should be whether or not the policies is discriminatory, i.e. does it apply to domestic products as well as imports? REACH passes this test and therefore it not a legitimate subject for a WTO challenge. It is a a widely held belief among consumer, environmental and public health officials in the U.S that TSCA has failed to adequately regulate the hazardous chemicals currently on the market, and that REACH's precautionary approach provides more protection to health and the environment than TSCA. Rather than undermining REACH, U.S. agencies and Congress should actively consider emulating many aspects of the REACH system. Likewise the EU could benefit by examining the U.S. tort system which can be utlitzed to hold companies responsible for public health harms and environmental damage and U.S. chemical "Right to Know" policies as EU nations move forward with the implementation of the Aarhus Convention's Protocol on Pollutant Releases and Transfer Registers.

CONCLUSION: The European Commission completed an internal technical consultation on October 10, 2003 and adopted the legislative proposal on October 29, 2003. REACH has now been submitted to Parliament and Council for finalization, which most likely will not occur before 2005.

Unfortunately, it appears that industry lobbying and threats of a trade war are already having an impact. A 2003 report from the American Chemical Council touts the combined industy/government effort to weaken the proposal and states that "These efforts… brought about significant concessions in the draft."[xvi] Indeed, the most recent version of the REACH legislation (following the public consultation) reveals that it has been weakened to comply with critic's demands. For example, instead of the previous version of the legislation which required chemical substances data on specific products – now registrants are only required to submit data if these chemical substances are intentionally released from the product, which significantly reduces the scope of data on chemical substances in products that are unintentially released. Additionally, the REACH legislation has increased secrecy of information allegedly to protect confidentiality for manufacturers who register toxicity data on chemical substances used. These and other changes to the draft that have weakened the proposal need to be reversed and there must be further improvements with regard to the treatment of consumer products.

TACD RECOMMENDATIONS

REACH should be strengthened and a trade war over the policy should be avoided:

1) **Hazardous chemicals should have no volume threshold for registration and authorization.** The main thrust of the REACH proposal is to prioritise chemicals on the basis of volume of production. However, as there is no correlation between between tonnage and hazard, the focus of the REACH instead should be on identifying the most hazardous chemicals. To accomlish this, industry should screen all their chemicals according to dangerous properties including identification of possible vPvB and PBT [xvii] properties. For these chemicals, there should be no volume threshold for registration and authorization. The screening of all chemicals can be done if the computer model QSAR is used as a screening method. The newly created European Chemical Bureau should evaluate these data files within three years from registration.

2) **The authorization procedure for chemicals of high concern should be strengthened** This entails placing the principle of substitution as the core of the procedure to create an assumption that chemicals known to have safer alternatives will be removed from the marketplace. Furthermore, endocrine disrupting chemicals and sensitizers must be added to the group of high concern chemicals requiring authorization. Authorized substances (preparations and articles) must be clearly labeled with a hazard symbol, without regard of the concentration of the chemical.

3) **All consumer articles containing chemicals– domestic and imported – should be assessed, whether they are intended to be released or not.** Producers of consumer articles must also provide information about the chemicals used in their products. This information should be publicly available. As it currently stands, REACH grants industry excessive secrecy due to industry claims of business confidentiality and does not give citizens the right to know certain key information such as producers names, total tonnage, general exposure information etc. Furthermore REACH has no mechanism for appealing decisions on the withholding of information and such an appeals procedure should be developed in the final draft.

4) **REACH must be a horizontal measure integrated in with related product safety directives.** REACH should form the basis for all existing and future product directives, setting a horizontal obligatory minimum safety level for chemicals in all uses, whether paints, toys, cosmetics and pharmaceuticals, foods etc.

5) **The U.S. should immediately cease its campaign against REACH and the U.S. and the EU must avoid a trade dispute over REACH.** TACD believes that open, transparent and inclusive regulatory and trade-related processes are essential precursors to the development of sound public policy, and are necessary to avoid costly, potentially embarrassing and unsuccessful trade disputes. The U.S. government should cease its campaign against REACH and reassess its position on the matter by consulting a wide variety of interested parties. TACD once again calls upon U.S. agencies to solicit public comment on REACH and other public interest policies perceived to be trade irritants by posting notice in the Federal Register, holding public meetings and soliciting opinions from a balanced group of stakeholders. The EU could also improve performance in public consultation by soliciting testimony on the public health benefits of REACH and the costs of non-implementation.

6) **TACD once again calls upon the governments to incorporate the Precautionary Principle in regulatory decisions involved in consumer health and safety and the environment, particularly in cases of scientific uncertainty and complexity.** [xviii] We urge Congress to develop legislation to strengthen TSCA using REACH as a model and we urge the U.S. EPA to form a special committee to explore the overhaul of TSCA to provide for the registration and authorization of chemicals on the market that predate the U.S. law utlitizing REACH as a model. We call upon the committee to solicit testimony from U.S.and EU experts on the benefits of a REACH approach as well as the costs, and to examine the costs of nonaction on U.S. public health, environment and taxpayers.

ENDNOTES

[i] Environment California Research and Policy Center, "Body Of Evidence: New Science In The Debate Over Toxic Flame Retardants And Our Health," Feb. 2004 available at http://www.environmentcalifornia.org/envirocaliftoxics.asp?id2=12239. "As Flame Retardant Builds Up in Humans a Ban is Debated at EPA, Industry Cites Lack of Proof PBDEs Hurt People, But EU and California Act," Wall Street Journal, Oct. 8, 2003.

[ii] Chemicals of high concern include: CMRs (carcinogenic, mutagenic, toxic to reproduction); vPvB: very persistent and very bioaccumulative chemicals; PBT: persistent, bioaccumulative and toxic chemicals; substances identified as having serious and irreversible effects to humans and the environment equivalent to these other categories.

[iii] "The Promise and Limits of the US Toxic Substances Control Act," Oct. 10, 2003, Lowell Center for Sustainable Production at 3.

[iv] REACH proposal, Article 1 –Subject matter (…) "This Regulation is underpinned by the precautionary principle whose conditions of application are outlined in the Communicaiton from the Commission on the precautionary principle (COM(2000) 1 final)."

[v] "U.S. Opposes EU Efforts to Test Chemicals for Health Hazards," Wall Street Journal, Thaddeus Herrick, et. al, Sept. 9, 2003

[vi] "Powell Urges EU Member Striates to Oppose Chemical Policy, Seeks Reassessment," Inside U.S. Trade, May 9, 2003.

[vii] U.S. House of Representatives Committee on Government Reform-Minority Staff Special Investigations Division, "A Special Interest Case Study: The Chemical Industry, the Bush Administration and European Efforts to Regulate Chemicals" April 1, 2004 at i-ii. This committee relied on documents garnered by the U.S. Environmental Health Fund via a Freedom of Information Act Request.

[viii] *Id.*

[ix] "Business Meets its Match," The American Prospect, July/August 2003.

[x] European Chemicals Industry Council, Communication on Commission's Proposal for Regulation on Registration, Evaluation, Authorisation and Restrictions of Chemicals, Dec. 4, 2003.

[xi] Letter to Romano Prodi , President of the European Commission, dated Berlin, 20 September 2003

[xii] Rio Declaration on the Environment and Development, Principle 15; The Earth Summit: The United Nations Conference on Environment and Development.

[xiii] Powell, Goldstein, Frazer and Murphy, LLP, "Executive Summary: Trade Implications of the EU White Paper - Strategy for a Future Chemicals Policy," April 9, 2002 at 12.

[xiv] Industry lawyers claim that the policy violates the General Agreement on Tariffs and Trade (GATT), which sets the basic terms for trade in goods and is enforced by the WTO. GATT Article III requires that the non-discriminatory regulation of "like" products be treated the same for regulatory purposes regardless of where they are produced. REACH is volume based placing increased testing requirements on chemicals of high volume. U.S. industry argues that this system is discriminatory as it may require more testing by importers who bring in a higher volume of a chemical than it does of EU producers of the same chemical. Similarly, it is argued that the EU cannot place higher requirements on a foreign manufacturer of a plastic chair, for example, than they do on a European manufacturer of a wooden chair. Also industry asserts that REACH violates a dozen provisions of the WTO's Technical Barriers to Trade Agreement (TBT) including; Article 5.1 which states that conformity assessment procedures must not be prepared, adopted and applied under conditions that are less favorable to foreign suppliers of like products than those conditions applied to domestic suppliers of like products; Article 2.2 which requires that technical regulations "not be more trade restrictive than necessary;" and Article 2.4 which requires countries to use international standards as a basis for their technical regulations. In the later instance, the likely competing international standard is the ineffective and voluntary chemical registration process developed by the International Council of Chemical Associations (ICCA) and housed at the OECD. The National Fair Trade Council produced a long analysis of REACH's alleged violation of trade rules in "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," May 6, 2003. The NFTC's membership is approximately 300 private companies, such as UNOCAL, Haliburton, Bechtel and Exxon Mobil Corporation. Powell, Goldstein, Frazer and Murphy, LLP, "Executive Summary: Trade Implications of the EU White Paper - Strategy for a Future Chemicals Policy," April 9, 2002.

[xv] More and more governments around the world are pursuing a precautionary regulatory approach with regard to genetically modified organisms similar to Europe's, while the U.S. government policy does not provide for safety testing, traceability or even labeling of these new and controversial products.

[xvi] U.S. House of Representatives Committee on Government Reform-Minority Staff Special Investigations Division, "A Special Interest Case Study: The Chemical Industry, the Bush Administration and European Efforts to Regulate Chemicals" April 1, 2004 at i-ii.

[xvii] vPvB: very persistent and very bioaccumulative chemicals, PBT: persistent, bioaccumulative and toxic chemicals.

[xviii] TACD is on record supporting the Precautionary Principle as a "priority" agenda item for the governments. In the 2001 priorities statement, TACD calls on the governments of the US and the EU to incorporate the Precautionary Principle in regulatory decisions involved in consumer health and safety and the environment.