

Europe's Global REACH :

**Costly for the World;
Suicidal for Europe**

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Introduction

Regulations enacted in the European Union (EU) increasingly are having worldwide impacts, warranting greater attention among policymakers in the United States and around the world. Not only do EU directives affect the 25 EU member nations, EU regulations can become trade barriers and impact thousands of businesses around the globe that are directly or indirectly linked to the EU's substantial share in the world market through international trade. In addition, passage of regulations in the EU builds constituencies for them to be introduced as global standards through intergovernmental organizations. These actions are bolstered by those who think that global standards will «level the playing field» or make compliance schemes uniform and efficient. Unfortunately, such rationales are often used to edge out competition and promote protectionist policy.

Currently on the horizon is the proposed EU Chemicals Policy, which represents what will be perhaps the most expansive regulation of the chemical industry ever. Known as REACH—which stands for registration, authorization, and evaluation of chemicals—this directive is likely to cost society billions of dollars, reduce innovation, and limit U.S. access to EU markets. Its protectionist effects are expected to trigger World Trade Organization (WTO) disputes. Meanwhile, the benefits of the proposal are likely to be small given that it attempts to reduce the effects of trace levels of chemicals, which have produced little documented adverse effects on public health.

The EU chemicals policy would employ the so-called precautionary principle by requiring companies to prove that their products are safe before their introduction into commerce. Currently, government officials bear the burden of proof and must prove a product unsafe before removing it from the market. REACH would reverse this burden, demanding that firms conduct extensive tests to demonstrate product safety. Since manufacturers can't prove anything is 100 percent safe, this policy will likely produce arbitrary bans of many relatively safe substances and discourage innovation.

The impact of this new program is likely to expand if left unchecked. The Organization Economic Cooperation and Development (OECD) and the United Nations (UN) Environment

Program are looking into applying REACH globally. In particular, REACH is likely to become a focus of the UN's Strategic Approach to International Chemicals Management (SAICM), a relatively new effort designed to create institutions that will coordinate global chemical and waste policies. Although SAICM is supposed to represent a voluntary effort, its proposed declaration, policy statement, and global action plan indicate that it will be an ambitious attempt to develop, expand, and enforce a wide slate of chemical and hazardous waste regulations around the world. It is potentially a powerful vehicle for those who seek REACH expansion. The details of the SAICM program are still being negotiated, but the UN is expected to finalize its declaration, overarching policy strategy, and global plan of action in February 2006.¹

In addition, U.S. states—starting with California—are looking into enacting their own versions of this law. Most recently, Sen. Frank Lautenberg (D-N.J.) has begun working in tandem with environmental groups to build momentum for a U.S. version of REACH. To that end, he commissioned the Government Accountability Office to assess the need for revisions to the Toxics Substances Control Act—amendments that could transform that program into a REACH-styled law. Sen. Lautenberg followed that report with the introduction of legislation designed to get the process moving in the direction of a U.S. REACH law, which he has euphemistically labeled the «Child, Worker and Consumer Safe Chemicals Act» (S. 1391).

In addition to impacting U.S. trade, REACH will build momentum for global chemical bans under various international agreements. For example, the U.N. Environment Program's Global Convention on Persistent Organic Pollutants (POPs), which currently bans 12 substances, has provisions for additional bans. European nations are already using the POPs treaty to propose worldwide bans on substances they have already eliminated domestically, even when such products have valuable uses in the United States. For example, Europeans have proposed banning the pesticide lindane which is used in the United States to fight lice and other vectors. As the EU bans more products under REACH, you can be sure that they will propose them as bans under POPs or other agreements—potentially removing more valuable products from the world market.

REACH is currently undergoing some revisions as part of the legislative negotiations on the policy. But modifications are unlikely

to mitigate the fundamental problems outlined in this paper. Indeed, the basic concept is fatally flawed. Its benefits are highly dubious and the costs to economic freedom and development—even if mitigated by reducing REACH's scope—are likely to remain substantial.

BACKGROUND

REACH Timeline

REACH emerged as a serious policy proposal in 2001 with the release of a European Commission white paper.² In 2003, the Commission released an official proposal and held a public comment period during May through July of that year, which generating more than 6,000 comments from businesses, governments, and non-governmental organizations around the world.³ The Commission allegedly reviewed all these comments and was able to revise the proposal by October 2003. Since then, the issue has moved to the European Parliament, where it is being debated. The Parliament is expected to do a «second reading» of the bill (which brings it close to final action) in October 2005. The Council of Ministers is expected to accept REACH and the final legislation is expected by 2007.

The REACH Process

As the name implies there are several regulatory components of REACH. These include registration, evaluation, and authorization of chemicals. Not included in the name is the potential result of authorization: restriction. The restriction portion of REACH is perhaps the least studied and least discussed, but it is where regulators will be able to deny firms the right to engage in commerce by banning substances or seriously limiting their use. Products are likely to be eliminated during the other stages as well. For example, various studies have noted that the costs of registration will lead some firms to cancel products and «substitute» them with others that are already registered or more easily registered.

The effects of substitution are broader than one might expect as few things are easily substituted. It will demand that many firms reformulate products, which may produce inferior products and may trigger need for new registrations. In addition, reducing the number of products on the market—even

by a few percent—can have serious and adverse impacts for public health and well being, as this paper will show in subsequent sections.

The entire process is implemented by various agencies and governments, which make it complicated and difficult to understand. Entities that are the most involved include the European Chemicals Agency (to be located in Helsinki, Finland), which will act somewhat like the U.S. Environmental Protection Agency in governing the process. Regulatory bodies in member states will play key roles in the process along with the European Commission. The interplay between all these parties eventually determines what products will be sold in Europe and under what terms. The following attempts to offer a relatively broad overview of how this process works, what is required, and what entities and products are covered.

Registration. The registration phase mandates that firms register products when they produce or import them at levels of one metric ton or more per year. The European Chemicals Agency will receive registrations and manage the registration process. The agency will work with the registrant until its registration meets all requirements, after which the agency forwards the proposed registration to one of the EU's member states for evaluation.

During the registration phase, manufacturers and importers produce and submit to the agency a «dossier» detailing environmental and public health data of each substance. Some registrations may require testing if existing data are not sufficient to validate safety claims. In that case, firms will propose what testing they need to do in their registration to the agency, which regulators will consider in the evaluation stage. Many substances should go through registration without additional testing although the registration process may still prove quite expensive in terms of paperwork and legal fees. In addition, the agency will charge registration fees.

Firms that produce or import a chemical in amounts of 10 metric tons or more will also have to file a chemical safety report with their registration to the agency. In this report they must detail whether the chemical is carcinogenic, accumulated in human tissue, or persists in the environment. They will also have to develop «exposure scenarios» detailing all «identified uses» of the chemicals

and detail risk management measures for use of the chemical, with which downstream users must comply.

Each party who wants to import or produce a substance in amounts over one metric ton would have to gain its own registration. Once a company completes the process and it is registered in one EU member nation, it can sell that substance in all member nations as each will basically provide reciprocity for registrations. According to the Commission, firms may form consortia to register substances jointly, sharing costs of registration preparation and each paying only one third of the regular registration fee. Consortia members can deny other firms the opportunity to join in their effort, but they cannot deny access to animal test data for registration as long as they compensate the owner of the data. This provision is supposed to reduce costs by promoting data-sharing. However, it is also designed to reduce the amount of animal testing under REACH, and thereby reduce political opposition to the program from animal rights organizations.

Firms in United States and other nations with imports to Europe will not be able to register their products directly, nor can they directly participate in consortia. Rather those EU parties that import products into Europe must file the registration or the foreign manufacturer must hire an EU-based representative (called an «only representative») to take its product through the EU registration process.

The Commission maintains that it will be able to register all chemicals covered under REACH over a period of 11 years. It sets schedules and deadlines for various substances to apply and gain registration, allowing continued marketing of the products during this process. During the first three years, substances produced or imported in amounts more than 1,000 metric tons will be registered. By year six, those produced or imported at levels of 100 to 1000 metric tons will be registered, and those at levels of 10 to 100 metric tons will be registered by year 11.

Evaluation. Under REACH, evaluation responsibilities are divided among regulatory bodies in member states, with each designated to handle certain substances on a rolling basis. Most substances will only go through registration, which alone will likely be costly and bureaucratic. The second stage—evaluation—is

	Industry	Chemicals Agency	Member States	Commission
Registration	Collects and submits data. Assesses risks and identifies risk management measures. Keeps registrations updated. Proposes testing schemes.	Receives registration dossiers. Checks them for completeness. Maintains the database and provides information to the public.	Enforcement	
Evaluation	Provides further information if required.	Coordinates the work of the member state authorities. Develops evaluation criteria. Takes decisions on requesting more information from industry if all member states agree.	Review individual dossiers. Prepare rolling plans for substance evaluations and carry them out. Prepare draft decisions on further information requirements.	Takes decision on requesting more information from industry if member states don't all agree.
Authorization	Submits application dossier.	Publishes applications on its website. Recommends priorities. Committees draft opinions. Supports Commission in decision-making.	Submit proposals for substances that are considered to pose serious and irreversible effects equivalent to CMRs, PBTs, and vPvBs..	Takes decisions on priority setting (step 1) and on granting authorisations (step 2).
Restriction	Provides socio-economic assessments.	Provides opinions and comments. Publishes the member state restriction proposals and its Committee's draft opinions on the Internet.	Submit proposals.	Takes decisions on restrictions of production, marketing, and use.

Source: European Commission, «Q and A on the new Chemicals policy,» REACH, MEMO/03/213, October 29, 2003, <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/03/213&format=HTML&aged=1&language=EN&guiLanguage=en>.

conducted by member states. It will apply to substances that are used in high volumes, are deemed chemicals of special concern, or both. These chemicals include those that are «persistent» (substances that don't break down easily in the environment), «mutagenic» (substances classified as cancer causing), or «highly toxic» (caustic substances), and so-called endocrine disrupters (substances that supposedly create health effects in humans by disrupting hormones). An initial list of such high concern substances will be listed in Annex XIII of the REACH document. Of note, it is helpful to know some of the acronyms that the Commission and others use for some of these substances :

- CMRs: Carcinogenic, mutagenic or toxic in reproduction.
- PBTs: Substances that are persistent and bioaccumulative (those that collect in human and animal tissue, such as the pesticide DDT).
- vPvBs: Substances that regulators deem very persistent and very bioaccumulative.

Such substances will undergo what is called «dossier evaluation»—a process in which EU member governments review the registration data. One member state—rather than all states in which the product would be produced, imported, or used by the particular registrant—will take the lead in deciding whether additional information is necessary. At this point, the designated member nation can—if all member nations agree—call for further study. This will require companies to undergo additional expenses related to studies after which regulators can eventually propose regulations governing marketing, use, or both. If member nations don't agree to additional studies, the European Commission can decide whether such studies are necessary.

Authorization. Substances of high concern—those that EU bureaucrats decide are highly problematic (CMRs, PBTs, vPvBs)—will undergo authorization. In that case, these substances will not be allowed to enter EU commerce unless the manufacturer can demonstrate that risks can be adequately controlled or that the socio-economic benefits of allowing the substance in commerce outweigh its risks. In addition, regulators will consider whether there is a substitute product.

With all that said, it appears that the EU and member states can ban substances on a whim if this process doesn't give them enough justification for such bans. According to the Commission, member states and the Commission can suggest immediate restrictions of chemicals that are especially problematic—without waiting for any testing to be done. As a Commission paper notes: «In this way the [precautionary principle] could be implemented in cases where it would take too long to establish the data necessary for a scientific evaluation or where data does not allow the risk to be determined with sufficient certainty.»⁴ This basically suggests that the Commission can remove products from the market based on political considerations—without any scientific justification.

Restriction. The Commission refers to REACH restrictions as «the safety net of the system.» Chances are, the costs of reaching this stage will be significant and hence many firms will «voluntarily» remove products beforehand. However, widely used products of great value that have few good substitutes may work their way through the maze of REACH regulations and finally reach this stage. Then the Commission will be able to ban specific uses of such products, such as banning use in consumer products, or to ban them completely despite their value to society.

Chemicals Covered by REACH

According to the Commission, REACH will require the registration of an estimated 30,000 substances that were developed or entered into commerce before 1981 when the EU began regulating the entry of new products into the market. REACH will also cover the 3,000 or so chemicals developed since 1981, as well as chemicals or chemical products that will be developed in the future. The Commission estimates that up to 1,500 chemicals will undergo authorization.⁵

Chemicals including metals. REACH applies the term «chemicals» in the broadest sense, covering all substances involved in commerce including metals, which sometimes are not lumped into the category of chemicals for regulatory purposes. Metal alloys will not be regulated as separate substances because each metal in an alloy will have to be registered separately.

Intermediaries. In addition to chemicals produced for sale, REACH applies to some «intermediaries»—substances created in the process of making others. REACH applies to intermediaries produced at 1,000 metric tons or more a year and that transported from one place to another. It does not cover intermediaries that never leave the manufacturing site where they are created, or those produced in amounts less than 1,000 metric tons per year. For these substances, only some of the REACH requirements apply (those in Annex V). According to the commission, up to 40,000 intermediaries will require registration, but the process will be «lighter» than it is for other substances.⁶

Chemicals incorporated as or into products. REACH also applies to products that are produced or imported if they are

designed to release chemicals (such as an air freshener or ink cartridges). The substances in these products must be reported if they are classified as dangerous and are produced or imported in amounts over one metric ton. In addition, businesses will need to notify the European Chemicals Agency of any substances that are unintentionally released from products (such as the release of formaldehyde fiberboard), which will then decide if registration is necessary.

Exemptions. The 2003 version of REACH includes some exemptions, some of which are listed in REACH's Annex II. Criteria for additional exemptions are listed in Annex III. Things that the Commission viewed as obviously safe, such as water, are among those items exempt as are some products that are regulated under other directives such as medical products, food additives, cosmetics, and pesticides. In addition, the 2003 version of REACH added an exemption for most polymers. This exemption enabled the Commission to bring down cost estimates of the policy, but the Commission has indicated that polymers may be added into the REACH process in the future.⁷ One should not be surprised if REACH is extended to other items currently on the exempt list.

Regulated Entities

Manufacturers, importers, downstream users. Existing regulations currently only cover firms that manufacture chemicals. REACH covers anyone who produces, imports, or uses a regulated substance at a level of one metric ton a year or more. REACH also covers downstream users, extending the regulatory scope considerably. Downstream users include formulators (such as a paint manufacturer) and firms that use chemicals in producing their products. Downstream users must ensure that the manufacturer or importer from whom they receive a chemical provides a registration for that chemical. They will then have to make sure that their use of the chemical is covered in the registration. If not, they will have to either file a registration for their use or demand that the supplier file a registration for their use. If the downstream user wants to keep its use a confidential business secret, it will have to conduct its own safety assessments and may have to propose and eventually conduct additional data studies if they are necessary to demonstrate safe use of the substance.

REACH an Improvement to existing regulation?

REACH is supposed to address serious flaws in the current EU chemical regulatory process, increasing knowledge about substances while not leading to excessive use of animals in laboratory experiments. Under a test-run of the program—cosponsored by the European Commission, industry, and member states—major corporations made their best effort to register products with EU regulators. All businesses that participated flunked, and in a real world scenario would be subject to additional bureaucratic demands.⁸ Clearly, compliance won't be easy or quick. But there are lots of additional reasons to doubt REACH's efficacy.

Under existing directives, government agencies request information from manufacturers about «new chemicals» (about 3,000 chemicals developed after 1981) and conduct risk assessments, while no such requirements apply to the older «existing» chemicals. This process has proven slow and not particularly effective according to the Commission. It notes that since 1993, agencies had only identified 141 high-volume substances as priorities for risk assessment studies that would hopefully lead to risk reduction policies. Of these, only 27 chemicals have completed the process.⁹

The Commission premise that REACH will solve inefficiencies in the current process is highly questionable as it increases the workload of member nations, the European Chemicals Agency, and the Commission. Supposedly, these bodies will process an estimated more than 30,000 pre-1981 developed chemicals, 3,000 or so chemicals produced after 1981, any new products that might be developed, and an estimated 40,000 intermediaries—all in just 11 years! It is true that businesses will do much of the research, but the European Chemicals Agency, EU member governments, and the European Commission will have to process a monumental load of paperwork, evaluations, and recommended regulations. Also, expecting that industry can work through this maze of regulations and complete the numerous tests in this time frame is highly doubtful.

Claims that this system won't substantially increase the number of animals used in laboratory experiments are perhaps even more unbelievable. Demanding additional testing on

potentially thousands of substances is certainly going to dramatically increase the number of animals used in laboratory tests. Ironically, while some animal testing is valuable in increasing scientific knowledge, the testing practices commonly done to assess chemical toxicity—those in which rodents are administered massive doses of substances—actually have little or no relevance to the impact of chemicals on humans exposed to much lower levels, because it is often the dose, not the chemical, that creates adverse impacts in lab animals.¹⁰ Hence, the findings are likely to encourage regulators to eliminate valuable products that are relatively safe, and unnecessarily sacrifice a lot of rodents in the process.

REACH's Economic Scope

REACH's worldwide impacts could be substantial given the size and importance of the EU's chemical industry and its significant trade relationships with the United States and other nations. The EU chemical industry, the largest industry sector in Europe, accounts for 2.5 percent of the gross European product. European businesses produce 34 percent of the world's chemicals, with Germany producing the largest share. Eight nations—Germany, France, the United Kingdom, Italy, Belgium, Spain, The Netherlands, and Ireland—produced 92 percent of that production; and new member nations produce 4 percent.¹¹ According to the European Chemical Industry Council (CEFIC), the chemical industry «employs around 1.7 million people directly, and several million more work in sectors that supply the chemical industry or depend on its products. Taken together, these figures are equivalent to the total working population of Belgium.»¹²

Caution is warranted before imposing such an incredibly heavy regulatory burden on such an important industry sector. According to CEFIC, REACH will place considerable burdens on its members. A CEFIC publication notes: «Already today, bringing a new chemical to the EU market takes three times longer and costs 10 times as much as in the U.S. Substance innovation with new chemicals, which the future of the industry depends on, is therefore mainly taking place outside the EU.»¹³

REACH will make things worse, it maintains, noting that small and mid-sized firms will be hit hardest, particularly those in the fine

and specialty chemical sectors. CEFIC has indicated that it expects that firms will stop producing as much as 10 to 30 percent of substances currently produced at relatively low levels (1 to 100 metric tons per year), as the costs or regulations may make them unprofitable. Such market changes will cause some firms to relocate to non-EU countries, leading to job losses for Europeans. In addition, CEFIC points out that REACH will significantly reduce innovation as lower profits and the costs of registration will leave few resources for new product research and development. In addition, there may be fewer kinds and reduced amounts of raw materials available as importing costs grow substantially higher.

The impact of REACH on small and mid-sized firms should be a great concern for anyone interested in promoting a prosperous European economy. Ninety-five percent of chemical firms in Europe employ less than 250 people. These firms are responsible for 30 percent of chemical sector's production and they employ 36 percent of the sector's workers.¹⁴

But REACH's impact isn't only going to fall on Europe because the United States and other nations are inextricably linked to the EU economy through trade. The U.S. exports more than \$20 billion in chemical products and invests more than \$4 billion in the EU chemical and related industry sectors annually. In addition, U.S. firms export more than \$400 billion in products containing chemicals, some of which may fall under the scope of REACH regulations. The U.S. also imports more than \$40 billion of chemicals from Europe each year.¹⁵

The U.S. government mission to the EU has pointed out that REACH is expected to adversely impact tens of billions of dollars of trade in chemicals and products. Affected sectors will likely include textiles, pharmaceuticals, electronics, automobiles, and advanced materials. According to the Commission's own study, users of specialty chemicals are likely to suffer serious repercussions.¹⁶

Other likely impacts, according to U.S. officials, include:

- Chemical manufacturers may stop production of many products if the demand for the products isn't high enough to justify the costs of registration. Accordingly, some minor yet important uses of certain products may simply be eliminated.

- Smaller companies—particularly non-EU firms—will not have the resources to comply with REACH, forcing them out of European markets.
- REACH's impacts on importers in general are likely to be high. The U.S. government notes: «A typical distributor may import 1,400 preparations from outside the EU. Based on the current proposal, such a firm would have to register each substance included in the 1,400 preparations if its imports of the substance exceed one ton per year.»¹⁷ Clearly, compliance with REACH won't be easy, it won't be cheap, and it will be time consuming.
- Estimates for product removals range from the Commission estimate of 1 to 2 percent to industry estimates of up to 10 percent. The impacts of such product removals should not be dismissed. U.S. officials point out that the typical preparation can contain up to 500 substances. Removal and replacement of just one substance may require reformulation of the products and may require additional registrations. Such changes can be expensive, time consuming, and reduce the quality of the final product.

Given REACH's potentially high regulatory costs, it seems peculiar that Europeans would market the program as something that will help their ailing economy. However, these REACH supporters may naively believe that some obvious protectionist effects of REACH will improve the EU's economy. While protectionism will in fact harm the EU's competitors like the United States, it will also undermine economic growth in the EU. Hence, REACH will have adverse impacts on both sides of the Atlantic—raising costs of doing business for everyone and creating barriers to mutually beneficial trade.

REACH does indeed present serious trade implications. One issue might emerge from the fact that the U.S. and other nations exporting to the EU will not be able to register their products directly and are unable to directly participate in consortia. They must depend on importers to file the registration or hire an «only representative» to register products and participate in consortia. This system promises to disadvantage firms located outside the EU. If a U.S. firm demands that importers register their products for it, that would make importing that company's products more burdensome than

buying them locally, reducing incentives to import. If a foreign firm hires an «only representative,» that would relieve importers of the burden, but their registration costs would probably be higher, making their products more expensive and less competitive.

In a presentation to the EU Parliament last January, Dr. Marco Bronckers, who is chair of the World Trade Organization (WTO) and international trade law professor at the Law University of Lieden, detailed many trade-related problems of REACH. He noted that under international trade agreements, regulations must be «not more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create.» REACH's volume-focused requirements are likely to violate this WTO requirement. Since low risk substances will be regulated under REACH simply because of their high volume, the regulations may be deemed arbitrary.¹⁸

In fact, the REACH Alliance—a group of manufacturers who define themselves as users of «minerals, ores, other substances occurring in nature, recovered materials, and wastes»—is already complaining that REACH unfairly affects raw materials that are low risk but used in high amounts. The Alliance members point out that other raw materials are exempt—such as gas, crude oil, and coal.¹⁹ It could be argued that such exemptions, along with the fact that many of these substances pose little risk, make REACH's approach more arbitrary than public health-focused.

Australia may be among one of the first nations to bring such a complaint. It provides Europe with 96 percent of its imports for nickel and 20 percent of its lead and zinc imports—constituting about €600 million in trade in the three materials. In a study on the topic, the Australian government notes that REACH's biggest problem rests in its protectionist effects on these substances. The Australian study notes: «In broad terms, the results indicate that the indirect costs associated with reduced market access for Australian exports are likely to have a larger negative impact on the viability of these industries than the direct costs of the legislation.»²⁰

Further, Bronckers notes that REACH likely violates the WTO requirement that imported products shall receive «treatment no less favorable than that accorded to like products of national origin.» Several aspects of REACH are problematic on these grounds,

according to Bronckers. One example is the fact that domestic producers in the EU are more likely to have complied with REACH and hence products containing their goods—those covered because they may release chemicals into the environment—will not need to be registered by downstream users. Firms that want to import such products into the EU may have to meet a higher standard since the products were produced in countries where REACH regulations were not already applied to their component parts. REACH will also encourage firms to promote the purchase of domestic raw materials since they will already be registered by domestic manufacturers, relieving downstream users of any registration responsibilities.

Bronckers also raises concerns about REACH's violations of WTO rules concerning the release of confidential business secrets and intellectual property. REACH demands sharing of data from animal tests and only provided limited protection for other information. In addition, it requires a substantial amount of information on the Internet. According to Bronckers, these provisions likely violate the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, and they may enable competitors to piece together enough information to access confidential business secrets.²¹

REACH also threatens to undermine efforts by developing nations to expand trade and promote economic growth. Malaysian Deputy Minister for International Trade and Industry Ahmad Husni Hanadzlah has raised some concerns. «Developing economies and especially SMEs (small and medium enterprises) may not be able to comply with REACH requirements due to insufficient capacity,» he told an international conference on chemical policy.²² Indeed, these nations are least able to afford such regulatory burdens. REACH will likely undermine economic growth in developing nations by impeding free trade. This is particularly unfortunate as these nations greatly need development not only to ensure a better quality of life for their citizens but to improve environmental quality.

Most of the world's most serious environmental problems are the effects of poverty in developing nations. On the top of the list of environmental problems are the effects of inadequate sanitation. This is something that only economic growth can address by increasing access to chemical disinfectants—such as chlorine. Next is limited access to modern energy sources—including such things as electricity and fossil fuels—which means that the rural poor around

the world must rely on burning biomass fuels—such as cow dung—in their homes as an energy source. Resulting pollution leads to an estimated 1.7 million deaths annually associated with respiratory illnesses.²³ And as Europe laments the potential that someone might consume trace levels of chemical found in plastic packaging, the absence of such sanitary packaging and refrigeration in developing nations kills tens of thousands every year.²⁴

The solutions to poverty and resulting environmental problems involve greater economic development. The authors of a World Bank report document the fact that pollution and environmental problems decline as GDP increases. Economic growth would certainly help nations attain some much needed improvements. The World Bank suggests that developing nations need to focus on: attaining improvements in water connections in rural areas, improving personal hygiene, controlling malaria, improving stoves through greater use of kerosene and LPG stoves in rural areas, and improving urban air quality through the introduction of cleaner technologies.²⁵ All these things cost money, and all have been largely addressed in developed nations. Unfortunately, as detailed, the regulatory measures that REACH may impose on all its trade partners may prove counterproductive to such progress.

REACH Studies

According to a study produced for the Nordic Council by U.S. researchers at Tufts University, «There is little doubt that REACH will produce health and environmental benefits, but there has been little agreement about the resulting costs.»²⁶ Yet, a more rational review of the studies and data reveal the opposite. There are dozens of studies demonstrating significant costs, but not a single convincing study demonstrating health benefits. A review of each area follows.

Economic Studies

There have been quite a few studies on the potential costs of REACH—offering a variety of approaches for assessing the program. The Dutch Government overviews 36 such studies in a report²⁷ that it did on the costs of REACH, and since then at least three additional studies have emerged.²⁸ The conclusion of REACH advocates about these studies is that they somehow

indicate that REACH is affordable. However, if these studies reveal anything it is that few people are considering the full implications of REACH. But even relying on these limited studies it is clear that the impact is going to be substantial and detrimental. It is clear that REACH will most certainly hit small businesses very hard; trigger trade disputes; reduce the number of products available on the market; and cost a substantial sum.

Early Commission Studies. The most cited studies are the ones funded by the European Commission, which produced them as part of their efforts to promote REACH. The first Commission-sponsored study was produced by the consulting firm Risk and Policy Analysts Ltd. (RPA) and the Swedish government agency Statistics Sweden.²⁹ It assessed the impacts of the first draft of REACH, claiming that it could cost somewhere between €1.7 and €7 billion.

DG Enterprise, a division of the Commission that deals with business concerns, offered new estimates in November 2003 after REACH was revised, and these estimates are being used as the main statistics on REACH's cost today. However, not noted in the news is the fact that this study (like many others) only estimates a fraction of REACH's costs; it only considers the costs of registration. The assumption is that this phase is the most substantial. Yet there are likely to be many unaccounted indirect impacts as well as substantial costs associated with evaluation, authorization, and restriction stages of REACH, increasing REACH's bottom line. Nonetheless, the Commission-funded study estimates that the registration phase of REACH would cost €2.8 (over 11 years) to €3.6³⁰ (over 15 years) as a lower bound range. A higher end range estimated registration costs of €4 billion (over 11 years) to €5.2 billion (over 15 years). The higher range assumes that manufacturers will substitute 1 to 2 percent of products on the market, thus raising costs.

This Commission-funded study assumes that the «majority» registration costs will be passed from chemical manufacturers and importers on to downstream chemical users. It leaves out the impacts of reduced competitiveness that REACH may produce for downstream users, and it does not consider the economic costs resulting from reduced innovation.³¹

Joint Studies: Industry and Commission Collaboration. Most recently, the Commission released a couple of studies that were the result of a memorandum of agreement between the Commission and industry groups—the UNICE (an employers organization) and CEFIC (Europe's chemical industry association). Both industry and the Commission agreed on a KPMG study to assess the potential effects of REACH at various levels—considering impacts on producers to downstream users.

Yet like other Commission-funded studies, the KPMG study only attempts to measure a slice of REACH costs—it primarily considers *registration* costs and some impacts associated with such costs (including whether firms would remove products from the market rather than pay for registration).³² By not fully considering costs associated with authorization and possible restrictions, the study refuses to consider what will be perhaps the very expensive and burdensome parts of the program—particularly regulations and bans that will result from the authorization phase.

The KPMG study suggests that REACH will produce a one-time 6 to 20 percent increase in production costs, which, spread over many years, is supposedly a manageable burden. Groups like the World Wildlife Fund and some public officials say that this proves that business can afford registration, which means REACH is affordable.³³ But this only means that it might be affordable to big business. Meanwhile, more than 99 percent of EU businesses are small to mid-sized firms that provide two thirds of the jobs in Europe. This study should be little comfort to these firms, their employees, and the consumers who will eventually shoulder the costs of REACH.

The study also alleges—and REACH advocates highlight—that respondents in the survey believed there would be few substances vulnerable to elimination because of registration costs. However, even the elimination of just a few substances at this point in the process—not to mention the loss of products during, evaluation, authorization, and restriction stages—could be substantial. The KPMG study points this out noting that formulators of chemical substances could suffer considerably:

«Formulators typically use a particular critical substance in many of their formulations. So the loss of only a few critical substances would affect a large part of their portfolio, resulting in large scale re-formulation. In itself that would already be a significant impact. On top of that, however, newly formulated preparations require extensive testing and approval procedures at both

formulator and downstream user level. In some instances they even require fundamental changes at process and/or product level (with a large associated cost increase for EU companies).»³⁴

In addition, while the study found that large companies might not eliminate many substances, it did note that small companies may be in a completely different boat. For example, the study noted that one small firm reported that 17 percent of the substances in its portfolio were vulnerable because of REACH registration costs. Hence, for some companies the impacts of REACH could be quite substantial, and perhaps significant enough to put them out of business.

The KPMG report notes other issues of concern. In particular, it notes that price increases on products will have a «limited impact» on downstream users, but that such impact may be problematic because the profit margins of these firms is already very low and even small price changes can lead firms to relocate. A key problem is that it will be difficult for downstream users to pass costs along to consumers when competing in global markets. The study also shows that business executives are very concerned that REACH will undermine their intellectual property and confidential business secrets.

The second study—of which only preliminary findings are available—reveals serious problems with REACH's disparate impacts. Conducted by the EU's Institute for Prospective Technological Studies (IPTS), early findings of the study reveal that REACH will reduce innovation and harm businesses in the nations that need development the most—the newer EU members in Eastern Europe.³⁵ So far, data has been collected for Poland, the Czech Republic, and Estonia; and it's not encouraging.

The report finds that REACH is likely to undermine trade between the new EU members and non-EU nations. Many firms in new member nations (probably others as well) will feel compelled to import chemicals from firms within the EU because it will be easier to demonstrate that suppliers are REACH compliant. Firms producing chemicals in new EU member nations may also have to raise prices of their products because of REACH compliance costs, which will make their products less competitive elsewhere in already highly competitive world markets.

In its conclusion, the report maintains that, while large businesses will be able to cope with REACH, small businesses will not. It notes: «The heaviest burden will be on SMEs which cannot consistently fulfill the REACH requirements and so it is predicted that most of them may face financial troubles, may be taken over by bigger ones, or even shut down.»³⁶

The IPTS report also pointed out that data on REACH benefits has thus far been «entirely neglected.» Indeed, the alleged benefits of REACH are largely rhetorical and based on assumptions that studying chemicals, filing paperwork, and pursuing politically driven product bans will somehow reduce cancer rates. This is ironic, since the vast majority of cancers are not caused by manmade chemicals.

Nordic Council Study. A study commissioned by the Nordic Council of Ministers maintains that REACH's economic impacts would be insignificant.³⁷ Produced by researchers at the U.S.-based Tufts University, this study estimated an 11-year total cost of €3.5 billion for REACH's direct costs, plus 1.5 to 2.3 times that amount for indirect costs. Hence the total cost would be somewhere between €11.5 billion and €28 billion. They say this cost is «unlikely to harm European industry,» and they note that «several studies have suggested that the health and environmental benefits of REACH will be substantial.»³⁸ They make these claims on the basis that the total annual cost to the industry as a whole would come to 0.06 percent of sales revenue.

However, such assessments ignore how such costs might be allocated, which sectors might be hardest hit, and whether small businesses can bear their share of the burden. Such factors play a substantial role in how the program will impact European and world marketplaces. It is clear that there will be winners and losers. Among some of the losers might be consumers who may be deprived of certain valuable products on the market today and smaller firms that could be driven out of business. Moreover, before initiating any single policy that could cost up to €28 billion to any economy policymakers had better be very certain that it will deliver very substantial public benefits. Despite claims to the contrary in the Tufts study, there is no guarantee that REACH will deliver any benefits and certainly not more benefits than would a less regulated marketplace. Indeed, «benefits» research is equally, if not more, disappointing. These are discussed the subsequent sections of this paper.

The Tuffs study also highlights a program in the United States—the so-called Massachusetts toxics use reduction program, or TUR—attempting to suggest that it represents a successful example of a REACH-type program. It is simply not accurate or reasonable to suggest that Massachusetts has a REACH-styled program, and European leaders should be suspect of anyone who makes this claim. The regulatory scope of the Massachusetts program is vastly smaller, and the program is of a completely different character. The TUR law is outlined in about 30 pages and covers about 600 companies and about 250 chemicals within one U.S. state.³⁹ The proposed REACH exceeds 1,000 pages, covers tens of thousands of companies, potentially upwards of 93,000 chemicals (30,000 existing chemicals, 3,000 «new chemicals» created since 1981, and 40,000 intermediaries), and governs 25 nations and hundreds of its trade partners. REACH's coverage of downstream users expands its scope even further beyond anything ever envisioned for the Massachusetts TUR law.

Moreover, the Massachusetts program is little more than an accounting program. It is supposed to encourage firms to reduce «toxics» used in their industrial processes by mandating that they inventory certain chemicals and submit plans on ways to reduce so called «toxics.» There is no registration, no testing of chemicals, no evaluation, no authorization, no restrictions, and it is not governed by the precautionary principle.

And if REACH did mimic the Massachusetts program, that would be enough reason to reject it. There is no reason to believe that the Massachusetts law delivers any public health benefits, because toxics use reduction does not consider public exposure and actual risk levels. That is one thing it has in common with REACH—it focuses on regulating chemicals based on their volume rather than focusing on setting up priorities that address actual risks. According to Dr. George Gray of the Harvard Center for Risk Analysis, this program isn't particularly useful because «Chemical use does not equal chemical risk...Different applications of a chemical pose different opportunities for exposure and risk...Simply knowing how many pounds are used provides no information about health and environmental risks.»⁴⁰

Many of the program's advocates—regulatory agencies, educational bodies funded by the program (such as the Toxics Use

Institute), and environmental activists—praise the TUR program as a huge success in reducing toxics in the state, but such claims should be viewed with skepticism. For example, a study produced by the U.S. chemical industry association several years back, reported serious problems with the program and claims that it has reduced toxics in the environment. The state had reported that the program lead to a 71-million lb. reduction in toxic chemical use between the years of 1990-1995. But the industry report found that shutdowns of three industrial plants produced a 116-million lb. reduction. The study concluded that, «without the reductions due to plant closures, total use in Massachusetts increased. In fact, the long-term use trend in both New Jersey and Massachusetts is likely to be upward, matching national trends.»⁴¹

Australian Government Study. The report released by Australia in 2005, which was noted earlier, offers a more dynamic analysis that provides insights on indirect costs—which few other studies address. The authors note: «Even though the direct costs of REACH could potentially be significant, particularly for small- and medium-sized enterprises, the indirect costs of the legislation are likely to be much more considerable. These indirect costs would arise from distortions in regional protection and trade patterns across the whole minerals supply chain.»⁴²

In particular, they note that the act exempts organic materials like coal and natural gas while it regulates inorganics such as mineral oils. This disparate treatment, according to the authors of this study, will unfairly disadvantage inorganics, which may be replaced by organic substances in some cases. Such substitution is not grounded in science or justified by any safety concern. Consumers will end up paying higher prices without gaining anything in return.

In addition, the report maintains that REACH's application to minerals may raise prices for these products in global markets, drive jobs and production out of Europe, and hinder the EU's economic growth. Currently, the EU imports a considerable amount of these raw materials, such as nickel, which it uses to make intermediaries for export. But if the costs of importing nickel rise too high, firms may find it easier to shift production to less regulated nations.⁴³

German BDI Study. In 2002, the Confederation of German Industries (known by its German acronym BDI) released a study it

commissioned from the consultant firm Arthur D. Little.⁴⁴ Unlike most other reports which only focus on a fraction of REACH's cost, this study attempted to be more comprehensive. It considered the costs of registration, impacts on innovation, and the cost of potential restrictions.

To that end it developed three scenarios in which to assess REACH's impact. The «clouds» scenario, the most conservative, assumes that REACH is implemented in «the most practical way.»⁴⁵ That is, it assumes that registration costs half the maximum amount the Commission suggested in its white paper would be acceptable, that intermediates and polymers would not be registered, that there are no problems with confidential business secrets, and that firms would form substantial consortia to share costs.

At the other extreme is the «hurricane» scenario. It is based on «assumptions and experience of industry, chemical trade and authorities with the current practice in the regulation of substances.»⁴⁶ Based on costs of existing regulations for chemical testing programs, it estimated registration costs that were double those found in the EU white paper. It also assumes that formation of consortia would be «problematic» and would lead to multiple registrations of the same substances by different firms. It also assumed that existing data would not be sufficient for most registrations, in contrast to Commission studies. A scenario in between these two extremes was dubbed the «storm» scenario.⁴⁷

BDI found that a loss of German gross added value in all scenarios starting with a 0.4 percent loss in the «clouds» scenario, 2.4 percent loss in the «storm» scenario, and a whopping 6.4 percent loss in the hurricane scenario. In that case, job losses for these scenarios would be 150,000 in «clouds,» 900,000 in «storm,» and 2.35 million in the «hurricane» scenario.⁴⁸ The BDI report further concluded that REACH would lead to substantial reduction of substances on the market, reduced research and development, less innovation, reduced investment in Germany, decreased German exports, and competitive disadvantages.

In July 2004, the BDI released an update of their 2002 study to assess the October 2003 REACH draft.⁴⁹ It noted that the new legislation has reduced the costs substantially by 1.5 times, yet remaining costs were still substantial for Germany. According to BDI,

the 2003 version of REACH will produce an estimated loss of 2.7 to 3.3 percent in gross added value for Germany and a loss of 1 to 1.2 million German jobs.

French Chemical Industry: Mercer Study. A study produced by Mercer Studies for the French chemical industry focused on costs to downstream users. It concluded that the costs of REACH will be much higher than estimated in many studies because most studies only focus on the costs of testing. A number of factors create a «domino» effect, creating cost impacts down the entire supply chain. The report noted the following points:⁵⁰

- β Testing costs for substances produced in small volume would be substantial enough to cause the firms most adversely impacted (i.e., intermediate chemicals, fine chemicals and some specialist-item manufacturers) to stop using as much as 10 to 30 percent of the substances they currently use.
- β Some formulators of chemicals and some downstream users will be forced to redevelop and remarket 20 to 100 percent of the current formulations.
- β Some downstream users of specialty substances will suffer productivity losses (e.g. metallurgy). Others (electronics, textiles, automobile) will lose business to finished-product importers because importers only have to register chemicals that might be released from their products.

The Mercer report uses four case studies to demonstrate how certain industries are particularly vulnerable. One example is the microchip sector. It takes 10 years to produce a microchip, which might be marketed for two years. It requires more than 400 stages and more than 100 different process items to manufacture a chip. During this process, the component manufacturers use more than 150 substances in the process to produce a chip. The substances used to make these products are designed specifically for this industry, and for most products there are no good substitutes.

Changes to such complex processes will be expensive, time consuming, and simply not affordable for some. The Mercer study reports that such changes present a serious threat to the industry:

«Prices are fixed by a world market. An overcost in a given geographical area cannot be passed on to the customer. Chip manufacturers outside Europe will incur no cost since the end product does not contain the products used in its manufacture. The competitive gap between a European producer and an importer of semiconductors will therefore be sizeable.

In view of the risks of such overcosts, and given the manufacturing units' margin levels, some units will be compelled to relocate their manufacture and phase out their investments in Europe: a risk of a 15% loss of production within 10 years may be foreseeable depending on the options taken by the regulators. In the long run, these decisions would entail a loss of skills in a high-innovation sector, with some 15,000 jobs directly threatened.»⁵¹

Mercer offers similarly dismal scenarios for the finished textiles industry, windshield wipers manufacturers, and the steel sector. Unlike aggregate cost estimates, these examples should be a reminder that REACH costs will not fall equally on businesses. Some sectors will bear far greater burdens than others, which will likely produce much greater indirect costs than are acknowledged by those who simply calculate costs as percentage of overall industry profit margins.

Activist NGO Studies. Many of the activist studies on REACH are simply just critiques of other studies, particularly industry studies.⁵² The BDI report has come under particular criticism because it attempted to more fully consider the scope of REACH costs.⁵³ It is true that all studies have flaws in that they attempt to predict the future with very limited information on how things will eventually fall into place (or apart as the case may be). Yet assumptions under the BDI are not all that unreasonable given the heavy burden of a REACH program. In addition, the study includes one scenario that relies on the Commission assumptions about REACH, which are perhaps more unrealistic in their optimism about REACH's impacts.

These groups say that one reason the BDI study is inadequate is because it does not consider the economic «benefits» of REACH such as those noted in a study produced by the World Wildlife Fund (WWF). The WWF found a net financial gain of about \$283 billion euro over 30 years.⁵⁴ But a close look at this study shows that activists are more likely playing fast and loose with the facts. Unfortunately, they are not acting alone. The next section of benefit claims and studies demonstrates the failure for anyone to come up with truly convincing findings about the potential for any measurable REACH benefits.

REACH Benefits Rumor Mill

Most of the claims made about REACH involve speculative comments sprinkled throughout various REACH related studies. These speculations have taken on the character of gossip; they gain credibility simply by being repeated and some are embellished in subsequent reiterations. But by checking data supposedly underlying such claims, one either finds sources are lacking or that the claims greatly mischaracterize the research they cite. Consider some examples.

Rumors about the number of «problem» chemicals. The 2003 Commission white paper that launched REACH estimated that 1,400 substances would undergo authorization. That assumption was based on the idea that 900 substances already classified as carcinogenic, mutagenic or toxic in reproduction or as persistent organic pollutants would need authorization. In addition, the Commission simply guessed that there might be an additional 500 chemicals that would need regulation once their effects were studied.⁵⁵ Despite the fact this number is pure speculation, it is being cited as if there were some scientific basis for it. The consultancy Risk & Policy Analysts Ltd (RPA) uses in its attempt to rationalize REACH in a benefit study (discussed below), and it then cites the European Commission white paper as if that were enough to support this assertion.⁵⁶ Unfortunately, such guesswork science is likely to not only bolster REACH passage, it might encourage regulators to eventually use this figure as an arbitrary target, eventually condemning at least that many chemicals even if they have no good scientific justification.

Rumors about lives to be saved. The Commission's 2003 Extended Impact Assessment of REACH claims that REACH might save 4,500 lives based on data provided in a World Bank study on environmental health risks around the world.⁵⁷ This claim is repeated in the Tufts study discussed earlier. «To illustrate the possible magnitude of benefits of REACH,» the Tufts study notes, «the Commission's study employs a World Bank analysis of the total amount of disease attributable to harmful chemical exposures. Drawing from the conservative end of the range of World Bank estimates, the study assumes that 1% of all disease attributable to chemical exposures. It estimates, further, that 10% of these impacts

could be addressed by REACH, implying that 4,500 lives could be saved by REACH.»⁵⁸

Similarly, this World Bank figure is used as the basis of net benefits offered by the World Wildlife Fund's analysis,⁵⁹ which sets up three scenarios to assess REACH benefits. Two of the three scenarios suggest that the costs of REACH will exceed benefits. A third scenario estimates that REACH will produce a net benefit result of €283 billion, a number that is now being touted by activists who use it as evidence that REACH will produce a net good.

Of note, The WWF researchers claim that their effort underestimates the benefits. They explain: «Since our models exclude all environmental effects, we argue that our benefit estimates are understatements. Overall, our own judgment is that we feel confident that REACH generates net benefits.»⁶⁰ But the confidence of the WWF researchers' «feelings» should be of no comfort to those who bother to examine their data and find that it—like the Commission and like the Tufts study—grossly misrepresents the finding of the original World Bank source.

The World Bank report relates to problems as associated with high-level exposures to agro-chemicals, most of which are related to improper use of chemicals. Acute poisoning is «the most often cited health consequence of pesticides use.» It notes that health problems usually «arise from improper application or container disposal.» The World Bank report goes on to note that in addition to such occupational misuse of pesticides, there are cases of high exposure to pesticides through drinking water sources, yet «Even under these conditions, however, at levels several times higher than the quality standards, the resulting buildup has rarely been linked with observed or expected health problems.»⁶¹

REACH is not designed to address acute poisoning from or misuse of chemicals whose properties are well known. In fact, many of the substances involved in the World Bank study are likely pesticides that will be exempt from REACH regulations as they are already extensively studied and regulated under other directives. Hence, this statistic is completely irrelevant to REACH's benefits calculations, which the researchers involved should have known. The fact that the Commission and the Tufts study even attempt to use the data is indicative of the fact that

they simply don't have any good data to validate their claims about REACH benefits.

Perhaps even most disturbing is the fact that these researchers and the Commission appear to have missed the entire point of the World Bank publication. The very first paragraph in Chapter One of the report highlights the main point. It reads: «Health and development are irrevocably interrelated... Better health is both an outcome of and a vehicle for achieving economic prosperity and poverty eradication.»⁶² It reports that the truly serious environmental health threats relate to poverty and the subsequent lack of access to the benefits of modern industrial societies—not from trace level chemicals in such societies. It is not surprising that REACH advocates miss this point as the entire REACH paradigm fails to consider the value of prioritization of risks.

Allergy Rumors. As with other examples, the REACH rumor mill related to impacts on allergy sufferers starts with the Commission. In its original white paper on REACH, the Commission estimated the total health care costs associated to allergies amounts to €29 billion annually in Europe. The Commission asserts: «If the new strategy makes even a small reduction in the €29 billion of allergy costs, this will outweigh the costs of the strategy.»⁶³

That assumes chemicals are causing or aggravating a significant portion of these allergies, and that REACH will solve the problem. Both assumptions are highly questionable in any scenario, but most importantly, they are not validated by science. Nonetheless, in an effort to justify REACH, the Commission white paper notes that asthma cases have risen in the United States by 40 percent since the 1970s—implying that chemical pollution was the cause. Yet in cities where asthma cases increased, pollution levels decreased. If there was any relationship between the two it would be that pollution reductions produced increased levels of asthma, which isn't plausible. There are other, more likely explanations. For example, reduced ventilation in buildings might be an important factor.⁶⁴ If EU officials truly want to address allergy problems, REACH is not the answer.

Despite the absence of data on the claims that REACH will reduce asthma, it has gained ground as a rationale. The World Wildlife Fund takes the claim to a new level, stating that allergies «are believed to be reduced a few percent with stricter chemicals

regulation,» citing the Commission white paper as its source. Not only is there no basis for this claim, it misrepresents what the white paper claims. Nowhere does it claim that REACH would reduce allergies a few percent. It only basically states that if it has an impact that would make REACH worth the costs.

Commission-Funded RPA Benefits Study. In addition to sprinkling benefit suppositions throughout various REACH publications, the Commission commissioned RPA to produce a study to come up with some hard numbers documenting REACH benefits in terms of occupational safety. This report does one thing right. It acknowledges that REACH benefits will not result from better management of chemicals risks that governments manage today. This admission further undermines the Commission's claims based on World Bank data associated with illnesses caused by the misuse of chemicals that nations already regulate.

According to the study, REACH isn't supposed to address health concerns related to chemicals that are already studied and whose effects are well documented—existing worker directives will do that. REACH is supposed to help identify chemicals that possess undiscovered dangerous properties. Then this RPA study attempts to do something downright silly: It attempts to quantify illnesses that are caused by unknown chemical sources. But if the causes are unknown, how can anyone deem them to be caused by chemicals used in the workplace? Could they not be caused by exposures outside the workplace, or be caused by natural allergens, or be associated with genetic factors?

Such ambiguity leads to some really slippery «science.» The study design is the first and most obvious problem. A good study collects data in a systematic and consistent way, using a clear set of scientific standards. In contrast, RPA collected data from government agencies in various EU nations, and each of these used different data collection methods—some good, some not so good. In addition, rather than using one year as a sample year, RPA used different sample years for different nations based on what each nation had available. And while some of the information comes from government studies, some is better characterized as hearsay. Indeed some of the RPA study references involve nothing more than telephone conversations, which have little place in this type of study.

Another problem with the study is that it attempts to take all the murky data for a limited set of countries and extrapolate risks for the entire European Union. When a study makes such extrapolations, it should at least have a reasonably representative sample. But the haphazard nature of this data collection effort makes such extrapolations nothing more than a desperate attempt to generate something from nothing.

The extrapolations for the entire EU are based on illnesses listed in government reports under one of two categories: 1) illnesses reported as caused by «unspecified» chemicals or 2) illnesses whose causes are designated «unknown.» Using these categories, RPA developed an upper-bound estimate based on first category and a lower-bound estimated based on the other. But there doesn't appear to be any logical reason for using these designations for upper- and lower-bound estimates.

Moreover, there isn't a good rationale for assuming that REACH would have any impact on such cases. In the first instance, simply because a government lists an illness as the result of an «unspecified chemical» does not mean that it is caused by unknown chemical sources. The causes may have been clear (such as accidents and misuse of chemicals), but the case was simply reported in a miscellaneous category because it didn't fit under any of the typical categories used by public officials. RPA admits as much in a parenthetical comment noting: «although in the case of unspecified chemicals it [the data] may also reflect poor or incomplete reporting.»⁶⁵

The other category on which RPA bases its extrapolations—the «unknown» cause of illness category—is even murkier. If the cause of an illness is unknown, there is no good reason to simply assume it resulted from a chemical whose dangerous properties are yet undiscovered. Indeed, there is no evidence that such cases reflect the use of manmade chemicals at all. It is very likely that many of such cases are related to natural sources, at-home exposures, and possibly even worker stress. Yet RPA lumps these cases into their estimates. To top off the irresponsibility, RPA assumes that REACH will eliminate such health effects.

To more fully grasp RPA's misuse of the data, this analysis back references some of the original data. It finds that not only is the data

mischaracterized, RPA's numbers don't appear to directly match some of the original sources. The following overviews the data used to derive estimates on the number of respiratory illnesses allegedly caused by chemicals whose dangerous properties are yet to be discovered.

RPA estimates that annually there are about 275 to 3,680 annual respiratory illnesses related to unknown chemical sources within the EU as a whole. These figures were extrapolated from studies on occupational illnesses in just five nations: Austria, Finland, Spain, Sweden, and the United Kingdom.⁶⁶

1) Austrian Data. The data for Austria includes 69 asthma cases that are attributed to exposures to «unspecified chemicals.»⁶⁷ Yet there is no study to back reference that will scientifically support the claim. Instead, RPA cites a «personal communication» with the public official in the Austrian Federal Ministry of Economics and Labor.⁶⁸

2) Finnish Data. One of the data sources is a 1999 Finnish government report. According to RPA, the Finnish report found 627 cases of respiratory illnesses, of which 61 were caused by known chemical sources and 43 by unspecified chemicals, and another 8 caused by «unknown» chemical agents.⁶⁹ How RPA came up with 627 cases is unclear as this report lists 749 «allergic respiratory diseases» in the text of the document and 750 cases in a table in its appendix.⁷⁰ In the Finnish Report chart, there is a category for illnesses caused by «other chemical agents,» which RPA apparently used for its category of unknown chemical causes. Based on the remaining sources listed, RPA calculated the 43 illnesses related to «unspecified chemicals,» but it is unclear how RPA derived this number. The only categories for «unspecified agents» left include: one case for «glues (unspecified),» 15 cases of «organic materials (not specified),» and 12 cases related to «unknown factors»—a total of 28 unspecified causes.

But had RPA only used the 28 cases as unspecified, it would still raise questions about the integrity of this study. Simply because the Finnish report didn't list which glues caused problems, it doesn't mean the causes were unknown or that REACH would correct these problems; and counting illnesses caused by the ambiguous category of «organic materials» as unknown chemical illnesses is even more wrongheaded. Finally, counting the 12 cases related to «unknown

factors» also isn't reasonable because there is no reason to simply assume that every unknown illness is related to a chemical that has undiscovered, dangerous properties. Unfortunately such leaps in logic and misguided assumptions form the basis for the data in the RPA report.

But perhaps more disturbing is RPA's—as well as the Commission's— failure to acknowledge the more substantial findings of this report and others like it. The report shows improving worker health, and it demonstrates that chemicals aren't a significant source of the remaining problems—facts that undermine the cause for more chemical regulation under REACH. Specifically, the Finnish data show that occupational illnesses in that nation declined from about 45 cases per every 10,000 workers in 1990 to 23 cases per 10,000 workers in 1999.

In this mix, chemicals are a minor source of Finland's problems—with most cases related to non-chemical related ailments. Ranked more significant to least significant, occupational illnesses are caused by: 1) repetitive stress injuries, 2) noise-related hearing loss, 3) skin diseases (mostly from known sources), 4) allergic reactions (large majority due to Mother Nature), and 5) a category for «other.»

In the respiratory illnesses section, most cases (630/750) were caused by Mother Nature:

Flour, grains, and fodder	151
Species of wood	25
Plants	28
Plant derived dusts and substances	2
Animal hairs, cells, and secretions	145
Animal derived dusts	1
Molds	218
Mites	60

Not only are chemicals not a significant source of problems for workers, chemical manufacturers rank relatively low when compared to the number of occupational illness cases (per 10,000 workers). Out of 21 industries listed, fourteen ranked higher than the chemical industry for having more occupational related illnesses. Hence if policymakers wanted to focus on protecting

workers, it makes little sense to target an industry with the fewest incidents.⁷¹

3) Spanish Data. RPA claims that Spain experienced 295 cases of asthma and other illnesses related to unspecified chemicals in one year. This number accounts for a significant chunk of the cases used to extrapolate total cases for the EU, yet there isn't any scientific document to reference. The source for this finding is listed as a personal communication with an unspecified person at the Spanish Ministry of Employment of the Institute of Occupational Safety and Health sometime during 2001.⁷²

4) Swedish Data. According to RPA, Sweden reports 138 occupational illnesses for 1998 that were related to «unspecified chemicals,» which supposedly would be eliminated if we had a REACH program.⁷³ But as it had done with the Finish data, it appears that RPA is simply using this Swedish study to boost its benefits extrapolation for REACH using numbers that are not necessarily relevant to REACH.

The only part of the Swedish report that lists respiratory illnesses along with causes is found on page 37.⁷⁴ It includes 12 substances or products responsible for illnesses in Sweden for year 1998. RPA notes that it did not count illnesses related to isocyanates or metals, which removed three of the 12 items from the list. It also appears that RPA did not count illnesses listed as caused by mold spores and water. That leaves seven other listings, which add up to 138 cases—RPA's number. But if you look at the list, the items are not really unspecified or unknown. Instead they are simply grouped in categories. These include: solvents and dilutants, paints and glue, cleaning agents, plastics, asbestos, rubber, and oil. Using these cases to suggest that REACH will eliminate such illnesses is simply ridiculous.

5) British Data. In its chart listing respiratory illnesses and causes, RPA claims that annually in Britain there are 688 occupational illnesses related to unspecified chemicals and 47 related to «unknown chemicals.»⁷⁵ RPA notes that the source of these figures is the United Kingdom's Health and Safety Executive website, but it doesn't provide an Internet address or clearly note a source document. RPA then notes how it comes to its calculations in the footnote.⁷⁶

The explanation is a bit confusing and there appears to be mistakes in the footnote and in RPA's chart summarizing the data, but the following is an attempt to decipher RPA's complicated explanation. According to the footnote, RPA drew data from the Health and Safety Executive's website, which it used to estimate that about 11 percent of worker-related asthmas result from unspecified and unknown chemical causes. Then using EU data from a completely separate source—the European Union's statistics agency, Eurostats—RPA estimated that there are, on average, a total of 1,679 work-related asthma cases in the United Kingdom in any given year. Eleven percent of that figure comes to an estimated 188 asthma cases annually being caused by unspecified and unknown chemicals combined. Of these, RPA notes, about 47—an estimated 2.8 percent of the total number of cases—are cases that fall into the category as caused by unknown chemical sources.⁷⁷

Hence the chart should read that there are, on average, an estimated 141 cases related to unspecified chemicals (188 minus 47) and 47 cases caused by unknown sources. Instead, the chart reads that there were 688 cases caused by unspecified chemicals plus 47 cases related to unknown chemical sources.⁷⁸ The chart numbers represent what was probably an honest typographical mistake, but it is unclear as to which figures the RPA used for its extrapolation of cases for the entire EU. If it used the chart numbers, it would have been working with a figure that is nearly four times higher than its actual estimate for the United Kingdom.

Such mistakes should be caught when a study is peer reviewed. However, there is no mention in the study about passing any peer review. Perhaps if it had been reviewed, it would have been discarded or at least seriously critiqued in a public forum. Instead, in addition to the questionable approach it used to measuring respiratory illnesses, the RPA benefits study makes equally suspect claims about REACH's ability to reduce work-related illnesses in the areas of skin diseases, eye disorders, nervous system disorders, and cancer. Given the misuse of data in the respiratory example, there is little reason to believe any of the conclusions in this study. The entire study should be discarded as irrelevant in the REACH debate.

Actual Data on Chemicals, Cancer, and Other Health Impacts

If chemicals were a source of health problems, one might expect that as chemical use has increased around the world, there would be

some measurable adverse impact on life expectancy, cancer rates, or other illnesses. Yet in developed nations, where chemical use has greatly increased, people are living longer, healthier lives. According to the World Health Organization (WHO), the average worldwide human life span has increased from 45 years in 1950 to about 66 in 2000 and will most likely continue to increase to 77 years by 2050.⁷⁹

It is true that developed nations have higher cancer rates than developing nations and that there was an increase in cancer incidence during the 20th century. The WHO reports that developed nations face cancer rates that are more than twice as high as that of developing nations.⁸⁰

This finding has raised the question as to whether the rise of chemical use has caused elevated cancer rates. The data clearly indicate that chemical use and related pollution are not sources of this problem. Other factors better explain these trends. In particular, cancer is largely a disease related to aging, which means that along with the improvements in life expectancy come increased cancer rates. In addition, rates will appear even larger because the median age of the population is getting older. Not surprisingly, the WHO reports that cancer deaths and incidence grew 22 percent between 1990 and 2000. These trends are expected to continue regardless of chemical use because, as the WHO reports, the number of individuals over 60 will triple by 2050.

In addition, developed nations experienced a dramatic increase of cancer incidences in the past century because of an increase in smoking, which causes several types of cancer in addition to lung cancer. The WHO says that tobacco is the main known cause of cancer, producing up to 30 percent of all cancers in developed nations. A large portion of cancer-rate increases in developed nations⁸¹ occurred during the last century because of smoking-rate increases earlier in the century.

For example, in the United States, researchers from the University of Alabama Schools of Medicine and Public Health report that smoking is responsible for making what was once a rare occurrence—lung cancer—one of the most common cancers today. They note: «When the mortality from all smoking-related cancers is excluded, the decline in other cancer from 1950 to 1998 was 31 percent (from 109 to 75 deaths per 100,000 person years).»⁸² These

researchers noted further: «A typical commentary blamed ‘increasing cancer rates’ on ‘exposure to industrial chemicals and run-away modern technologies whose explosive growth had clearly outpaced the ability of society to control them.’» But their research finds: «There is no denying the existence of environmental problems, but the present data show that they produced no striking increase in cancer mortality.»⁸³

The WHO’s *World Cancer Report* includes some statistics on world cancer rates. We can see improvements in these data and cannot find any chemically caused cancer crisis. For example, it notes that during recent decades breast cancer incidence has increased in many developed nations, but it does not identify chemicals as the culprit. Instead of an actual increase in rates, the WHO notes that increased screening simply helped find more cancers. The good news is that, starting in the 1980s, mortality began a downward trend in Europe, North America and Australia thanks to better screening and improved treatment techniques. Because smoking rates have declined, lung cancer has finally begun to decline in developed nations—trending downward among men during the past decade, and beginning to trend downward for women (reduction of smoking among women has been slower).⁸⁴ Unfortunately, in most other nations, smoking related lung cancer continues to increase as they have not experienced the same decline in smoking rates, particularly in Eastern Europe, which partly accounts for that region’s higher cancer rates overall.

To get a better idea about cancer trends, there are several reports available, but first one needs to consider how the rates are reported to understand what they mean. Cancer data that is age-adjusted offers a clearer understanding about risk and actual trends than does non-age adjusted data.. Age-adjusting involves controlling for the fact that the portion of the number of older people in a population may be increasing or decreasing. Since cancer is a disease that occurs at older ages, when a larger share of the population is older, there will be more cancers, although the risk per individual might be declining or remaining constant. Hence, when researchers adjust for such changes in the population, they get a better idea as to whether cancer risks are increasing or declining. In addition, as a population grows larger, so does the number of cancers. So even if cancer risks to the individual are declining, absolute number of cancers for the population could be increasing.

Hence, risk is better measured by counting the number of cancers per 100,000 individuals.

A special report in the *European Journal of Cancer* offers an analysis on cancers around the world using age and population-size adjusted data.⁸⁵ A similar analysis was produced by the National Cancer Institute (NCI) in the United States. Both articles offer valuable analysis and explanations of the data that—when absent—can facilitate attempts to mislead the public and policymakers about the meaning of this data.

The *European Journal of Cancer* notes that rates for cancer are increasing overall because of various circumstances around the world that are not easily lumped into a single category—none of which include exposure to trace levels of chemicals. Yet in some places, both mortality and incidence is declining, particularly in industrialized nations where chemicals are used widely. Likewise, U.S. National Cancer institute reports: «Cancer incidence for all sites combined decreased from 1992 through 1998 among all persons in the United States, primarily because of a decline of 2.9 percent per year in white males and 3.1 percent per year in black males. Among females, cancer incidence rates increased 0.3 percent per year.⁸⁶ Overall, cancer death rates declined 1.1 percent per year.» This report shows that the incidence has increased among women, but that increase is largely due to increased rates of smoking among women.

It is difficult to come up with aggregate estimates for Europe as a whole because of very different circumstances among the various nations. In particular, progress in cancer reductions and cures are coming faster in Western Europe than in Eastern Europe where nations are at an earlier stage of development. According to one report: «The favorable trends in Western Europe over the recent years are similar to those observed in the U.S.A.»⁸⁷

In recent years, breast cancer among women has risen, particularly in developed nations. However, it is clear that a significant part of increases in recent years is simply the result of better screening and increased detection as noted by the WHO. In the United Kingdom, «the most notable change [in breast cancer incidence rates] has been acceleration in the slow increases noted in the 1970s following the introduction of screening in approximately

1988. Similar acceleration of reported breast cancers occurred in the United States, as mammogram rates doubled between 1987 and 1998 from 32 percent to 63 percent. The percent of women aged 50 to 64 who received a mammogram increased from 31 to 73 percent in that same time period.⁸⁸ Screening has had similar impacts in The Netherlands, Denmark, and Norway.⁸⁹

However, screening doesn't explain all incidence increases in breast cancer. The Research published in the *European Journal of Cancer* notes a number of important factors that have contributed to such increases that are often completely overlooked by those who want to pin the blame on chemicals. Risk factors associated with this cancer are related to lifestyle choices available to women in industrial societies—which explains why breast cancer is more common in Western nations. These include dietary factors such as: consuming too much fat, alcohol, or both; obesity among children (which increases risks as it can affect hormone levels and produce early menstruation); weight gain after menopause (which may increase risks by 2 percent per unit of body mass index); and gaining too much weight after 18 years of age (which has been «shown to be a strong independent risk factor for breast cancer compared with preservation of body weight»). Delaying or refraining from child bearing can also affect hormone levels, thereby increasing breast cancer risks. And finally, the use of hormones for birth control and menopause treatment may «slightly» increase risks.⁹⁰

As developing nations experience economic growth, we should expect breast cancer rates to increase with the introduction of risk factors associated with the lifestyles in developed nations. However, such increases should not be confused with—or exploited to claim—the existence of a chemically caused cancer epidemic.

In addition, studies assessing alleged chemically-caused breast cancers are not finding much of a link. U.S. researchers produced one of the largest studies among women in Long Island, New York, which found no link between the chemicals most often cited as a potential cause of breast cancer—DDT and other pesticides as well as PCBs—and an elevated level of cancers in that area.⁹¹

Not emphasized by anti-chemical activists is the fact that modern medicine—and its many chemicals—are saving women from breast cancer. In Europe, survival after one year is 91 percent, and survival after

five years is 65 percent. Survival in the United Kingdom increased nearly 3 percent a year between 1978 and 1985.⁹² Other European nations appear to be at an earlier stage in reducing rates but there appears to be declining mortality among younger generations.⁹³ In the United States, death rates from breast cancer decreased by 1.6 percent for all races combined from 1989 through 1995. Between 1995 and 1998, the death rate declined even faster at a rate of 3.4 percent.⁹⁴

Prostate cancer increases have also been a subject of controversy and the Commission suggested that these increases demand regulation of industrial chemicals.⁹⁵ Incidence for prostate cancer rose in recent years in both Europe and the United States, but has since leveled off in both sides of the Atlantic.

On both sides of the Atlantic prostate cancer rose with the introduction of better technology for detecting such illnesses—hence at least part of the increase is related to improved detection. European cancer researchers reported recently that such rate increases and recently reduced mortality are «consistent with a favorable role of improved diagnosis, but mainly of advancements of therapy.»⁹⁶

Likewise, the National Cancer Institute reports that prostate cancer incidence increased after 1973 at a rate of 2.9 percent annually and then at a steeper rate when improved screening methods identified more cases. Nonetheless, prostate cancer cases began to decline by 11 percent annually between 1992 and 1995, and have since leveled off. Mortality follows a similar trend, declining between 1995 and 1998 at a rate of 4.7 percent for white males and 3 percent for African American males.

Better detection probably doesn't explain all of the increase in prostate cancer. Environmental factors may be causing some additional cancers, but exposure to trace levels of chemicals is not among the likely or documented causes. Instead, dietary factors, such as increased intake of animal fats or increased infections related to more sexual promiscuity are more likely sources. Occupational exposure to pesticides (which is far higher than public exposure) is noted as a possibility by the National Cancer Institute, but it is not a strong probability as «it is unclear if this finding is the result of occupational factors or to concomitant lifestyle factors.»⁹⁷ Occupational exposures to

other chemicals show only «weak associations» and are far from conclusive.⁹⁸

NGO activists have also claimed that chemical use is somehow linked to a supposedly alarming increase of brain and other cancers among children. The Center for Children's Health and the Environment has run an advertising campaign against chemicals. In one advertisement, they proclaim: «More children are getting brain cancer. Why? Toxic chemicals appear to be linked to rising cancer rates.»⁹⁹

But policy makers should not fall for such claims. First, because childhood cancer is rare, an increase of even a relatively small number of cancer cases will appear more substantial when expressed on a percentage basis. Moreover, studies of the data in Europe report that better detection technology as well as improvements in the cancer registries played important roles in the increase of reported childhood brain cancers.¹⁰⁰ Fortunately, research also finds that childhood mortality associated with cancer in general is declining dramatically in developed nations. According to one report, mortality from childhood cancers has declined 50 percent in Western Europe, and is also declining in Eastern Europe, but at a slower rate.¹⁰¹

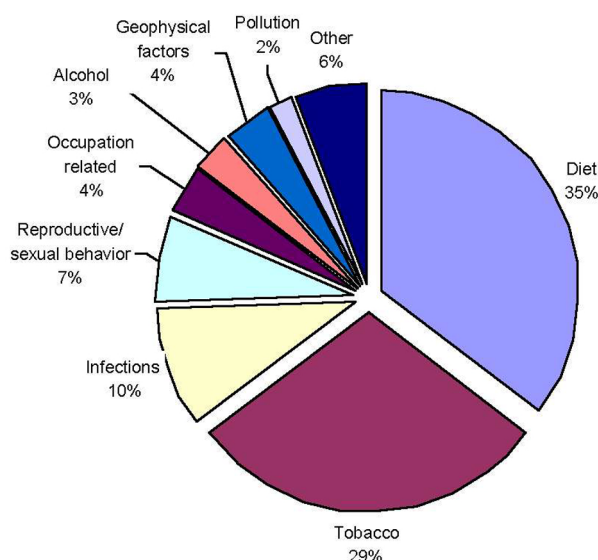
Similarly, according to the National Cancer Institute, the trends related to childhood cancer are anything but alarming in the United States. Cancer incidence among children is stable and the United States is experiencing «dramatic declines» in childhood cancer mortality overall. And the Institute attributes brain cancer increases to improved detection technology. It concluded:

«There was no substantial change in incidence for major pediatric cancers, and rates have remained relatively stable since the mid-1980s. The modest increases that were observed for brain/CNS [central nervous system] cancers, leukemia, and infant neuroblastoma [cancer of the sympathetic nervous system] were confined to the mid-1980s. The patterns suggest that the increases likely reflected diagnostic improvements or reporting changes. Dramatic declines in childhood cancer mortality represent treatment-related improvement in survival... recent media reports suggest that incidence is increasing and that the increases may be due to environmental exposures. However, these reports have not generally taken into consideration the timing of changes in childhood cancer rates, or important development in the diagnosis classifications of childhood cancers.»¹⁰²

Assessing Environmental Causes of Cancer

If European Union officials are actually concerned about cancer, they are clearly focusing on the wrong source of the problem. The World Health Organization estimates that 1 to 4 percent of cancers can be attributed to environmental pollution in developed countries. Indeed, trace levels of chemicals and environmental pollution are not the key causes of cancer as noted by the WHO.

The WHO cites a world-renowned study by scientists Sir Richard Doll and Richard Peto.¹⁰³ While Doll and Peto note that 80 to 90 percent of cancers are caused by «environmental factors,» this phrase encompasses anything other than genetics. It does not include pollution alone. Environmental factors include smoking, diet, occupational exposure to chemicals, «geophysical factors» such as naturally occurring radiation, manmade radiation, medical drugs and radiation, and pollution. According to Doll and Peto, pollution accounts for only 2 percent of all cancer.¹⁰⁴ Neither Doll and Peto nor the WHO mention exposure to chemicals through consumer products as a serious cause of cancer, which is a key focus of the chemicals strategy. In addition, the EU policy will not likely affect occupational exposures in the developed world since, as the WHO notes, «most occupational carcinogens have been removed from the workplace.»¹⁰⁵



Causes of U.S. Cancer Related Deaths

Doll and Peto report that tobacco use accounts for about 30 percent of all annual cancer deaths,¹⁰⁶ and dietary choices account for 35 percent of annual cancer deaths.¹⁰⁷ The WHO confirms these figures, attributing 30 percent of cancers to smoking and 30 percent to dietary factors.¹⁰⁸ The WHO notes that chronic infections—which are particularly a problem in developing nations—cause about 18 percent of worldwide cancers.¹⁰⁹ Genetic factors may lead to an additional 4 percent of cancers. That means less than 20 percent of cancers result from all other causes including—pollution, alcohol, occupational exposures, medical drugs, food and water contaminants, radiation, immunosuppression problems, and reproductive factors and hormones.

Nonetheless, the developed world's aging population does indeed present new health challenges that are important to address. The WHO suggests that cancer prevention efforts should focus on three factors: tobacco use, diet, and infections, which together account for 75 percent of cancer cases worldwide.¹¹⁰ Efforts to encourage people to change personal habits by eating better are likely the most effective cancer prevention policy. The EU chemicals policy won't have much of an impact on cancer rates or mortality. It may, however, absorb resources that could improve public health and well-being in other areas.

Endocrine Disrupters

The Commission and REACH supporters have also suggested that chemical regulation will somehow address the alleged problems associated with so-called «endocrine disrupters.»¹¹¹ Endocrine systems in both humans and animals consist of a series of glands that secrete hormones and send messages throughout the body. Working in conjunction with the nervous system, these messages trigger various responses such as growth, maturation of reproductive systems, contractions during pregnancy, etc. Foreign chemicals can disrupt proper functioning of the endocrine system and lead to health problems. Environmentalists refer to such external chemicals as «endocrine disrupters,» but others use more neutral terms because not all impacts will be negative or substantial. The American Council on Science and Health (ACSH) refers to them as «endocrine modulators.»¹¹² The U.S. National Academy of Sciences (NAS) calls them «hormonally active agents.»¹¹³

The «endocrine disrupter» alarm tactic focuses primarily on synthetic chemicals. Allegedly, because we have used and continue to use manmade chemicals—particularly a class of chemicals called organochlorines (such as DDT and PCBs)—the public are widely suffering with everything from infertility, neurological disorders, cancer, and developmental problems.

Concerns arose when it was discovered that children of women who took diethylstilbestrol or DES (a drug that was used between 1940 and 1970 to prevent miscarriages) experienced a higher incidence of reproductive tract problems. But the relevance of these cases to low-level environmental exposures to other potential endocrine modulators is highly tenuous. As toxicologist Steven Safe notes: «DES is not only a potent estrogen, but it was administered at relatively high doses...In contrast, synthetic environmental endocrine-disrupting compounds tend to be weakly active.»¹¹⁴ The ACSH report notes that putting environmental exposures to synthetic chemicals in perspective requires that we compare the potency of such to that of the human produced estrogen, 17b-estradiol. Scientists have found synthetic chemicals DDT and PCBs (the most studied chemicals claimed to be endocrine disruptors) to be up to one million times less potent than 17b-estradiol.¹¹⁵ Similarly, the NAS recently reported that data is lacking to show that «hormonally active» compounds caused any adverse impacts.¹¹⁶

Yet more consternation resulted when Danish researchers conducted a statistical analysis (a type of study that scientists refer to as a meta-analysis) of 61 papers that included data on male sperm counts. They reported a «significant decline in mean sperm count» between 1940 and 1990.»¹¹⁷ But they noted that whether environmental estrogens were involved remained to be determined. The 1992 Danish meta-analysis, on which the declining sperm count claim is based, garnered criticism for numerous flaws, including the author's selection of data that left out low sperm counts in the early dates, simply creating the illusion that sperm counts in the later dates were lower.¹¹⁸ A re-analysis of the 61 studies found that an analysis published between 1970 and 1990 (which amounted to 88 percent of the population of the studies) found that male sperm counts actually increase in more recent times.¹¹⁹ To complicate matters further, while there were some additional studies that suggest falling

sperm counts,¹²⁰ other studies have undermined those findings by reporting no change or an increase in sperm counts.¹²¹ Claims of declining sperm counts remain largely speculative. And even Richard Sharpe, one of the strongest advocates of potential sperm declines, notes «it is only a hypothesis.» He defends the hypothesis only based on the idea that «all the facts fit» (despite many findings to the contrary).¹²²

As in the prior case, concerns about breast cancer caused by endocrine modulators arose with the publication of one key study. This time, it was a 1993 study led by Mount Sinai Medical School professor Mary Wolff that compared DDT levels in the body fat of 58 women with breast cancer with 171 control subjects.¹²³ Although still a small sample, the Wolff study was larger than prior studies, only one of which had more than 20 subjects. Wolff, et al., found higher levels of DDE (the metabolite of DDT) in breast cancer victims, indicating an association between the two phenomena.

While including a phrase of caution («these findings are novel» and «require confirmation»), the study was full of more explosive rhetoric. In the conclusion, the authors make strong statements about their «findings»—which lump in all organochlorine substances even though the study focused only on DDT metabolites—and make a plea for government action: «Our observations provide important new evidence related to low-level environmental contaminants with organochlorine residues to the risk of breast cancer in women. Given widespread dissemination of organochlorines in the environment, these findings have immediate and far-reaching implications for public health intervention worldwide.»¹²⁴ As Stephen S. Sternberg, pathologist with Sloan-Kettering Cancer Center noted: «With these statements, one can hardly consider that the investigators reported their conclusions cautiously.» The result was media hype about breast cancer risks. «The jury isn't in, yet you would never know it from the media reports,»¹²⁵ said Sternberg. Following this report, considerable criticism of the study quickly appeared in the scientific literature.¹²⁶

One group of researchers noted: «Their literature review excluded substantial conflicting evidence, their discussion of the Serum DDE and PCB measurements and the case-control analysis excluded important details, and their dose-response analysis, given their data used an inappropriate method. Also we do not believe that their data support their conclusion of a relationship between breast

cancer and organochlorines as a class,» noted one group of researchers.¹²⁷

The National Academy of Sciences also noted that among the problems with the breast cancer study were that the size of the study was too small to provide much conclusive information; methodological problems could mean that the disease was causing higher levels of DDE rather than the other way around; and adjustments that the Wolff study made to account for alleged losses of DDE levels because of lactation may have been inappropriate (controlling for these variables substantially increased estimated DDE levels in cancer victims).¹²⁸ Ironically, Wolff, who remains an advocate of the view that organochlorines likely play a role in breast cancer and other diseases,¹²⁹ participated in other studies that failed to find associations.¹³⁰

The National Academy of Sciences concluded that the Wolff study and all the ones published before 1995 «do not support an association between DDT metabolites or PCBs and the risk of breast cancer.»¹³¹ Subsequent studies further undermine cancer claims.¹³² Key among these was a study of 240 women with breast cancer and a control group of the same size, which could not find a link.¹³³ The NAS concluded about the studies conducted after 1995: «Individually, and as a group, these studies do not support an association between DDE and PCBs and cancer in humans.»¹³⁴

Ironically, the entire theory that industrialization is causing severe endocrine disruption falls apart when exposures to naturally occurring endocrine modulators are taken into account.¹³⁵ Plants naturally produce endocrine modulators called phytoestrogens to which we are exposed to at levels that are thousands and sometimes millions of times higher than that of synthetic chemicals. Humans consume these chemicals without adverse impact every day and some contend that these chemicals promote good health. In fact, hundreds of plants appear to contain endocrine disrupters, and lab tests have discovered endocrine disrupters in 43 foods in the human diet.¹³⁶ Soy products, particularly soybean oil, are found in hundreds of products many of which we safely consume on a regular basis.¹³⁷ While we safely consume them, phytoestrogens are 1,000 to 10,000 times more potent than synthetic estrogens. Because we consume far more phytoestrogens in our diet, the estrogenic effects of the total

amount we consume are as much as 40 *million* times greater than that of the synthetic chemicals in our diets, yet they are still safe.¹³⁸

Why REACH is Dangerous: «Precautionary» Stagnation

The EU white paper notes that the main rationale for REACH rests on the precautionary principle. It states:

«EU Chemicals Policy must ensure a high level of protection of human health and the environment as enshrined in the Treaty both for the present generation and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the chemical industry. Fundamental to achieving these objectives is the Precautionary Principle. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available.»

This statement is much in line with radical environmentalist thinking regarding chemicals and many other technologies. In his book, *Pandora's Poison*, Greenpeace's Joe Thornton calls on society to follow the «precautionary principle,» which «says we should avoid practices that have the potential to cause severe damage, even in the absence of scientific proof of harm.»¹³⁹ We should shift the burden of proof, he continues. Those individuals or firms introducing new chemicals must prove they are safe before introducing them into commerce and those chemicals already in commerce that fail to meet this standard «should be phased out in favor of safer alternatives.»¹⁴⁰

No one can ever prove anything 100 percent safe. Not surprisingly, Thornton also advocates a «zero discharge» policy, which calls for the elimination of all «bioaccumulative»¹⁴¹ chemicals. In particular, he has long called for the elimination of chlorine, about which he once noted: «There are no known uses for chlorine which we regard as safe.»¹⁴² More recently, perhaps in recognition that this standard is politically untenable, he suggested that we continue using chlorine for «some pharmaceuticals» and some «water disinfection» but only until other options become available.¹⁴³

Yet chlorine is essential for public health around the world. Pushing politically selected alternatives that may not work as well could jeopardize public health. About 98 percent of U.S. water suppliers use some form of chlorination, preventing disease outbreaks and saving millions of lives every year. For example, since local engineers and industry introduced chlorination in the 1880s, waterborne disease-related deaths in the United States dropped from 75 to 100 per 100,000 people to less than 0.1 deaths per 100,000 annually in 1950.¹⁴⁴ Nearly 85 percent of pharmaceuticals that we now use require the use of chlorine in their production.¹⁴⁵ Thanks to chlorine and other chemicals used for pharmaceuticals, combination drug therapy has reduced AIDS deaths by more than 70 percent from 1994 to 1997.¹⁴⁶ Fifty percent of the reductions of heart disease related deaths between 1980 and 1990 (total death rate decline of 30 percent) are attributable to medicines and the chemicals that compose them.¹⁴⁷

Places that lack adequate chlorination don't fare as well. In fact, more than 25,000 people die everyday in developing nations from waterborne diseases. According to the World Health Organization (WHO), in the developing world, diarrhoeal diseases (such as cholera and dysentery) kill about two million children under age five every year because of factors like poor sanitation and unsafe drinking water.¹⁴⁸ Rather than curtailing the use of chlorination as Thornton suggests, public health officials should be in a mad rush to expand access.

With its statement, the EU will codify a version of this impossible and dangerous standard. There will always be scientific uncertainty, as everything in life carries a risk. We take reasonable risks in life because of the tremendous benefits we gain. As CEI President Fred Smith notes: «Experience demonstrates that the risks of innovation, while real, are vastly less than risks of stagnation.»¹⁴⁹ Indeed, he asks, what would the world be like if we never introduced penicillin because we could not prove it's 100 percent safe?

Some products are beneficial because of their innately risky nature. Chemicals that are designed to kill insects and pathogens that otherwise would harm the public must carry some risk or they would not provide the public health benefits they promise. Drugs pose risks and often carry side effects, but we take them nonetheless to ward off more serious public health consequences. In a world laden with risks, so-called

«precautionary» policies that prevent technologies actually represent the truly risky approach.

In addition, EU's assumption that regulators can find less risky alternatives is unrealistic. The reason a product succeeds in the marketplace is because consumers found that it is the best alternative. The idea that regulators can pick better alternatives is naive and it ignores the fact that politics may play a larger role than science in government selection of alternatives. As a result, «politically correct» alternatives may win, while public health suffers.

Therefore, it makes sense to allow individuals maximum freedom to weigh the risks of various activities and then choose among risks for the maximum benefit. Members of the public make these risk-risk calculations and tradeoffs every day. Regulators too should consider the risks of their decisions to regulate as well as the risks they attempt to regulate. Rather than following a stagnating precautionary principle, regulators should follow a risk-risk principle, assessing even the risks of regulation. They should also recognize that regulation is the last resort because well-being is best promoted by maximizing freedom, which results in human progress.

Regulation in this area can be limited because, as demonstrated in the prior section of these comments, the risks associated with chemicals in commerce today are considerably low, particularly considering the benefits they generate. But the EU's «precautionary approach» will preempt products that pose tiny risks without regard to the cost to human well-being.

The idea that «decision-making must be based on precaution in order to prevent damage to human health and the environment» suggests that new products will be delayed or preempted based on mere potential adverse effects. This is an unusually easy standard for those who seek to preempt products and impose bans for other reasons. In fact regulations are already being used by some companies to push competitors out of the market, or by environmental activists who seek regulation of large firms simply because they don't trust industry, or by regulators whose job is justified by their exercise of power in the marketplace.

Today, precautionary approaches are already being employed and seriously adverse impacts are the result. Consider some

examples. An obvious example has already been raised: risks associated with chlorination elimination or reduction. Residents in Peru learned about the dire impacts of inadequate water disinfection in 1991. Inadequate chlorination has been cited in scientific literature as a key factor in a cholera epidemic that started in Peru and spread then throughout the hemisphere, leading to about a million cases of cholera and thousands of deaths.¹⁵⁰

Another dramatic example is the ban of the pesticide DDT. While people in developed nations have not felt the adverse implications as most had eradicated malaria-carrying mosquitoes (many using DDT themselves), individuals in the developing world are suffering miserably because they followed Western nations' lead in banning DDT. Currently about 2.1 billion people are at risk from mosquito-borne diseases every year, according to the WHO.¹⁵¹ In Africa alone 1.5 to 2.7 million people, mostly children, die from malaria every year.¹⁵²

When DDT was in use in developing nations to eliminate malaria risks, rates were declining substantially—but after the ban malaria cases have skyrocketed. After using DDT to nearly eradicate the malaria-carrying mosquitoes, South Africa stopped using it because of political pressure. After DDT use stopped, South African cases rose from 4,117 in 1995 to 27,238 by 1999 (or possibly as many as 120,000 if one considers pharmacy records).¹⁵³

According to research of tropical medicine specialist, Dr. Don Roberts (et al.): «Separate analyses of data from 1993 to 1995 showed that countries that have recently discontinued their spray programs are reporting large increases in malaria incidence. Ecuador, which has increased use of DDT since 1993, is the only country reporting a large reduction (61%) in malaria rates since 1993.»¹⁵⁴

After millions of people have died as a result of this policy, public health officials finally spoke against a worldwide DDT ban during the negotiations on the Persistent Organic Pollutants Treaty (POPs Treaty). During treaty negotiations, more than 350 public health officials—including three Nobel laureates—signed a 1999 letter supporting continued use of DDT to fight malaria.¹⁵⁵ The final treaty allows for limited use of DDT, but creates serious hurdles for those countries that want to use DDT. It will require developing nations to navigate an expensive, bureaucratic process before they can employ DDT to save lives.

Developed nations have not suffered nearly as much because we banned DDT after eradicating malaria. We also have the wealth necessary to put screens on our windows and employ more expensive pesticides. However, pesticide regulations based on absurdly cautious standards are beginning to cause public health problems in developed nations as well. In particular, numerous medical entomologists fear that excessive U.S. government regulation jeopardizes public health by reducing development of, and access to, much needed pesticides.

In 1992, a National Academy of Sciences report warned: «A growing problem in controlling vector-borne diseases is the diminishing supply of effective pesticides.» Because all pesticides must go through an onerous registration process at the federal Environmental Protection Agency, «some manufacturers have chosen not to reregister their products because of the expenses of gathering safety data. Partly as a result, many effective pesticides over the past 40 years to control agricultural pests and vectors of human disease are no longer available.»¹⁵⁶ The National Academy of Sciences continued, «The potential for vector-borne disease to emerge in the United States still exists...any reduction in vector control efforts is likely to be followed by a resurgence of the vector population. For a disease agent that is known or suspected to be transmitted by an arthropod vector, efforts to control the vector can be crucial in containing or halting an outbreak.»¹⁵⁷ Since the U.S. pesticide registration process is very similar to what the EU would implement with its policy, EU policymakers should pay heed to this lesson.

In addition, precautionary rhetoric has encouraged U.S. public health officials to decide against spraying pesticides during mosquito-borne disease outbreaks. For example, shortly after discovering West-Nile-infected mosquitoes in East Meadow and Hempstead, N.Y., in 2001, local health officials there also followed activist advice and decided against spraying. «We believe the risk of infection for...residents remains quite low,» Nassau County's Health commissioner told the press in early August 2001. But apparently, the risk was not low enough for East Meadow residents Adeline Bisignano and Karl Fink. Both became ill with the virus at the end of that same month and died the following November. We don't know if spraying would have saved these lives, but it surely would have reduced the risks.

During the U.S. outbreak of West Nile virus last year, the United States saw 4,000 serious West Nile illnesses and nearly 300 deaths—a level that is unprecedented for this disease. Pesticides were used in many communities to limit the toll on public health. Louisiana state epidemiologist Dr. Raoult Ratard explained during last year's outbreak why it was important for localities in his state to spray. Mosquito populations can be reduced by 95 percent when an area is treated for the adult insects and larvae. Without such mosquito control, «there'd be many, many more cases,» Ratard noted. Still there were many communities that chose not to spray based on unrealistic assumptions about pesticide risks.

Other Examples. Alleged «precautionary» approaches are also adversely impacting the provision of health care. For example, environmental activists pushed U.S. hospitals to eliminate products using mercury. When hospitals caved to those demands and began removing mercury-containing blood pressure equipment, doctors found that inadequate substitutes can have devastating effects. New York Times science reporter Gina Kolata notes cases in which readings of alternative equipment were so far off the mark that doctors provided damaging treatment. In one case, the alternative equipment produced an incredibly high blood pressure reading for one patient whose pressure was actually on the low side. The reading led doctors to administer medicine that reduced the woman's blood pressure so much that she had a stroke.¹⁵⁸

The United States Food and Drug Administration (FDA), for example, has delayed life-saving drugs, sometimes for decades. As thousands of people die, the FDA limits access to «be on the safe side.» For example, the FDA delayed approval of the Omnicarbon heart valve for 15 years, finally granting approval in 2001. Meanwhile this device was saving lives in Italy, Germany, France, Switzerland, and Japan since 1986, with nearly 30,000 of such devices implanted during those years of FDA delay. In 1998, still years before «cautious» FDA granted approval, Dr. Steven Phillips of the U.S. National Institutes of Health reported to the U.S. Congress that these valves «demonstrated a complication rate one-half that of equivalent valves approved by FDA.»¹⁵⁹ In 2001, CEI General Counsel Sam Kazman commented: «The FDA is afflicted by deadly over caution. Delay may protect the agency politically, but it can mean death to patients in need.»¹⁶⁰ It is not surprising that a 1996 CEI poll of cardiologists found that 65 percent agreed with a statement that the FDA approval process is too slow.»

The Competitive Enterprise Institute has documented numerous other cases. During the late 1980s, FDA blocked the release of the first drug that had been shown to open blocked coronary arteries. While patients in Europe benefited from these treatments, FDA delayed two years. Given that it was shown to reduce in-hospital deaths of heart attack patients by 18 percent, about 22,000 deaths (18 percent of 700,000 for each of the two years) could have been prevented if FDA had not delayed.¹⁶¹ Similarly it took FDA three and a half years to approve the drug Interleukin-2 (IL-2), which is used to treat a fatal form of kidney cancer. The president of the National Kidney Cancer Association noted the absurdity of FDA delays (European nations approved the drug much sooner): «The odds of being helped by IL-2 are about one out of four...The odds of dying from the therapy are about one out of 25. As gambles go these are not bad odds, particularly when... there is almost certainty of death if no risk is taken.»¹⁶²

It is true that there are risks associated with taking pharmaceuticals—far more than low-level exposures of chemicals in consumer products—but the key question is: Who shall decide? It is fine for governments to do studies and advise consumers, but there are very high costs when government denies access to products, as FDA does here, and as the EU will do if it enacts the chemicals policy.

Biotechnology policies offer more examples of over precautionary politics harming and even killing people. «Precaution» in this area has even led some nations to refuse food donated to starving people. For example, in September of 2002, the government of Zambia withheld food because it was produced using biotechnology, despite the fact that its citizens were starving. Eventually, people broke into sheds where the food was stored to avoid starvation.¹⁶³

If the EU continues down this path, additional products and their benefits will be placed at risk. For example, what limits and adverse implications will the EU policy have on agriculture? The EU can conduct prospective studies and hope they are right in their assessments, but unintended consequences are sure to arise, and many are likely to prove very negative.

The impacts could be dire since the world depends on modern farming with chemicals for food production. Such practices are why

output has outpaced population growth—providing people in both developed and developing countries with more food per capita. Per-capita grain supplies have grown by 27 percent since 1950 and food prices have declined in real terms by 57 percent since 1980.¹⁶⁴ The use of herbicides to control weeds decreases the need for tilling soil, which in turn reduces soil erosion by 50-98 percent.¹⁶⁵

The use of high yield farming—which employs chemical fertilizers, pesticides, herbicides, etc.—means we feed more people while farming less land, leaving more land for wildlife. If we had continued to farm with 1950s technology—when most of the world did not use pesticides and fertilizers—today we would have to plant 10 million square miles of additional land to generate the food that we now produce.¹⁶⁶ That's more land than all of the land in the United States, Canada, and Central America combined (which is about 8.6 million square miles) and almost as much of all the land in Africa (which is just under 12 million square miles).

Conclusion

It is astounding that REACH has made it this far through the EU policymaking process. Any serious analysis of the law reveals that the economic impacts for REACH are not good for Europe, the United States, and other Western nations, and its impacts could be particularly dire for developing nations and new EU member nations. Meanwhile, documented benefits of this program are nonexistent. Underlying all benefits claims is appallingly poor quality data, junk science, or mere supposition that is less reliable than gossip. Moreover, public health trends show that threats from trace-level chemicals are tiny, particularly compared to real world problems associated with such things as poverty. Unfortunately, failure to consider such realities and set reasonable public health priorities won't only hurt the nations that deliver such faulty laws, it promises to deprive individuals of basic economic freedoms and harm human well being around the globe.

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