NEW DIRECTIONS IN EUROPEAN CHEMICALS POLICIES: Drivers, Scope, and Status

Final Report

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Ken Geiser, Ph.D. and Joel Tickner, Sc.D.

Lowell Center for Sustainable Production

One University Avenue, University of Massachusetts Lowell, Lowell, MA 01854 USA
Tel 1-978-934-2980; fax 1-978-934-2025

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SUMMARY

The Lowell Center for Sustainable Production (LCSP) is undertaking research on new directions in European government chemicals management policies in order to promote discussions among government authorities and other stakeholders about the future of chemicals management policy in the United States**. We define chemicals policy as regulatory and voluntary policies designed to achieve long-term, integrated and prevention-oriented sustainable use of chemicals in production systems and products.**

The goal of this report is to provide an in-depth understanding of the development of European chemicals policies as well as the new proposed European chemicals policy called Registration, Evaluation and Authorization of Chemicals (REACH). We examine the history, drivers, and scope of policies at the EU and Member State levels as well as responses by key stakeholder groups. We conclude with lessons learned from the European experience that could prove useful in developing integrated chemicals policies in the United States and internationally. In examining European chemicals policies we focus primarily on efforts to control industrial chemicals and not pesticides or chemicals in cosmetics. The European Union has undertaken innovative policy initiatives to control problem chemicals in these areas as well. As the landscape of chemicals policy in the European Union is rapidly changing, we view this as a dynamic document that will be periodically updated and thus represents a historical snapshot of the evolution of European chemicals management efforts.

Nordic countries, such as Denmark and Sweden have actively promoted integrated chemicals policies over the past decade to address contamination of critical waterways. They have successfully used a variety of voluntary and mandatory policy tools – such as education, procurement, lists of chemicals of concern, ecolabeling, research and development on safer substitutes, and chemical phaseout requirements - to encourage companies using chemicals to reduce their reliance on harmful substances and to develop safer substitutes.

While previously isolated to particular countries, innovative and exciting European-wide policies to promote sustainable chemicals management are now moving forward. These policies have been spurred by several factors: (1) increasing recognition of the limitations of current chemicals policies and a lack of confidence in the chemical industry; (2) concerns over health and ecosystem impacts of chemical exposures, particularly from everyday products; and (3) a long-term political commitments to environmental quality improvement and reduction of hazardous chemicals - the so-called Generational Goal.

Through a slow, thoughtful and transparent education process and public debate among various stakeholders (industry, government, advocates, academics), over the past five years, the European Union and Member States have been able to build sufficient momentum for fundamentally restructuring chemicals management policies to create an integrated chemicals policy embodied in the REACH proposal. A sweeping change in chemicals management policies in Europe is inevitable. This new policy will require basic data on all chemicals in commerce, information on risks throughout chemical lifecycles, rapid evaluation of chemical risks, and substitution of those substances of highest concern. Developing a proposal to fundamentally

reform chemicals policy has involved addressing many complicated aspects of chemicals regulation as well as extensive stakeholder consultation. The new European chemicals policy is expected to be in force by 2006 and will likely set the global standard for chemicals management.

The new European policy will affect manufacturers in the United States and globally. It is important that stakeholders in the U.S. learn from the lessons being developed in Europe to stimulate discussion on an integrated approach to chemicals policy in the U.S. Some U.S. manufacturers, such as those in the electronics and auto industries, are already working to implement aspects of the REACH program and identify substitutes for those chemicals that may face restrictions. It is in the best interests of forward-looking governments and companies to be at the forefront of the global momentum to reduce the impacts of toxic substances on health and ecosystems by developing policies to gather data on chemical risks throughout their lifecycle as well as to identify and substitute harmful chemicals.

More information on the European policies, including links to policy documents and stakeholders can be found at www.chemicalspolicy.org. The Lowell Center for Sustainable Production has also produced a shorter summary of this document entitled, "Integrated Chemicals Policy: Seeking New Direction in Chemicals Management," available at www.chemicalspolicy.org

New Directions in European Chemicals Policies

1. INTRODUCTION

In February of 2001 the European Commission released a far reaching and important policy proposal called the *European White Paper on A Strategy for Future Chemicals Policy*. This document outlines the intentions of the Commission in developing new regulations to manage industrial chemicals. The centerpiece of this White Paper is the proposal to establish an innovative new scheme for chemicals management, called REACH – "Registration, Evaluation, and Authorization of Chemicals". The goal of this new policy is to ensure basic information on all chemicals in commerce, to place responsibility on industry for safety of chemicals and to allow expedited action on chemicals of highest concern. Based on feedback from the European Parliament and Council of Ministers, as well as various working groups, the Commission has drafted legislation to implement the REACH initiative. It is expected that the draft legislation will be finalized by fall 2003 and enacted by 2006.

The drafting of these sweeping new policy directions in the European Union is the result of years of extensive discussions and debates between the Commission and its Member States and stakeholder groups. The REACH proposal has been characterized as one of the most debated and developed pieces of environmental legislation in European history. Many of the Member States, particularly those in the northern tier of European countries, have been moving forward with bold new programs for the management of chemicals at the national level. These national policies have been one of the primary drivers for promoting and setting the directions for the European Commission's proposals.

In order to promote discussions among government authorities and other stakeholders about the future of chemicals management policy in the United States, the Lowell Center for Sustainable Production (LCSP) has undertaken research on new directions in European government chemicals management policies. **We define chemicals policy as regulatory and voluntary policies designed to achieve long-term, integrated and prevention-oriented sustainable use of chemicals in production systems and products.**

The goals of this research are:

(1) To provide detailed background on the development of current European chemicals policy efforts;
(2) To encourage a broad public debate about the future of chemicals management policies in the United States and internationally.

The specific objectives of the project are to research chemicals policies in Europe, their implementation, and impact; to understand constituencies at the state and federal level in the U.S. who could be effectively engaged in discussing innovative chemicals policy; to stimulate discussions and networking opportunities between U.S. and European government and other stakeholder counterparts; and to develop a framework for advancing long-term chemicals policy discussions in the United States.

The goal of this paper is to characterize the landscape of European chemicals policies. We examine the history, drivers, and scope of policies at the EU and Member State levels as well as responses by key stakeholder groups. We conclude with lessons learned from the European experience that could prove useful in developing integrated chemicals policies in the United States and internationally. We attempt to provide an overview of the richness of the European debates on chemicals management, including types of policy tools being used, stakeholder positions, and experiences. As the landscape of chemicals policy in the European Union is rapidly changing, we view this as a dynamic document that will be periodically updated and thus represents a historical snapshot of the evolution of European chemicals management efforts.

In examining European chemicals policies we focus primarily on efforts to control industrial chemicals and not pesticides. Pesticides regulation has generally occurred separately from chemicals regulation and the chemicals policy debate in Europe has for the most part focused on industrial chemicals though interesting efforts have been undertaken to reduce the use of problem pesticides through the European Union's Biocides Directive. Though there are some exceptions where pesticides have been included in chemicals policy efforts, such as discussions over persistent organic pollutants (POPs) and some pesticides used in commercial products – such as paints and wood treatment. Further, we do not focus on chemicals used in cosmetics, which are not covered under the European REACH proposal. Cosmetics have generally been regulated under health laws. However, through its Cosmetics Directive, the European Union has undertaken efforts to remove problem chemicals from cosmetics (ie carcinogens, mutagens and reproductive toxicants).

The report begins by defining the European context for chemicals policy. It then examines influences on the new chemicals policy developments, including: Member State influences, international agreements, and existing European chemicals legislation. An in-depth overview of the REACH proposal and its complicated implementation issues is then provided as well as an examination of stakeholder responses to the proposal. The last sections present an analysis of lessons learned on the strengths and limitations of the European approach, as well as recommendations for strengthening the proposal. This section provides important background for designing strategies for other countries, such as the United States, and regions.

The methodology used in compiling this report consists of document review, interviews with key stakeholders, participant observation, and dialogue with key European experts in chemicals policy. During a year and a half period, LCSP researchers collected key policy documents from the European Union and Member States as well as stakeholder positions and analyses and other reports. Through in person and telephone interviews, as well as discussions at European Chemicals policy conferences we interviewed more than 50 key actors from different stakeholder groups in the European Union. Through visits to six European Union countries and attendance at various conferences on chemicals in the region, we were able to obtain a thorough understanding of the politics, culture, nuances, and details of the European chemicals management system and emerging policies. We respectfully acknowledge the time and effort that all stakeholders provided in allowing us to gain an in-depth understanding of emerging European policies (see Section 13 Experts Interviewed).

2. THE EUROPEAN CONTEXT – THE DRIVERS OF A NEW CHEMICALS POLICY

The nations of Europe arise out of long histories with significant differences in society and culture. The Nordic countries of Northern Europe differ dramatically in terms of government, religion, language and traditions from the Mediterranean countries of Southern Europe. The differences east to west are almost as dramatic. However, with the creation of the European Union and its continued expansion, these countries are evolving into a powerful new integrated European community with a Europe-wide single market.

The European governing structure, the European Union, is still very much in the process of emerging. Created as a common market among six countries by the Treaty of Rome of 1957, the European Union is today composed of 15 countries with another ten eastern and southern countries preparing for entry in June 2004[1]. Although the common market has been in existence since the 1960s, the governing bodies of the European Union have only slowly emerged as legitimate entities with identities and functions beyond those of the Member States. Recent treaties, particularly the Single European Act of 1986 and the Maastricht Treaty on European Union of 1992, have steadily enlarged the responsibilities of these institutions. Today, the European Union is governed by several different bodies, with the European Commission being its administrative body and the Council of Ministers of the European Union (consisting of officials from Member States) and European Parliament the legislative bodies that enact laws (See Section 4). The European Commission, which consists of various agencies or Directorates-General has the lead role in proposing policy and legislation for the European Union. The Council of Ministers and Parliament revise and approve legislation, though in most cases the legislation remains structurally similar to the Commission's original proposals.

The European Union's judicial functions are conducted by the European Court of Justice, comprised of 15 judges and nine advocates-general appointed for renewal by agreement among the Member States. The Court interprets European Community law and hears cases where Member States are alleged to either fail to carry out European regulations or where Member States violate those statutes.

A history of feudalism and the emergence of social democratic traditions in Europe has resulted in contemporary governments dedicated to caring for the social and economic welfare of their citizenry. Long traditions suggest that national social and economic policies should be developed by elites in governments and the professions with periodic accountability to parliamentary review. Traditionally this has meant little direct participation by the wider public, but over the past two decades this has begun to change.

Although slow to commence, national environmental policies in European countries, particularly those in northern Europe, have steadily developed environmental regulations and, today, many consumer and environmental protection policies – such as those on food protection, waste

[1] The fifteen current European Union Countries include: Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Luxembourg, The Netherlands, Austria, Portugal, Finland, Sweden, and The United Kingdom. The thirteen accession countries include: The Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and Slovakia.

management and water quality - in those countries are more extensive and stringent than those in the United States.

This evolution in the European approach to chemicals management is not difficult to explain. A series of dramatic lapses in public health and food protection during the 1990's led to heightened public concern over environmental matters and a major re-consideration of the role of government services in protecting public health. The scandals over Mad Cow Disease (bovine spongiform encephalopathy) in the United Kingdom, HIV tainted blood in blood banks in France, and dioxin in Belgian chicken feed have all revealed not only worrisome public health threats, but, more importantly, efforts by government officials to downplay public concerns and cover up what was known and when. The results of these incidences include a breakdown in public trust towards government agencies and a renewed wave of rising public concerns about the environment. The Europe-wide boycott of Shell Oil over its proposal to sink the Brent Spar, the widespread public rejection of genetically modified foods, and the Italian protests over public exposure to low level electro-magnetic fields are all examples of a changed public attitude towards environmental and public health threats.

This change in attitude and behavior has brought with it changes in environmental policy. The UK Environmental Protection Act 1990 and the Environment Act 1995 have resulted in the government's advocacy of ambitious integrated pollution control strategies, a dramatic turn around from the limited government initiatives of the 1980s. The 1991 German Ordinance on Waste Packaging created a nation-wide program for the collection, recycling and reduction in the use of all product packaging. In several countries there have been both local and national policies for phasing out the use of polyvinyl chloride plastics in building materials and phthalates in children's toys. At the European Union level these changes have brought about a ban on the import (from the United States) of beef treated with synthetic hormones, a new directive on automobile recycling, a new policy for reporting on industrial releases of pollutants, and, more recently, the Directive on Waste from Electrical and Electronic Equipment which requires manufacturers to establish product take back programs for all electronic consumer goods.

These newer European policies also tend more towards a risk adverse and precautious approach. This is certainly true of the ban on beef hormones and the resistance to genetically modified organisms, where, in both cases, the evidence is far from complete, but there is reason for caution. Indeed, the Precautionary Principle was explicitly and formally incorporated into the environmental section of the Maastricht Treaty of the European Union, and, since then, it has been consistently referenced in various resolutions of the European Parliament and Council of Ministers.

This general awakening of concern and activism on the environment and public health directly affects European approaches to the chemical industry. The chemical industry in Europe is the fourth largest industry across the continent accounting for more than 11 percent of European manufacturing and employing directly some 1.6 million people. With annual sales of over 385 billion Euro the industry has traditionally grown faster than the European-wide gross domestic product and the manufacturing sector as a whole.

The chemical industry is a very old and established industry with many of the early advances in chemistry and chemical production emerging in 19th Century Germany, France, Switzerland and the United Kingdom. While every country has a chemical industry, the largest production of chemicals centers in Germany, France, and the United Kingdom, with additional large-scale production in Italy, Belgium, Luxembourg, Spain, the Netherlands and Switzerland. Even in smaller countries, such as Sweden, the chemical industry can make up a large sector of the economy. In many cases this involves large, multi-national corporations such as Bayer, BASF, Ciba Chemicals, Atofina, ICI, Akzo-Nobel, EniChem, Henkel, Shell Chemicals, Solvay and Hoffman La Roche, but it also involves thousands of smaller national and regional firms. Many of these firms produce large bulk commodities of inorganic compounds and petrochemicals, but many others manufacture highly refined specialty chemicals for well-tailored applications in electronics, telecommunications, plastics, and pharmaceuticals. In 1998, Western European chemicals production represented about 31 percent of world production, making it the world's largest chemical producing region followed by the United States and Asia.

Within the European Union only about 2,500 chemicals are produced in quantities of over 1000 metric tonnes per year. These tend to be basic chemicals. Chemicals which are produced over one million tonnes per year represent about 75 percent of production volume in the EU. Chemicals produced in quantities of less than 10,000 tonnes per year account for slightly more than one percent of the total volume of chemicals on the European market.

Concern about the impacts of industrial chemicals on ecosystems and health is not new in Europe. Early concerns about the hazards of the chemical industry focused on occupational risks. As public concern increased the focus shifted to emissions and wastes from processes. The North Sea Conferences, started in the early 1980s, brought attention to the risks posed by persistent and bioaccumulative industrial pollutants. Over the past decade public concern has again shifted this time towards the untested chemicals in everyday products and the effects of chemicals on human health. With each shift in focus, government attention and government policy focus on chemicals has shifted as well.

The drafting of sweeping new chemicals regulations in the European Union follows a flow of events and concerns about chemicals management. In 1998, at an informal meeting of environmental ministers, concerns (primarily by Germany and the United Kingdom) about the lack of testing of chemicals were raised. Following a stakeholder meeting on chemicals, in June 1999, the Council of Ministers published a statement recommending that the European Commission should develop a strategy by 2000 to reorient European chemicals policy. There were a series of drivers for this need to reconsider chemicals policy--what was termed a "a flow of worry"--including:

- Lack of testing and public data on chemicals in commerce;
- Bottom up market pressures for safer chemicals;
- The asymmetry between the new chemicals and existing chemicals regulation. The vast majority of existing chemicals were not being addressed;
- Lack of confidence in the chemicals industry due to various environmental incidents;
- The slow, resource intensive risk assessment process which places the burden on governments to demonstrate harm before preventive action can take place;

- The appointment of a Swedish European Commissioner for the Environment for whom chemicals is a key concern;
- Specific chemical concerns, such as endocrine disruption and persistence and bioaccumulation and the slow response to these problems.

In general concerns about emissions of hazardous chemicals – particularly those that are persistent and bioaccumulative – to waterways and their impacts on wildlife and human health have been the driving factor behind European chemicals policies, starting with policies developed in the 1980s in the Nordic countries.

The Solution: A New European Approach to Chemicals Regulation

Dialogues with Member States and stakeholder conferences resulted in the publishing in February 2001 of the *European White Paper on A Strategy for Future Chemicals Policy*. The White Paper was co-written by the Directorate General Enterprise and the Directorate General Environment (corresponding to European Union 'ministries'), which coordinate implementation of current chemicals legislation in the European Union. The White Paper called for the replacement of four existing regulations on chemicals with a new integrated chemicals policy.

The *White Paper on a Future Chemicals Strategy* outlines a new approach to chemicals regulation to address problems of the past. The policy eliminates the distinction between new chemicals and existing chemicals (those grandfathered in when laws came into effect in Europe in the 1970s and which represent some 99 percent of chemicals on the market today). The proposed policy aims to place burdens on industry to conduct testing and substitute safer chemicals for the most hazardous chemicals. The centerpiece of the White Paper is the REACH process (Registration, Evaluation and Authorization of Chemicals) process, which contains the following elements. These elements are explored in detail in Section 6.

- Registration. All chemicals manufactured over one metric ton per year must be government registered and have basic toxicity information available within an eleven year period (sooner for higher production chemicals). If such data is not available the chemical will be prohibited from the market. Manufacturers must also provide risk evaluations for their chemicals including impacts from products and disposal. Registration will apply to some 30,000 chemicals.
- Evaluation. Authorities will evaluate the registrations of those chemicals used in the greatest quantities or those of particular concern to develop risk reduction measures. Evaluation is projected to be required for about 5000 chemicals. Some chemicals such as those that are persistent organic pollutants (POPs) will be prohibited automatically.
- Authorization. Chemicals of greatest concern will have to undergo an authorization process much like drugs. Companies that want to continue using a chemical of very high concern will need to show that it can be used safely, or that there are no other alternatives or that the chemical is necessary for a particular use. Authorization will initially apply to about 1400 chemicals that are known or highly suspected carcinogens, reproductive toxicants or mutagens. (Additional debates have broadened the category of chemicals subject to authorization to those that are very persistent and bioaccumulative, substances

that are persistent, bioaccumulative and toxic, and other substances of high concern such as chemicals that disrupt the endocrine system).

3. EUROPEAN INFLUENCES ON A NEW CHEMICALS POLICY – THE ROLE OF EUROPEAN MEMBER STATES

The Member States of the European Union are required to directly implement or translate legislation passed at the European Union level into national policy. However, Member States play a critical role in influencing European-wide legislation. In the case of the REACH proposal, the impetus for a broad integrated chemicals policy has been heavily influenced by Sweden, Denmark, the Netherlands, the United Kingdom and Germany, countries which have developed their own chemicals policy initiatives over the past decade.

As part of a common market, a central goal of any environmental or health regulation is harmonization among member countries, so that market distortions can be avoided. Since chemical commerce is international in nature, restrictions in one Member State have the potential to disrupt the functioning of the European market as a whole. The extent to which chemicals policies can be implemented in Member States, for example chemical restrictions and phase outs, is a function of EU law, which can prohibit states from going beyond the European-wide policies.

With regards to the environment, there are two general types of legislation in the European Union:

- Legislation regulated by Article 95 of the Maastricht Treaty, covering "things that move." This is the internal market regulation – in this case, countries can only go beyond European Union regulation if they can demonstrate the need with the European Commission. To achieve derogations (exemptions) from European-wide policy, countries have to prove local conditions that warrant extra protection, such as a sensitive aquifer.
- Legislation regulated by Article 175 of the Maastricht Treaty covering environmental protection. While this article includes all environmental protection policies, it generally covers things that are fixed, such as production facilities. In this case countries can go beyond EU law – i.e., in banning emissions of a chemical, permitting, etc – but must respect the internal market.

Chemicals policy generally falls under Article 95 since chemicals are marketed and traded among Member States and the new chemicals legislation will probably be developed under this article.

On joining the European Union, Member States' regulations are reviewed and then the Commission can decide to accept the Member State standards or not. When countries such as Sweden joined the European Union, they were given five-year derogations for stricter standards (such as on cadmium) they already had in place. These derogations have since been renewed.

The European Union/Member State relationship is critical with regards to chemicals policies because REACH will likely have large internal market implications. Lobbying by various countries within (and outside) the EU will greatly influence the final REACH proposal. Some countries, such as Portugal, Greece and Spain have not expressed much interest in chemicals

policy but Italy, with many small and medium-sized chemical producers, has taken a position that is critical of such policies. European Member States with large chemical industries – such as the United Kingdom, Germany, and the Netherlands – as well as countries that have developed progressive chemicals policies since the 1990s – such as Sweden and Denmark – have a unique interest in placing pressure on the European Commission and its legislative bodies to ensure a new chemicals policy that fits their particular interests.

Sweden, Denmark, and the Netherlands are pushing for a very strong EU chemicals policy similar to their own (understanding that their more ambitious chemicals goals may be held back once the EU policy comes into force – that they will have greater difficulty in instituting national bans or testing programs). For example, the Dutch have held several chemicals policy workshops to demonstrate leadership in pushing the agenda on chemicals. While awaiting the EU policy, these countries are also moving forward towards implementation of their own chemicals policies, in order to get testing and some restrictions finalized before the EU legislation is finalized. Both Germany, with increasing unemployment and a very large chemical industry, and the United Kingdom are attempting to establish a middle-ground with the REACH proposal that supports environmental goals and the protection of their domestic industry. These countries are also attempting to move forward voluntary policies while the European-wide policy is being developed.

This section reviews chemicals policies initiatives that have been undertaken in Europe at the national level. In particular, we review policies in five Member States (Sweden, Denmark, Germany, the Netherlands and the UK) and one non-EU member (Norway), which is part of the European Economic Area[2] and thus falls under European single market (including many environmental) regulations. Other individual countries have undertaken chemicals policy programs, but these six have been most active in their efforts to develop domestic policy. The section is divided into Nordic States (Sweden, Denmark, Norway), which have relatively similar goals and programs on chemicals, the Netherlands, Germany, and the United Kingdom.

3A. The Nordic States – A Regulatory Framework

Innovative chemicals management policies and legislation have been developed in Sweden, Denmark, and Norway (not a European Union member) over the past several years, though discussions on chemical testing and restrictions have been on-going since the early to mid-1990s. All of the Nordic policies have a major focus on product-based risks, as officials in these countries believe that products – not simply point sources – are important pollutant sources. Government officials in each of these countries also believe they must develop policies to stimulate industrial innovation in safer technologies and products (though the extent to which government works with industry differs among countries).

The chemical management policies in each of these three countries are more developed (using many policy tools and widely implemented) and restrictive (strongly regulatory and focused on

[2] Members of the European Economic Area participate in the European Single Market without assuming the full responsibilities of Membership of the European Union. Such countries have the right to be consulted in the formulation of Community legislation but no decision-making powers.

restricting problem chemicals) than the more general policies of the broader European Union. Over the past decade there has been a long struggle to advance aggressive, health-protective chemicals policies in the Nordic countries, even as the policies of these countries must remain harmonized with those of the broader European Union. Officials in these countries understand the necessity of influencing the EU White Paper process (since their policies go beyond proposals in the White Paper) and have thus placed dedicated personnel resources to the working groups and discussions taking place in Brussels. While hesitant about moving forward with national policies until the new EU chemicals policy is finalized, officials in these countries believe they must move forward to some degree and believe that implementing parts of their policies will ultimately influence the EU policy in their favor.

There are several main drivers of the chemicals policies in the Nordic countries:

- Concern about persistent and bioaccumulative pollutants and endocrine disruptors. There is a long-standing political commitment to researching and addressing persistent and bioaccumulative pollutants in the Nordic region, due to dependence on the marine environment. More recently, concerns have been raised about the health effects of endocrine disrupting chemicals (for example, on human sperm counts) and the body burdens of chemicals (for example, brominated fire retardants in breast milk).

- Lack of life-chain information on chemicals. Officials in Nordic countries have been particularly concerned about the lack of information on chemicals. If there is ignorance on chemical risks, officials believe they cannot be managed. This ignorance extends to large gaps in information on risks throughout product lifecycles. These countries place a high premium on public information about product risks and eco-labeling as ways to increase knowledge.

- Elevated public concern about the environment and chemicals. An ecological consciousness has been central to the public acceptance of chemicals initiatives in the Nordic countries. For example, about 90 percent of Denmark's water supply comes from ground water that has been threatened by pesticides. Swedes have a close connection to forests and the ocean and are concerned that these interests are being threatened by chemicals contamination. The Danes have a robust organic farming movement. Such concern for the environment translates into strong environmental movements.

- Social-democratic political structures. Nordic governments have traditionally been strong supporters of environmental and health policies. Also, long social democratic traditions have resulted in social safety nets that protect workers who might be affected by chemicals policies. While the trade unions in these countries have not generally been involved as central players in the chemicals policy debates, they have been supportive of the directions being taken and have initiated their own programs on chemical risk reduction. For example, unions in Sweden have been instrumental in many single chemicals risk reduction efforts (e.g., isocyanates as workplace contaminants) and have initiated campaigns against carcinogens in the workplace.

- The generational goal. The Nordic countries seriously embrace the so-called "generational goal," which sets as a goal the reduction of inputs of hazardous chemicals into the marine environment within one generation (described further in Section 4).

Denmark – "Strategy for Intensified Efforts in the Field of Chemicals in Denmark, in the EU and Globally"

Danish chemicals strategy discussions date back to two 1996 reports – one by the Danish Board of Technology on the "Non-Assessed Chemicals in the European Union" and the other by the Danish Environmental Protection Agency (Danish EPA) on "Chemicals – Status and Perspectives." These reports were debated in the Danish Parliament and followed by a 1997 "Danish EPA Action Plan for the Danish EPA's "Chemical Inspection Service, 1997-2001". These discussions led to the 1999 "Strategy for Intensified Efforts in the Field of Chemicals in Denmark, in the EU and Globally," and a strong public awareness and discussion on chemicals problems

Several factors have driven the Danish national chemicals policy. Because of concerns over groundwater quality (the country obtains most of its drinking water from a single aquifer under the country), the government has, for many years, been engaged in pesticide use reduction programs. Emerging data on declining human sperm counts and endocrine disruption have been heavily covered in the media, prompting even more government attention and interest in reducing and preventing exposures. Finally, to influence the European policy development, the Danish government wanted to parallel the development of EU chemicals policy with its own vision.

The Danish policy prioritizes the following concerns: (1) restriction of persistent and bioaccumulative chemicals, as well as carcinogens, reproductive toxicants, mutagens, and endocrine disruptors; (2) hazards to children and other sensitive subpopulations; (3) consumer protection and information; (4) responsibility on manufactures and importers for providing information on product risks and avoiding risks; (5) rapid screening of non-tested and non-assessed chemicals; and (6) prioritization of "undesirable substances." The Danish government has attempted to ensure that Persistent, Bioaccumulative Toxics and Very Persistent/Very Bioaccumulative chemicals (regardless of toxicity) are included in the EU authorization process, as well as to ensure that the scope of the policy includes chemicals in consumer products, and that chemicals without data are prohibited from the market. Because Denmark is not a chemical producer, there is a strong focus in national policy on addressing lifecycle hazards associated with products. Of particular concern are chemicals in consumer products (such as cosmetics) that eventually end up in the environment – those to which people are directly exposed. This policy encourages a broad public debate on chemicals that is seen as critical to building a strong public voice for change. To this end, the government hosted a "consensus conference" – a layperson forum – on impacts of and policies to address endocrine disrupting chemicals.

The "Generational Goal" also drives the Danish policy, though the government understands that it is only a political commitment and requires specific actions. The Danish policy to move towards the "Generational Goal" consists of the following elements:

- The List of Undesirable Substances. This list, initially published in 1998 and updated since, outlines substances with harmful characteristics that are produced in large quantities. The Danish government sees the list as a guide or early warning to companies and purchasers as to substances whose use should be reduced or phased-out. It is a "red flag" list that indicates chemicals for which the government may take action and provides signals to users about chemicals to avoid in products and processes.

- Bans on problematic substances. The Danish policy closely regulates pesticides and industrial chemicals. For high priority substances on the List of Undesirable Substances, the Danish government will undertake bans. For example, arsenic was banned in treated wood in 1998, phthalates for use in children's products were banned in 2000, and bans have been placed on specific pesticides (e.g., tributyl tin). A Danish strategy on heavy metals was established in 1994, with a goal of long-term phaseouts in industrial uses (focused on lead, mercury and cadmium). Based on this strategy, the Danish government issued a regulation in 2000 initiating a general ban on lead compounds and products containing metallic lead. Additional bans have been implemented to address industrial greenhouse gases. The Danish strategy on chemicals bans is to await European Union movement whenever possible. However, where discussions are not moving forward, Denmark will issue its own bans and stimulate European-wide debate, so if and when a European Union ban does occur, implementation has already taken place in Denmark.

- Use of multiple market mechanisms. Being on the List of Undesirable Substances does not indicate automatic prohibition of a particular substance. The Danish government has attempted to use a variety of mechanisms to implement its chemicals policy, understanding that chemical bans are the most difficult to institute and subject to European Union policies. Some of the mechanisms being used by the Danish government to decrease the use of undesirable chemicals include:

    - Ecological taxes. The government has established taxes on chlorinated solvents, phthalates (used as plasticizers in PVC plastics), polyvinyl chloride (PVC)-based plastics, and industrial greenhouse gasses.

    - Green procurement. The government is developing environmental purchasing guidelines for government agencies and local governments on chemicals such as phthalates.

    - Action plans on problematic classes of chemicals. For chemicals found to pose particular risks, the government prepares action plans outlining problems with the substance, goals for reducing hazards, steps for reducing hazards, and costs of implementation. So far, action plans have been developed for reducing the use of phthalates, for reducing dioxin emissions, for reducing the use of brominated fire-retardants, and for protecting women and children from harmful chemicals. A

strategy for reducing risks associated with the lifecycle of PVC-based plastics has also been developed.

- Cleaner Products Support Programme. The Danish government subsidizes efforts by firms to develop safer chemicals and processes. There is a state fund for developing alternatives to problematic chemicals and decisions are made yearly for allocating funds to particular projects. Government officials believe that if they show that available alternatives exist there will be less resistance to change and that actions to restrict chemicals must be linked to the development of safer alternatives.

- Provision of consumer information. The Danish government places a high priority on examining risks associated with chemicals in products and providing this information to the public. The government has examined the chemical content of various consumer products, including cosmetics, and widely publicized its findings. Through such reports government officials hope to raise questions about why these chemicals are in products and whether they can be replaced. Linked to these studies are public information campaigns designed to reduce consumer use of harmful products and, thus, influence their production and use in Denmark. For example, a campaign on antimicrobials in soap (triclosan) resulted in its elimination from products sold in Denmark. A campaign on reducing the use of chlorine in households resulted in reducing household use of chlorine products. In addition, the Danish EPA has attempted to increase consumer awareness of ecolabels to encourage purchasing of more environmentally-friendly products.

- Rapid screening of chemicals for prioritization. In 2000, the Danish government issued an advisory list for the classification of dangerous substances. Through the use of quantitative structure activity relationships, the Danish government examined approximately 46,000 substances and classified about 20,000 according to acute lethal toxicity, sensitization, mutagenicity, carcinogenicity, and aquatic toxicity.

- Expanding information on chemical products. Denmark has a Product Register that contains information on the composition of a number of preparations containing hazardous chemicals used commercially. The register also provides authorities with information on the use of substances. However, the register is limited in the range of products covered (products not used in the home).

In addition to policies directed towards industrial chemical use, the Danish EPA has an ambitious Integrated Product Policy Program, which focuses on reducing the impacts of products throughout their lifecycle – their toxicity, material use, and waste. The government has issued several reports on sustainable product design and product environmental declarations, and has initiated a large program on environmentally-friendly product procurement.

Implementation to Date

In the absence of a new European Union chemicals policy, the Danish government is moving forward to implement parts of its Generational Goal strategy, while trying to influence the EU policy. So far the government has taken action to restrict or ban (through voluntary or regulatory means) the following substances: lead, arsenic in pressure treated wood, chlorinated solvents, tributyl tin, alkylphenolethoxylates in detergents, perfluorooctanyl sulfonic acid (PFOS – used in coatings such as teflon), brominated fire retardants, MTBE, mercury, cadmium, industrial greenhouse gases, triclosan, and phthalates. A 1987 voluntary agreement with the Danish Cosmetics, Toiletries, Soap and Detergent Industries on reduction of nonylphenol ethoxylates resulted in a complete elimination of nonylphenol use by trade association members in 1998 (though some nonylphenol was still used by companies not covered by the agreement). Whether there have been reductions in chemical use as a result of the List of Undesirable Substances is unclear.

The Danish efforts on chemicals policy have been somewhat modified by the election of a conservative government in 2001. The new government has stated its commitment to making the national chemical strategy a priority and in policy statements has maintained the same goals and policy directions as previous governments. At a September 2002 conference on chemicals, sponsored in part by the Danish government, the Danish Minister of Environment noted his strong support for implementation of REACH. However, the budget for the government's clean production and clean products initiatives, important to the Danish approach to chemicals management, have been cut substantially, and the state funding for the largest Danish NGO working on chemicals was completely eliminated as of 2002.

Sweden – Guidelines on Chemicals Policy

The Swedish government has played an active role in international chemicals policy debates since hosting the 1972 United Nations Conference on the Human Environment. The 1972 "Act on Articles Hazardous to Health and the Environment" endorsed precautionary action on problem chemicals by stating "good scientific grounds for suspicions about risks to health and the environment will be sufficient for the applicability of the Act." The 1985 Swedish Chemicals Products Act established the principle of substitution to guide decision-making on hazardous chemicals. This policy stated that "anyone handling or importing a chemical product must take such steps and otherwise observe precautions as are needed to prevent or minimize harm to human beings or the environment. This includes avoiding chemical products for which less hazardous substitutes are available." In that same year, the government established the National Chemicals Inspectorate (KemI) to oversee scientific research and to develop action plans on chemicals and pesticides. Over the following ten years, KemI (along with government agencies) initiated several programs including the Swedish Sunset Project. The goals of this project were to develop a procedure for the systematic selection of hazardous substances as candidates for phaseouts and to use this system to identify multi-problem chemicals as candidates for risk reduction. The project narrowed down the chemical universe into a list of

100 multi-problem chemicals for action and the development of a Swedish "observation list" on chemicals.

When Sweden joined the European Union in the 1995, it was offered derogations on environmental policies that might affect the internal market. Sweden had issued bans on several chemicals including cadmium, trichloroethylene, pentachlorophenol, arsenic in treated wood, and tributyl tin. These derogations have either been extended for additional periods of time or policies have been passed in the European Union implementing the Swedish policies.

From 1984 on, the Swedish government has established various chemicals commissions to study the status of chemicals management efforts in Sweden and recommend risk reduction and broad chemical policy measures. The 1996 Chemicals Commission, consisting of government representatives, academics, various stakeholders, and international observers issued a 1997 report entitled "A Sustainable Chemicals Policy," outlining a long-term approach to chemicals management. The commission solidified several goals of chemicals control in Sweden: (1) knowledge on the risks of chemical substances and products; (2) available information to those who use such products; (3) the least hazardous products possible should be chosen and to the degree possible harmful substances should be substituted with less harmful ones; and (4) health and safety risks should be minimized by safe use and handling of chemical substances and products.

In 1999, the Swedish Parliament enacted a law called the "Swedish Environmental Quality Objectives," which outlines fifteen environmental quality objectives to be achieved by 2020. One of the environmental quality objectives is "A non-toxic environment." This is defined in the act as "the environment must be free from man-made substances and metals that represent a threat to health or biological diversity. This means that: the levels of substances that occur naturally in the environment must be close to background levels; and the levels of man-made substances in the environment must be close to zero."

The government then commissioned KemI to develop sub-goals and propose action strategies to achieve these goals. These sub-goals include:

1. Address the lack of information on dangerous properties of chemicals. By 2010 minimum hazard data should be available for chemical substances on the market.

   Through years of risk assessment research, the government has determined that chemical-by-chemical assessments of risk are too resource- and time- consuming and, as a result, few have been done during the last 20 years. However, it is possible to identify inherent characteristics in chemicals that give rise to risks. The information collected on hazards will be used to prioritize chemicals for further testing, substitution, and to develop lists of chemicals of concern. More intensive testing requirements should be based on production volumes, known toxicity, and exposure.

2. Address lack of knowledge of chemical content of products. By 2010, there should be adequate information on health and environmental risks of chemicals used in finished products and how the chemicals flow through the economy and into the

environment.

To implement this goal, KemI is focusing on augmenting voluntary efforts in ecolabeling and procurement. Sweden has a Product Register in which all chemical products produced or imported must be registered; these registrations must contain information on function and uses of the chemical products. KemI's budget for industrial chemicals work is financed by a fee the collection of which is based on data from the register. KemI uses the database to conduct analyses on product groups (e.g., paints, glues, cleaning chemicals) for planning, prioritization, enforcement, and follow-up on trends.

3. Implement phaseouts of the most harmful substances. The health and environmental risks associated with chemical substances in products and processes should decrease along with the use of chemicals that impede recycling of materials.

   Through years of research and conferences among scientists, the KemI scientists have determined that persistence and bioaccumulation are sufficient characteristics to give rise to reasonable concerns. Historically, substances that are persistent and bioaccumulative have turned out to be problematic. Also, even if a full toxicological profile is available for a substance, there may still be gaps in toxicity information.

   Additionally, heavy metals and chemicals that are known or highly suspect carcinogens, reproductive toxicants or mutagens should be phased out based on inherent characteristics.

4. Implement risk reduction and substitution for potentially harmful chemicals not covered by the previous sub-goal (phaseouts). Human and environmental exposure to substances with particularly dangerous properties should cease by 2020. This is a risk screening, risk reduction and substitution goal. As authorities do not have sufficient resources, industry must take responsibility for conducting risk assessments and governments must ensure that these assessments are realistic and of high quality. Such assessments should consider by-products of production, disposal and the entire product lifecycle.

   Substitution is a centerpiece of the Swedish chemicals policy, established in the 1985 chemicals act and reestablished in the 1999 environmental code. The responsibility for substitution applies not just to producers and manufacturers but also to retailers and consumers. The government views substitution broadly, as not just chemical-for-chemical substitution but also encompassing non-chemical methods. For example, in recent discussions about substitution of brominated fire retardants, the fire marshals suggested that these chemicals serve little purpose in preventing a major cause of injury and death from fires – smoke. Thus appropriate substitution may include providing smoke detectors.

5. Establishment of exposure limit values for potentially harmful substances not covered by sub-goal 3. These limit values should not be exceeded by 2020. The government

is developing a system for measuring total human exposure from consumer, worker, and environmental exposures.

Nonetheless, the government believes that the goal is to avoid having to set limit values for harmful substances. Such limit values are often not set based on scientific rationale and engender long debates over safe levels and failures in compliance. The first priority should be to try to substitute safer alternatives for those substances.

In 2000 the Environmental Objectives Committee, a new committee established to implement the Swedish Environmental Quality Objectives, proposed interim objectives and measures for addressing harmful chemicals already in the environment and developed a set of guidelines for implementing the Environmental Quality Objectives. These guidelines are intended to provide guidance for companies in their product development and serve as a long-term goal to measure implementation. The guidelines require that:

- New products introduced into the market are largely free from: synthetic substances that are persistent or bioaccumulative or those substances that give rise to persistent and bioaccumulative substances; synthetic substances that are carcinogenic, mutagenic, reproductive toxicants, or endocrine disruptors; mercury, cadmium, lead, and their compounds.
- Metals are not released into the environment to a degree that causes harm to the environment or human health.
- Synthetic substances that are persistent and bioaccumulative occur in production processes only if the producer can show that health and the environment will not be harmed.

The Swedish government established a Committee on New Guidelines on Chemicals Policy to propose how to implement these guidelines. The Committee's charge was to provide more precise definitions of hazards, to review instruments for implementing the policy, to examine its consequences, and to offer suggestions for strengthening EU legislation and policy. The Committee consisted of members of government, academia, environmental organizations and industry. It held consultations with government agencies, business groups, researchers, and with environmental organizations throughout its research and drafting process.

The Committee's report had a number of important recommendations that were incorporated into a Parliamentary bill passed in June 2001. The bill is viewed by government officials as a "Swedish position" on the future of chemicals policy. It is a statement of intent rather than a specific piece of legislation because the Swedish government did not want to confront the existing European Union policies. Some of the main conclusions of the Chemical Committee's report include:

- <u>The need to couple chemicals and product policies</u>. In May 2000 the Swedish Government submitted a communication to the Swedish Parliament regarding its environmentally oriented product policy. The policy describes its strategy for establishing requirements and responsibilities for lifecycle product risk reduction to minimize resource and energy use as well as toxicity of products. The strategy envisions

establishment of rules and guidelines addressing the entire lifecycle of products and outlines tools for achieving this, concluding producer responsibility, product declarations, procurement, taxes and charges, and environmental management systems. In particular, since products are a major source of chemical pollution, they should be particularly addressed in any chemicals management strategy. The Committee concluded that further work is necessary to implement a product policy that integrates safe use of chemicals and establishes databases on products' chemical content. In 2002, the Swedish Environmental Protection Agency developed a detailed guidance document on integrating chemicals and product policies.

- Increased knowledge on chemicals. The Committee concluded that all existing and new substances should have the same documentation requirements. For all high production volume substances, basic testing, corresponding to the European Union's new substances program requirements, should be completed as of 2005. For all other substances this should be completed by 2010. Data requirements should be extended to include information on persistence and bioaccumulation and endocrine disruptive properties, as soon as methods are available.

- Phase out of substances with particularly dangerous properties. The Committee recommended a general approach to phasing out those most dangerous substances and criteria for doing so. Chemicals requiring phase out include: new substances that are persistent and bioaccumulative should not be allowed in preparations or finished products after 2005; existing substances that are particularly persistent and bioaccumulative should not be in chemical substances, preparations, or products after 2010 (2015 for all other persistent and bioaccumulative substances); substances that have been classified as known or highly suspect carcinogens, mutagens or reproductive toxicants should not be allowed in consumer available products later than 2007; the use of mercury (by 2003), lead (ammunition and sinkers by 2008) and cadmium (already underway) or their compounds should cease.

Tools for implementing the Chemicals Policy

The Swedish government has established a set of regulatory and market tools to implement its chemicals policy vision. These range from strict emissions limits to the encouragement of voluntary environmental management systems. The government understands that it will not be possible to fully implement its policy statements on phaseouts until a final European Union regulation has been established.

- The Swedish Observation List. One outcome of the Swedish Sunset Project was the development of an Observation List. The list, which is maintained by KemI, contains information on about 250 chemicals and chemical groups that are problematic, used in large quantities, and should be avoided where possible. Research conducted by the Chemicals Committee found that the Observation List has been used widely by companies and authorities in chemicals oversight, public procurement and other management projects at the local and national level. The list is particularly useful to

authorities that have great discretion at the local and regional level in establishing multi-media permits for firms.

The Observation List provides strong signals and as a result some retailers and manufacturers have developed policies requiring that these chemicals not be used in products. KemI has sought to develop criteria for chemicals to assist companies and authorities in promoting risk reduction and substitution. These criteria would identify properties in chemicals that lead to problems and provide important information to firms regarding the types of substances that should be avoided (to minimize risk-risk trade-offs).

- Efforts with user sectors to move towards safer chemicals. The Ministry of Environment and KemI have established "dialogues" with companies in various sectors – textiles, building, etc. – to discuss problem chemicals and establish goals for reductions in their use. Part of this effort includes assisting firms in developing their own observation lists. Consequently, companies like Ikea and Volvo have developed lists of chemicals to avoid in production and products.

- Proposed bans with other countries. While it is difficult for Sweden to institute a unilateral ban on a chemical or class due to the internal market rules of the European Union, Sweden does work with other countries to propose bans. It is thought that if several countries propose bans, the impacts on the internal market cannot be ignored by the European Commission and debate on a European-wide ban will be necessary. Even so, such bans are still difficult to implement, as each country will need to define the particular circumstances of the country that place it at greater risk (in some cases this is easy as in groundwater contamination in Denmark). Another option being discussed by the Nordic countries is to use the United Nations Stockholm Treaty on Persistent Organic Substances (POPs)'s provisions for addition of new POPs as a mechanism to establish bans (e.g., on polybrominated fire retardants).

- Public procurement. The government has established a Committee for Ecologically Sustainable Procurement to integrate environmental considerations into public procurement processes. Part of the guidelines to be developed by this committee includes criteria for avoiding hazardous substances in products.

- Ecolabeling. Sweden has been active in the development of ecolabeling and product declaration schemes to provide information on chemical hazards to consumers, retailers, and small companies. There are several ecolabeling schemes on-going in Sweden initiated by governments, private institutions, and environmental groups and covering a wide range of products, including detergents, cleaners, cosmetics, and paper. The Swedish Environmental Management Council presides over a national system for certified environmental product declarations, providing lifecycle impact information on products. This impact information has been developed for ten product groups and is targeted towards manufacturers and professional purchasers in industry and government.

Implementation to Date

The main goal of the Swedish chemicals policy is to influence and promote a strong European Union chemicals policy that shares its vision for chemicals research and management. As a result, the government has allocated substantial resources into the EU process (e.g., individuals have been placed in each of the EU working groups on chemicals). Even though Denmark and the Netherlands have remained strong on chemicals policy, despite political changes, Sweden has been forced to assume the strongest voice in influencing the EU process. The country is well-situated to do so with a Swedish European Environment Commissioner and a Swedish head of the chemicals unit in the Directorate General Environment as well as a Swedish Director General in the European Council Secretariat. The head of the chemicals division of the Swedish Ministry of Environment was also placed on assignment in Brussels to assist in the development of the REACH legislation.

In 2001, the Swedish government provided research funding for the NewS (A New Strategy for the Risk Management of Chemicals) Project. NewS is a collaborative research program dedicated to creating a scientific base for the international work on controlling chemical substances. It has hosted conferences on chemicals risk management and has established a multi-stakeholder working group to develop tools for chemical "sunsetting" and substitution. It is expected that the project will provide important input to on-going Swedish chemicals management efforts.

Yet, in absence of the new European Union chemicals policy, the Swedish effort has focused on developing detailed guidelines and criteria to promote movement towards implementation of the chemicals policy goals through voluntary or other non-regulatory measures. The government establishes aggressive long-term goals, establishes mechanisms for achieving those goals, and through public dialogue, establishes strong signals for industry. The various chemicals committees have served an important role in establishing public debate and awareness about chemicals that can move retailers and users of chemicals. The Swedish government's policy statements focus on new products and preparations not just new chemicals. Rather than banning products on the market today, the chemicals guidelines set standards for the future – i.e., products cannot be made with certain chemicals after a specific date.

In terms of actions on particular chemicals, Sweden has taken action on cadmium, pentachlorophenol, tributyl tin, arsenic, chlorinated paraffins, azo dyes, hexachloroethane, lead in certain materials, nickel in jewelry, mercury, trichloroethylene and other chlorinated solvents, and chlorine in certain uses (for example the pulp and paper industry has almost completely eliminated its use of chlorine). The Swedish government has significantly restricted brominated fire retardants through voluntary and regulatory measures.

KemI has conducted consequence analyses on some of these restrictions but would rather not expend efforts on such analyses but, instead, focus on new hazards. However, where completed, these analyses show the health and ecosystem benefits of policies. For example, since 1972, Sweden has engaged in voluntary efforts to phase out nonylphenol ethoxylates. Between 1990 and 1995, total nonylphenol use was reduced by 70-80 percent and, in some uses, such as household cleaners and industrial cleaning products, nonylphenol has been nearly or completely

phased out. From 1992-1997, levels of nonylphenol in effluent from sewage treatment facilities was reduced by a factor of 10, demonstrating the success of the program.

Studies of the Swedish policies on cadmium show similar effects. Sweden banned the use of cadmium in pigments, stabilizers and surface treatments in 1987. As a consequence of these prohibitions a 1997 study by KemI researchers found that the use of cadmium in these three applications had dropped from 100 tons in 1975 to 2.5 tons in 1995. Indeed, no cadmium pigments are used in plastic production and no cadmium stabilizers are used in PVC production in Sweden today. In addition, the import of cadmium in commercial products is estimated to have been reduced by 75 tons per year.

An indirect impact of the chemicals policy is the movement among particular large firms to restrict the use of certain chemicals. Volvo has established a list of chemicals to avoid and Ericcson has established goals of eliminating lead and brominated fire retardants in its products. Ikea has also established goals for chemicals in products (i.e., no formaldehyde based particle board and no brominated flame retardants in upholstery). Other companies, such as Skanska (a large construction firm) and Electrolux, have initiated ambitious chemicals policy programs.

While there have been reductions in the use of single chemicals, there has been less achieved for broader groups of chemicals such as those on the Observation list. By and large the aggregated volumes of such broader groups have remained unchanged.

Norway

Norway has a unique and important role in the development of European and international chemicals policies. Norway has a relatively high per capita income and provides the largest per capita development support of any nation in the world. While not a primary chemical producing country per se, Norway does have large industrial sectors dependent on chemicals including petroleum, metals, pulp and paper, and energy intensive processing. The country also has many chemical formulators.

While not a European Community Member State, Norway is a member of the European Economic Area and a signatory of the European Free Trade Agreement. This means that as a general rule, Norway must follow European Commission regulations and directives on chemicals. Norway participates in working groups developing chemicals legislation. To a certain degree Norway has the ability to go beyond European regulations on chemicals or modify Commission regulations and directives, thus serving as a driver for European regulations. Norway places emphasis on the cooperative work under the Nordic Council of Ministers, the North Sea Conference, and the Oslo and Paris (OSPAR) Convention. Norway's central role in these two efforts, provides authorities an important opportunity to place pressures on the EC for a more ambitious chemicals policy and to motivate international policy efforts. While the Nordic Council (consisting of the Ministers of Environment of the Nordic countries) is primarily a consultative body, it does formulate common policies on chemicals and other issues through its working groups, for example on polybrominated diphenyl ethers.

Norway's concerns about chemical contamination date back more than 30 years. Diffuse runoff from land-based sources along with pollutants from off-shore oil and gas exploration contaminated Norwegian fjords and rivers, affecting important fish and shellfish stocks. Additionally, heavy metal contaminants and persistent organic pollutants, carried by air and ocean currents from other countries, have also contaminated soils, waterways, and vegetation. While contamination has been reduced in recent decades due to legislation addressing emissions from industrial facilities, Norway's authorities realized the importance of addressing diffuse sources of contamination from products.

Norway has had since the 1970s two major acts regulating chemicals in production systems and products: the Pollution Control Act and the Product Control Act. The Pollution Control Act addresses emissions to the outdoor environment with a goal of preventing pollution. The act sets up a permitting system for those activities that might pollute the environment. The Product Control Act is intended to prevent injury to health or the environment caused by products. It allows for approval of potentially harmful products, and establishes a duty of care and information on manufacturers and importers, as well a process for setting up criminal liability and enforcement.

In the late 1990s, as a result of its participation in the Nordic Council and other international efforts and its interest in influencing a more ambitious European Union policy, the Norwegian Minister of Environment developed an Action Plan for Hazardous Substances. A 1996 government white paper to the Norwegian Parliament on future environmental policy identified the need for more elaboration on a future chemicals strategy. The factors influencing the development of the new policy were the lack of information on most chemicals, the need for a more general approach to chemicals that is more efficient than the current chemical-by-chemical approach, and the Esbjerg Declaration goal of reducing emissions of chemicals which pose a threat to health within one generation. The Action Plan is a political document that lays out a vision for Norwegian chemicals control efforts. While never approved by the Norwegian Parliament or officially adopted by subsequent ministers of environment (the current Environment Minister's focus is on clean up of contaminated soils and fjords), the Action Plan is still used as a "blueprint" to guide Norway's chemicals efforts.

In the 1996, as a result of its participation in international efforts and interest in influencing a more ambitious European-wide policy, the government presented a white paper to the Norwegian Parliament entitled Environmental Policy for Sustainable Development. The white paper included ambitious new chemicals policy goals. The factors influencing the development of the new policy were the lack of information on most chemicals, the need for a more general approach to chemicals that is more efficient than the current chemical-by-chemical approach, and the Esbjerg Declaration goal of reducing emissions of chemicals which pose a threat to health within one generation. The chemicals policy goals outlined in the 1996 white paper have been confirmed and strengthened by subsequent white papers on environmental policy. The 1999 Action Plan for Hazardous Substances reiterates the earlier white paper's goals and provides an in-depth description of Norwegian policy efforts

According to the 1996 white paper and updates since, the goals of Norwegian chemicals policy are:

1. Elimination or reduction of releases, by certain deadlines, of dangerous substances on a national priority list. The latest 2003 white paper on environmental policy proposes that the list is supplemented by criteria on health and environmental hazards, ensuring that all of the most dangerous substances are encompassed by the national goals. The list includes:

   - Emissions to be reduced by 2000 and possibly eliminated by 2005: chlorinated short chained paraffins, PCBs, pentachlorophenol, nonylphenol, and octylphenol.

   - Emissions to be substantially reduced by 2010 at the latest: lead, cadmium, copper, mercury, chromium, brominated flame retardants, 1,2 dichloroethane, dioxins and furans, hexachlorobenzene, chlorinated alkyl benzenes, musk xylene, tetrachloroethene, trichlorobenzene, trichloroethane, tributyl tin compounds, tryphenyltin compounds, and polycyclic aromatic hydrocarbons.

   To achieve these phase out goals, the Norwegian government uses different measures for particular chemicals, including taxes, research, destruction of unused stocks of prohibited chemicals, measurement, and enforcement.

2. Achieving the generational goal. Norway has adopted the one generation target as a national target for reduction in hazardous substances.

3. Reduction of Risk for all substances. Two centerpieces of risk reduction are the substitution principle (see below) and protection of children's health. Norwegian policy provides a key role for industry in studying risks and developing less hazardous products. It lays out a number of policy tools to facilitate risk reduction, including: research on alternative technologies, procurement, taxes, emissions limits, information, and enforcement.

   Provision of information on hazardous properties of substances and alternatives is critical to reducing risks from hazardous chemicals. This includes information on chemicals in products, information on least hazardous products, and a responsibility on manufacturers and importers to develop and provide information, along with a responsibility on authorities to provide information in a publicly accessible manner.

<u>Aspects of Norwegian chemicals policy efforts</u>

The government has made progress on several key priority areas. These include:

- <u>Chemical restrictions</u>. In the past two years, Norway has moved to phase out three sets of problem chemicals: short chained chlorinated paraffins (banned in all uses) since 2001; pentachlorophenol since 2000; nonyl phenols and octyl phenols (banned in all uses except paints) since 2002; and copper chromium arsenate (CCA) treated wood (banned in

most uses since October 2002). Additionally, the new application of tributyl tin (TBT) to ships is banned from 2003 and all use of TBT is prohibited from 2008. Phthalates have been prohibited in toys for children under the age of three since 1999. Finally, the Norwegian government is encouraging a European-wide ban on polybrominated diphenyl ethers, and, with other Nordic countries, has also proposed their addition to the international list of persistent organic pollutants (POPs).

- Substitution Requirement. An amendment to the Product Control Act, which went into force on January 1, 2000, institutionalizes the substitution principle in Norwegian chemicals policy. Section 3a states:

  > "Any enterprise which uses products containing chemical substances that may have an impact of a type set out in section 1 of the Product Control Act shall evaluate whether there are alternatives that entail a lower risk of such impacts. If such alternatives exist, the enterprise shall use them provided that this does not cause unreasonable cost or inconvenience."

  The substitution requirement applies to producers and users of chemicals though not private individuals. Through the substitution requirement the Norwegian government hopes to promote a movement towards safer chemicals.

  The substitution principle applies to all products containing chemicals that may be hazardous to health (including workers) or the environment, including raw materials, intermediate products, the finished product and all stages of a product lifecycle including waste. In applying the principle, companies have a duty of care to: assess whether there is a risk of emissions of the hazardous substance during its entire lifecycle and the extent of the risk; consider whether there are alternative chemicals or methods that can be used for the same purpose and involve less risk to health and the environment (including changes to production); and assess alternatives for their risks to health and the environment. In applying substitution, companies should broadly consider the full health and implementation costs of substitution and are not required to substitute if costs are unreasonable or disproportionate to benefits. The Norwegian government has developed a set of "criteria for undesirable properties" to aid companies in their substitution efforts.

  Since the substitution requirement is relatively new, Norwegian authorities are still developing processes for its implementation. Thus, although the authorities can issue legally binding substitution decisions, they have not done so as of yet. The goal for the Ministry of Environment is to use the concept of substitution as a flexible tool, to get firms to internalize the "substitution mindset." To date, they are doing this by putting pressure on firms to consider alternatives to particular chemicals and products (including developing documentation on alternatives analysis) as well as integrating substitution into enforcement and permitting decisions. Additionally, the Ministry of Government has financed a project called the GRIP Centre for Sustainable Production and Consumption which works with government agencies and industry to develop substitution tools, create information on substances that might be harmful to the environment and develop guidelines for eco-efficient purchasing. While it is difficult to measure the successes of

substitution efforts, the Ministry believes that its efforts are leading to changes in thinking about chemicals management.

- Product Register. Like Sweden, Denmark, and Finland, Norway maintains a product registry. Established in 1981, the register maintains information on all domestic and imported chemical products (paints, adhesives, etc. but not finished products, for example textiles, and cosmetics) that are on the market in Norway above 100 kg per year and are required to be labeled as hazardous according to European Commission classification and labeling regulations. The register contains information on approximately 25,000 chemical products, and the registration number is required on safety data sheets. Companies are required to submit information on the full contents of the product, but this information is highly protected from public access by authorities. The government is considering ways to improve the product register to extend it to chemicals in products, to expand public access to data, and to improve the ability of government to use the register's data, in part due to limitations resulting from protection of trade secrets.

- Observation List. In 1999 the Ministry of Environment developed its observation list as a tool for indicating chemicals that could be problematic in Norway. Authorities see the list as a tool for reducing quantities of hazardous substances. While not a legally binding list of prohibited substances, the list is meant to encourage substitution. The list also includes Norway's priority substances for which there are reduction targets. The list was developed based on a series of criteria: the Norwegian List of Dangerous substances; the criteria for undesirable properties; and chemicals on the Product Register above one metric ton per year. The list contains between 100 and 200 chemicals and authorities use the list to monitor trends in chemicals use and to encourage manufacturers, distributors, users, and retailers to implement reductions.

- Criteria of undesirable substances. To support the Observation List and substitution efforts the Norwegian government developed a list of undesirable properties in hazardous chemicals. The criteria provide cut offs for particular endpoints and information on test methods. The goal of the criteria is to identify chemicals for inclusion on the Observation List and to ensure that companies do not substitute one problematic chemical for another and take appropriate precautions to avoid transfer risks. The criteria of particular concern to authorities are high bioaccumulation and low biodegradability. Other properties of interest include: acute toxicity; ozone depleting potential; sensitizing properties; chronic toxicity (mutagenicity, reproductive toxicity, carcinogenicity); and other properties such as hazardous byproducts, endocrine disruption, greenhouse gas emissions and immunotoxicity.

- Other tools. Authorities have engaged in a number of other tools to support their chemical substitution efforts. These include green procurement (the Green State Initiative); funding for research into alternative technologies and products (such as that funded through the GRIP Centre); ecological taxes and Demonstration Projects. One important demonstration project underway is the Eco-build project designed to integrate eco-efficiency into the building industry by focusing on chemicals used during construction, renovation and demolition. Coordinated by the GRIP Centre (and funded

by industry and government for about US$7 million) this project has engaged the major actors in the building sector and has resulted in various pilot projects as well as research and development activities. A recent report by Norway's National Statistics Office found that as a result of a tax on the solvents perchloroethylene and trichloroethylene, sales dropped 89% and 83%, respectively, between 1997-1999 and 2000. Overall use of substances classified as carcinogens, mutagens, or reproductive toxicants fell 60% between 1999 and 2001 according to the report.

The Norwegian authorities have attempted, through various initiatives, to link the chemicals management efforts to a broader Integrated Product Policy, but to date this has been more of a piecemeal effort. Authorities will work in coming years to better integrate the chemicals risk reduction goal with a more integrated product policy approach.

3B. The Netherlands

The Dutch government initiated its "Strategy on Management of Substances" (SOMS) process in 1998. The goal is to "ensure that the potential risks and hazards with the use of substances in each stage of their lifecycle are sufficiently controlled so as to remove, or to reduce to negligible level, any harmful effects caused by substances on man or the environment." The SOMS process consists of the development of an initial policy document (published in March 2001), an interim report (published in December, 2001), a second interim report (published in October, 2002) and a final memorandum of implementation to be published in the autumn of 2003.

In late 1998 the Dutch government hosted a multi-stakeholder workshop to examine the problems with chemicals management. Following the workshop the government set up a two year process to develop a long-term chemicals policy, with a leadership team composed of one government representative, one chemical industry representative, and one environmental advocacy representative. The Dutch have a strong tradition of consensus-based policies, and this structure allowed the problem definition, key areas of focus for the policy, and solutions to be developed in as non-confrontational manner as possible. While there were differences between the stakeholders on how to address the chemicals problem, in general most agreed that the process was critical to build consensus for broad change.

The Dutch government presented its first SOMS document to Parliament in March 2001, outlining the policy and steps towards its implementation. The policy covers all industrial chemicals—new and existing—and may be expanded to include pesticides and veterinary medicines. In April 2001 the Confederation of the Netherlands Industry and Employers issued a "letter of intent" announcing how the industry would implement elements of the new chemical policy.

There are several overarching goals of the SOMS policy:

- A stepwise process. The Dutch have designed their process to be pragmatic and achieve short and long term goals. Rather than demand a resource intensive data set, the Dutch would rather not wait for full information before acting. Thus, they have developed a

rapid screening process for prioritization, while data gaps are filled in over a longer period of time. The process involves beginning with a small universe of hazardous chemicals to implement restrictions, analyzing results, and then updating the program. The Dutch prefer a slow, careful process over one that is rapid and open to wide criticism.

- Flexibility. The Dutch process is designed to be flexible, taking into consideration inherent properties of substances, their use categories, and feasible alternatives in determining appropriate restrictions on chemicals. The government plans to use various regulatory and market mechanisms to implement the policy, including bans, product chain responsibility agreements, and public information. The government does not see its responsibility as creating the alternatives but rather as providing the conditions and pressures for the alternatives to be developed and risk reduction measures to be implemented.

- Integrated environmental and public health pillars. The SOMS process is built on an integrated approach to environmental policy, worker health and safety, and consumer protection (within the Ministry of Environment). The Dutch view chemicals risks as emanating from the entire product lifecycle, so policy must address workers, consumers, and the environment. The Ministry of Social Affairs (the occupational health and safety authority) has been involved from the beginning in the development of the Dutch policy. The SOMS process provides companies with opportunities to link occupational safety and health and environmental goals through one policy.

- "Controlled responsibility" for industry. Industry must carry greater responsibility in and burden for chemicals management, according to the Dutch government. Industry must collect the necessary data, present high quality hazard profiles, and classify substances. Government then prescribes applicable measures for industry to take based on hazards, and provides guidelines for implementation. It is industry's responsibility to then implement risk reduction measures. The government expects that industry will do a reasonably good job in the quick screen process, since questions will arise from government and the public if industry categorization differs substantially from available data (which will be publicly available). However, hazard profiles will be verified independently.

- Life chain focus. For many years, the Dutch have examined the lifecycle chains of various substances in society. The SOMS policy looks at inherent hazards of chemicals and their impacts throughout the product lifecycle. An important part of the policy is to create product chain responsibility, linking responsibility for risk reduction among producers and users of chemicals alike, and providing public information on risks through the lifecycle.

- Demonstration projects. The Dutch have a long tradition in instituting demonstration projects or "experimental pilots" to demonstrate the practicality of policies. In 2002, the government initiated several of these projects to show how the data collection and risk reduction portions of the SOMS policy would be implemented (seven industry projects

and two government projects were initiated). The government has worked closely with industry in developing these projects, providing some financial support for them. These projects cover sectors and supply chains. NGOs have initiated their own demonstration projects to similarly demonstrate the benefits of substitution in user sectors.

The Dutch SOMS process is described as a three-tiered approach, "from knowing nothing to doing a great deal." The phases are as follows:

1. Before the end of 2004, industry is to prepare a "substance profile" (a screening profile) for all substances currently sold or used in the Netherlands on the basis of available data (these profiles should initially be completed by the end of 2002). This is termed the "quick scan". The quick scan is supposed to be relatively simple to perform, not resource intensive, relevant to decision-making, and minimize the use of animal testing.

   Data for the quick scan can come from any one of a number of sources: toxicological testing, in-vitro screens, structure activity relationships, etc. The Dutch government has developed minimum data requirements for assessing hazards ("soft" and "hard" data) and detailed criteria for how hazards should be qualified (i.e., persistence and bioaccumulation categories) and decision rules for combining and weighting the hazard categories (for example, what level of persistence, bioaccumulation and toxicity combined leads to concerns).

   Chemicals are then classified according to five levels of concern based on the hazard profile for the substance: very high concern, high concern, concern, low concern, and no data/very high concern. The government expects most chemicals to fall into the low concern category and only a small number to be of very high concern. Chemicals are then further classified by their category of use from well-controlled exposure/emission to uncontrolled wide-spread use/emission: site limited intermediate, substances in industrial applications, substances in consumer applications, open professional use of substance. The onus is on industry to do the categorization for each substance (companies can use whatever data they have but they will be verified by government).

   Based on a combination of both sets of categories, a set of "in-principle" measures has been established to outline actions to be taken, based on the hazard and particular use of the substance:

   a. Substances with no data are considered to be very high concern and subject to restrictions.
   b. Substances with very high concern should no longer be used except in very limited circumstances where environmental exposure is unlikely. Very persistent and very bioaccumulative substances should fall under a general ban.
   c. Substances of high concern should not be permitted for consumer uses or open professional use (except under special circumstances). Restrictions on these chemicals should be achieved through various measures by 2010.
   d. Substances of concern should be permitted in most applications provided that controls are in place to minimize risks by 2010.

e. Low concern chemicals can be used with no additional restrictions, though general responsibilities to minimize risks still apply.

Based on the categorization, industry is required to take specific risk reduction measures and government can use its authority under the Hazardous Substances Act to undertake immediate measures. In implementing measures, such as bans, government will consider availability and technical feasibility of substitutes and risk reduction measures, social consequences, etc.

Beginning in 2005, chemicals for which profiles have not been prepared or for which they are of poor quality will be restricted or banned.

2. Before 2010, risk assessments will be required for all chemicals of concern after the quick scan and for which certain production volume thresholds are reached. Such assessment will not postpone required measures based on the results of the quick scan.

3. Before 2015, industry will provide a risk assessment profile for all substances sold or used in the Netherlands; and no later than 2020, risk reduction measures will be required to contain hazards from all substances in commerce.

Implementation to Date

Reviews of the implementation of restrictions on particular chemicals are not regularly conducted in the Netherlands. In one case, a voluntary agreement with the Dutch Detergent Industry Association resulted in the phaseout of nonylphenols in household cleaning agents and a substantial reduction in their use in industrial cleaners. However, the Dutch government has moved forward substantially with its SOMS process.

In December 2001, the Dutch government completed an interim report detailing the quick scan and categorization procedures under SOMS (described above); the report noted the intention to require companies to complete the quick scan by the end of 2002. A July 2001 Dutch Parliament resolution provided non-partisan support for the SOMS policy and requested that the government start implementing the policy by addressing very high concern chemicals. The Parliament and government have suggested an immediate ban on these chemicals with POPs like characteristics (some 200 very persistent, very bioaccumulative substances). The Dutch Ministry of Environment has been holding meetings with European government chemicals experts about interim actions (within the purview of existing regulations) that can be taken while the REACH legislation is being finalized. The government has termed this “reaching for the borders in regulation”. Such measures as strict emissions limits, market mechanisms, bans under existing regulations, etc. are anticipated to provide important input to the EU policy process.

In early 2002, a center-right government was elected in the Netherlands. As in Denmark, it appears that the change in government has not affected development and implementation of chemicals policy proposals. In October, 2002 the Dutch Ministry of Environment issued its Second Progress Report on Implementation of the Strategy on Management of Substances. The report outlines progress made in the previous years towards its implementation and outlines the

differences between the Dutch and European Commission approaches towards new chemicals policy initiatives. It notes that the Dutch approach is to guarantee adequate protection for humans and the environment through an integrated, practical approach that focuses on short term prioritizing substances of concern and product chain responsibility. These are elements the Dutch government sees as essential to a European policy. Key elements of the Second Progress Report include:

- Arguing for implementation of Quick Scan prioritization/pre-selection in the European Union REACH process. The report notes that, consistent with recommendations by the European Council of Ministers and Parliament, the Quick Scan process is the ideal way to ensure rapid submission of information on chemical risks as well as action on problem substances, reduce costs to industry, reduce animal testing, and reduce agency burdens. The Quick Scan method would incorporate all available data and test data on hazardous properties and use of the substance, allowing more rapid responses. Based on evidence from new chemicals submissions, a preliminary analysis by the Dutch government estimates that at least 10,000 of the 30,000 to 70,000 existing substances that would be covered under REACH could be exempted from testing based on quick scan results which indicate that they pose no danger to humans or the environment (categorization as low concern). This could save an estimated 800 million Euro in test costs. Quick Scan data should be publicly available to encourage voluntary action by industry on those chemicals raising concern.

- Operationalizing product chain responsibility through better communication. The Dutch government notes that "parties concerned with marketing certain substances also bear product chain responsibility for their consequences and for the application of those substances in products." Implementation of product chain responsibility should be done through publicly available information as well as partnerships between suppliers and customers. To operationalize this responsibility and implement pending European chemicals policies in national legislation, the Dutch government has published a draft Chemical Substances (Classification and Registration) Decree and parliament is debating rules on product chain responsibility to integrate in the Dutch Environmental Management Act. These two pieces of legislation represent a Dutch response and contribution to the European legislative process. The Decree allows for short term implementation of the SOMS process pending finalization of EU legislation while the Environmental Management act would implement the new REACH process.

The Progress Report also outlines efforts through 2002 to implement the SOMS process as well as integrate chemicals management across media programs. Some of the implementation actions, include:

- Establishment of a Chemicals Expertise Centre. In 2002, the Dutch government established the Chemicals Expertise Centre at the National Institute of Public Health and Environmental Protection (RIVM). The goal is that this chemicals bureau (much like the Swedish Chemical Inspectorate) would serve as an independent and expert institute to advise and support authorities in risk assessment and risk management of chemicals, as well as implementation of the existing new European and Dutch chemicals policies. The

Centre would be in charge of Dutch evaluation and authorization under the REACH program.

- Establishment of a list of high concern chemicals. Based on a list published in the first SOMS Progress Report of twenty-two substances classified as very persistent and very bioaccumulative, RIVM was requested to investigate whether these substances were produced or used in the Netherlands as well as the industrial uses of these substances. RIVM noted that there is no central point of access in either the Netherlands or EU where information can be obtained on substances in production, including production volumes, making such an analysis very difficult. On the limited data they could obtain, RIVM found that seven were pesticides, not covered by the EU chemicals policy; four were substances subject to legal restrictions, and three were not produced in the EU. They noted that a ban on the remaining eight substances was warranted unless the industry produced data that would eliminate the need for a ban, which should be undertaken at the EU level.

- Implementation of SOMS in existing policy frameworks. The Dutch government is working to integrate SOMS classifications into water and air emissions regulations, such that the most harmful substances based on their properties would be subject to strict emissions controls – a duty to minimize. The government is working to integrate the Quick Scan process into binding Company Environmental Plans, starting with the one for the oil and gas industry. Starting in 2004, in required annual environmental reports, companies will be obliged to report on emissions of the most harmful substances identified under the SOMS quick scan process. Under its Product-Focused Environmental Care Program, which funds projects on product-focused environmental stewardship, those companies receive must implement the SOMS program. The Dutch eco-labeling program has integrated results from the Quick Scan program so that products containing substances of very high or high concern are no longer eligible for eco-labeling. The SOMS process is also being phased into government procurement processes, including army purchasing, so that products containing substances of very high concern or with little or no information will be prohibited. Manufacturers of products containing substances of high concern would have to submit information on efforts they have taken to reduce risks from those products. Finally, the Dutch government is undertaking efforts to develop means to avoid animal testing, including development of quantitative structure activity relationships.

- Implementation of SOMS in industry. The Dutch government has worked on a voluntary basis with industry, in particular the Confederation of Dutch Industry, the Dutch Chemical Industry and Union of Traders in Chemical Products, to implement SOMS, based on the notion that industry is responsible for managing substances safely. In February 2002, the Dutch industry declaration of intent on the chemicals policy was developed into an actual workplan. The chemical industry is working similarly on an agreement to implement the policy which might obviate the need for mandatory measures. In spring 2002, the Dutch government invited applications for a funding scheme for SOMS pilot projects allowing experience to be gained with the new policy in several sectors, including: paper, lubricants, industrial clothing, building materials, and

soaps. The seven pilots, expected to be completed by mid-2003 focus on integrating Quick Scan, lists of priority substances and integrated approaches to chemicals management in firms. In addition to these pilot projects, a number of industry trade groups have initiated the development of action plans for implementation of SOMS, including the Soap and Detergent Association, the Paint and Printing Ink Manufacturers, the Car Bodywork Industry, and the Federation for Rubber and Plastic.

Despite the Dutch government's efforts to move forward with SOMS, it has suffered some setbacks. The European Commission and industry have expressed concerns about the Quick Scan legislation and as a result the Dutch government has had to postpone its proposal to make the process mandatory. Further, as a result of lobbying from the European chemical industry - following publication of the EU White Paper on the future chemicals management and the circulated drafts of the REACH proposal - the Dutch industry's support for the program is now less clear. Despite these setbacks, the Dutch government is convinced it can implement and achieve results on parts of its SOMS initiative.

3C. The United Kingdom

The United Kingdom (UK) is Europe's third largest chemical producing country, with the industry being one of the nation's largest. While different from most European nations in terms of history and political structures, the UK has traditionally had a very active environmental movement and concern about chemicals.

When the Labour government came into power in the mid-1990s environment was one of its top issues. The nation was suffering from a lack of confidence in government due to its mishandling of Mad Cow Disease and newspaper headlines were regularly featuring stories on chemicals in everyday products, such as baby formula, toys, etc. Further, several UK studies on feminized fish in British waterways raised government and advocacy concerns about endocrine disrupting chemicals. In 1997, the UK Department of Environment Transport and the Regions (DETR, now called the Department for Environment, Food and Rural Affairs, Defra), initiated its own review of policies on chemicals. That review resulted in a July 1998 consultation paper entitled "Sustainable Production and Use of Chemicals". Following on that initial paper and consultation with stakeholders, in December 1999, the government published "Sustainable Production and Use of Chemicals: A Strategic Approach – the Government's Chemicals Strategy", outlining its policies and goals for chemicals for the next twenty years. This report outlines the concerns that have led to the establishment of a long-term chemicals strategy – a lack of information on chemicals, a lack of understanding on risks, a need to improve understanding on health and ecosystem effects of chemicals and the need for rapid precautionary actions on problematic chemicals.

The overall goal of the UK Strategy is to "avoid harm to the environment or to human health through environmental exposure to chemicals." It outlines a non-legislative approach to advance progress on chemicals management and has three primary objectives:

- To make full information about the environmental risks of chemicals publicly available;
- To continue reduction of the risks presented by chemicals to the environment and human health while maintaining the competitiveness of industry; and
- To phase-out early those chemicals identified as representing an unacceptable risk to the environment and human health.

The Strategy (viewed as an interim measure until a European-wide policy is functional) covers health and environmental risks of commercially available chemicals and does not explicitly cover worker health or pesticides, transport, or food processing chemicals. The Strategy establishes a "basic duty of care" on manufacturers and users of chemicals to provide information on chemicals throughout the manufacturing chain so that risks can be adequately assessed, and to take action to reduce exposures to the most hazardous chemicals. The Strategy is built on a voluntary approach to chemicals management, supplemented with targeted legislation/regulations and policy tools.

With regards to improving the information on chemical toxicity and risks, the Strategy proposes:

- By 2000, the government would produce any guidance necessary, in addition to that published by OECD to expedite companies' hazard and risk analyses. The government would also develop criteria to enable rapid identification of chemicals that are likely to cause serious or irreversible damage to the environment.

- By 2004, the chemical industry would complete hazard and initial risk assessments for 1,000 high production chemicals under the auspices of the voluntary International Council of Chemical Associations Testing Program.

- By 2004, the government would review progress in assessments, initiate national or European-wide legislation to require testing and pull from the market those untested substances on this initial list.

- By 2015, the chemical industry would complete all hazard assessments on all of the 4,100 high production volume chemicals on the OECD list.

- By 2020, at least sufficient data to characterize hazard would be available for all commercially produced products.

Additionally, the government expects that a package of information on each chemical's hazards be passed down the manufacturing chain to commercial users for understanding health risks . The government would be supported in the development of guidance, criteria, and risk management planning by a special Stakeholder Forum, which the Strategy would establish.

<u>The Stakeholder Forum</u>

A centerpiece of the UK's chemical strategy is the establishment of the UK Chemicals Stakeholder Forum. The primary goal of the Forum is to "promote a better understanding between stakeholders of the concerns which people have about chemicals in the environment."

The goal of the Forum, by providing advice to the government, is to ensure that stakeholder concerns are reflected in the development of UK policy on chemicals. A secondary goal is to speed up progress in implementing the government's Chemicals Strategy and progress towards the substitution of dangerous chemicals. The Forum was established in September 2000 and meets every three months. It consists of 19 members from industry, environmental, animal protection, labor, and consumer organizations and scientific groups. The terms of reference for the Forum are: to advise the government on managing risks to the environment and health from chemicals in accordance with the 1999 Strategy; to advise the government on the development of chemicals policy; and to make recommendations on research and monitoring. Meetings of the Forum are open to the public.

The Forum is supported by a government Secretariat. It is also supported by various government agencies. Since the Forum is not an "expert committee" – but rather a body formed to represent the views of a range of stakeholders, it is further supported by a statutory advisory committee, the Advisory Committee on Hazardous Substances (ACHS). This is an independent government advisory board established in 1991 to support the government in assessment and risk management of chemicals. Its role is to provide the Forum with analysis and research support on chemical prioritization, ecotoxicology, and risk assessment.

The first priority for the Forum has been to develop a set of criteria to enable rapid identification of chemicals of concern, leading to consideration of risk management strategies proposed by industry. The criteria provide red flags as to problematic substances and center around key properties of persistence, bioaccumulation and toxicity (human and ecological). The Environment Agency (the day to day environmental permitting agency for England and Wales) has applied this to data received from the ICCA program as well as the European Union's database of high production volume chemicals and other sources such as structure activity relationships to identify 100 priority chemicals for risk management. The ACHS was asked to provide additional criteria for a "safety net" for chemicals that do not meet the Forum's criteria but are of similar concern.

The Forum has developed a second set of criteria for chemicals of lesser concern. The idea of this list – similar to the Swedish Observation List – is to identify chemicals for which industry is advised to analyze for safer alternatives. While the list of chemicals of concern has been published, to date these lists have not been formally adopted by the government, and it is unlikely the government will adopt them as they stand.

The second priority for the Forum was to develop a risk management framework for its deliberations. Based on a fictitious case study, the Forum determined the types of information needed to reach conclusions on risk management – including information on uses, properties, alternatives (and their risks), exposures, monitoring – and developed a decision tree for risk management review.

In addition to this decision-tree, the Forum has reviewed the accelerated risk management procedure outlined in the Strategy and discussed actions on a number of substances including initiatives on two in particular: medium chained chlorinated paraffins and nonyl- and octyl-phenol and their ethoxylates. The Forum has also recently updated its criteria of concern to

harmonize them with new EU technical guidance criteria and has published a list of over 100 chemicals which meet its criteria on the basis of available information.

For nonylphenol and octyl phenol, understanding the time for the European Commission to develop a risk reduction strategy (about four years), the Forum issued its first recommendation encouraging industry to begin phasing out particular uses of these substances that could lead to high human or environmental exposures and established a process to monitor progress. The Forum's recommendation also called for action to restrict releases from production, manufacturing and preparation, and disposal. In October 2002, Defra announced that it would seek a voluntary agreement with industry to implement the Forum's recommendation. Nonetheless, since 1976 the UK government has been negotiating voluntary agreements with industry to reduce their use of nonyl phenol. The 1976 agreement resulted in a nearly complete phase out of nonylphenol based home cleaning products and a 1996 agreement has resulted in removing all alkyl phenols from industrial and institutional detergents (except solvent degreasers). Concerns about the endocrine disrupting effects of nonylphenol have also resulted in a drop in sales of the chemical in certain sectors, such as detergents.

The Forum is also developing comments for the UK government on the EU White Paper and legislation and contributing to discussions to increase public participation in advising on chemicals policy, and on indicators of environmental exposure so as to measure progress towards targets for risk reduction.

Government Efforts to implement the Chemicals Strategy

Various government agency efforts designed to implement an integrated approach to chemicals are outlined below.

- Defra. Given the internal market, Defra has focused much of its efforts on pressing for the rapid introduction of an EU chemicals strategy and integrating UK concerns into the White Paper process. In absence of the White Paper legislation, to move management forward, the UK has taken on as Rapporteaur the risk assessment and risk management work for several chemicals of national concern, such as nonylphenols, chlorinated paraffins, brominated diphenylethers, and organofluorines.

  In absence of particular chemical restrictions, the Defra approach has been to use various mechanisms to advance chemicals management. These include: education and information, subsidies and taxes, and voluntary agreements with industry sectors, some having been used more than others. The goal of these efforts has been to get industry to take a broader approach to chemicals management, in particular downstream sectors which have not been involved in the EU chemicals discussions to a great degree. Defra has also developed monitoring for chemicals of national concern and development of voluntary strategies to address them, such as dioxins. Integrated Product Policy has not been effectively integrated into the chemicals strategy, though Defra has a consumer products committee and is engaging in projects in ecolabeling.

- Environment Agency. Supplementing Defra's work, in June 2002 the Environment Agency for England and Wales developed a Consultation Document entitled Managing Chemicals for a Better Environment: The Environment Agency's Strategy. The document outlines the Agency's strategy through 2007 to implement the UK Government's Chemicals Strategy. The Agency's strategy covers emissions of chemicals to the environment (not in the home or workplace) throughout a chemical's lifecycle and is focused on prioritizing hazardous chemicals for preventive action and addressing those points in chemical lifecycles where exposures/hazards can be reduced. The Agency notes that its strategy is based on the principles of reduction of emissions and losses of hazardous substances to the environment, where economically and technically feasible, and the need for sustainable production and use of chemicals.

  The Agency's approach is centered around an integrated approach to chemicals management, including research, reduction targets, pollution prevention, outreach and education, and monitoring. It contains provisions for additional monitoring of problem chemicals; development of pollution prevention programs and standards for pollutants of concern; dissemination of information on chemicals of concern; and support to small- and medium-sized enterprises to implement the strategy.

  To date, the Agency has identified the following substances and groups of substances as priorities for action: brominated flame retardants, chlorinated paraffins, plastic additives, perfluorinated chemicals, alkylphenols, hexavalent chromium compounds, copper and zinc, tributyl tin, bisphenol-A, and dioxins.

- Department of Trade and Industry. The Department of Trade and Industry (DTI) is in charge of protecting and enhancing the UK's industrial competitiveness. It also is in charge of consumer protection including chemicals used in products and cosmetics. Given the dominance of the chemical industry in REACH discussions, in fall 2002 the DTI established a Downstream Users Group to provide information on concerns, chemical flows, and implications of chemicals management policies for innovation so that potential effects on these sectors can be minimized. A goal for this group is to enhance coordination through supply chains and to better understand chemical uses and categories of downstream users.

  DTI also established a multistakeholder Chemicals Innovation and Growth Team to develop a vision for the chemical industry for the year 2020 that is vibrant and complies with the law. Reports from the committee were published in spring 2003. In 2001, DTI worked with the Royal Society of Chemists, the Institute for Chemical Engineers, and industry to develop a "Green Chemistry Network" to focus on education, outreach and training on innovation in chemicals and production processes though its efforts have been limited to date. It forms part of a series of "Faraday Partnerships", designed to generate collaborations between academic and industry in innovative technology. The 1999 UK Chemicals Strategy extended the government's Environmental Technology Best Practice Programme until 2005. This Programme, coordinated with Defra, is a technology transfer and research support program to introduce companies to cost-effective waste minimization and cleaner production technologies.

- Health and Safety Executive (HSE). HSE is in charge of occupational health as well as coordination of the EU's new substance notification program. The UK has a long-standing commitment to occupational health, with the concept of substitution being integral. However, over time the HSE's role in chemicals management has changed. While in the 80s the agency had a broad mandate, including coordination of UK chemicals efforts, it is now focused more narrowly on specific occupational diseases and problems.

  Within the context of current chemicals management activities, HSE has been active in government discussions, particularly on issues regarding intermediates and other worker health concerns (such as accident risks). In particular, the HSE has developed guidance to help firms, particularly SMEs, evaluate chemical risks and control options to fulfill duties under the EU Chemical Agents Directive and the UK Control of Substances Hazardous to Health (COSHH) Regulations called COSHH Essentials. COSHH Essentials is a generic assessment scheme (a toolbox) that allows firms to take basic hazard information and knowledge about chemical use to understand risks and what protections are needed. The goal of the program is to internalize chemicals management within the firm. While designed to assess purely worker health concerns, HSE is coordinating with other agencies to develop a package that examines risks throughout the lifecycle of a product.

Two other initiatives of the UK government are worth mentioning: the UK House of Lords reports and the Royal Commission on Environment and Pollution. The UK House of Lords (Parliament) Select Committee on the European Union is charged with analyzing and issuing non-binding recommendations on European Union documents and other EU related issues for the UK government. In February 2002, the Committee issued a report entitled Reducing the Risk: Regulating Industrial Chemicals, which outlines numerous questions with regards to implementation of the EU White Paper. The Committee expressed particular concern as to resources for the EU and Member States to implement the program as well as the rapid development of alternatives to animal testing. The Royal Commission is the equivalent of a national academy of sciences, charged with investigating and providing advice on complex environmental and pollution related issues. In 2001, RECP initiated a study into the long-term effects of chemicals and options for controlling them. The goal of this expert-based, multi-disciplinary and consultative process that goes beyond REACH is to make recommendations "to reduce the chance that chemical use will cause long-term damage to the natural environment or human health." The study was published in late June 2003 and recommended a more integrated approach to chemicals management including monitoring, more effective, rapid screening of chemicals, a diverse set of drivers, and a greater focus on tools for substitutions.

Conclusion

While the UK has traditionally been seen as a laggard in European environmental policy, during the late 90s, it began to address chemical concerns – particularly endocrine disruption and slow risk assessment processes. The government's approach has been to use a variety of voluntary approaches, in particular the Stakeholder Forum, to encourage industry to act as well as to

influence the development of the EU policy. The government is using the Forum to identify chemicals of concern and bring industry to internalize chemicals management. On paper, the UK approach is highly integrated. Environment, health and safety, and industry agencies coordinate on implementing the 1999 Chemicals Strategy; these agencies have programs or projects addressing chemical substitution; monitoring chemicals in the environment; research on risks, development of pollution prevention and green chemistry options, and worker health and safety as a package. In practice, it is unclear how much integration actually takes place, for example on worker health and safety. Some observers argue that there are strong tensions between the environment and trade agencies (along with a strong chemicals industry), which result in a less ambitious implementation of the Chemicals Strategy and greater focus on research than action. Due to recent food scares there is a general distrust in government, which has led to NGOs focusing efforts on markets (e.g. getting retailers to commit to reducing chemicals in products) as a key tactic in their strategy to move chemicals policy forward.

3D. Germany

German national law on the management of chemicals is generally congruent with the policies laid out by the European Union. While other European nations such as Sweden, Denmark and the Netherlands have proposed and adopted new policies that go beyond the general policies of the European Union, the German chemicals policies are compatible with and seldom more than the European Union policies. This is not particularly surprising, as German industry and government officials have been dominant forces over the years in developing European Union environmental policy, and chemical policies, in particular.

The German Context

The significant role Germany plays in shaping European Union environmental policy is largely due to the scale and composition of its national economy and the environmental activism of its citizenry. The German chemical industry is the largest in Europe and, therefore, Germany has had a strong interest in European chemicals policy and a willingness to monitor, guide, and intervene in those policy initiatives that might directly affect its industrial interests. In addition, public awareness and interest in environmental issues in Germany is relatively high. Over the past several decades this has resulted in well-organized and articulate German environmental organizations, and in particular, the development of the German Green Party. Germany is often thought of as one of the leaders of environmental policy in Europe, initiating regulations that eventually become European-wide policies. For example, Germany was a leader in advocating for restrictions on tributyl tin and for greater oversight and regulation of endocrine disrupting chemicals. Germany was also an important advocate for strong chemicals policies in the North Sea region.

The German chemical industry is a large and diverse industry with products ranging from bulk to specialty chemicals and from industrial intermediates to finished commodity products. The largest three German chemical corporations–BASF, Bayer, and Hoechst–rank among the largest in the world. They are highly diversified multinationals, with a broad range of innovative products produced in facilities throughout the world.

Both the management side and the labor side of the chemical industry play a significant role in national environmental and occupational health policy making with strong influences often coordinated among the Chemical Industry Association (VCI), the Federal Association of German Industry (BDI), and the Industrial Trade Union for the Mining, Chemicals and Energy Industries (IG BCE). Given increasing unemployment in Germany (and in particular chemical industry sectors) in recent years, the strength of the labor-industry alliance has greatly increased.

The relationship between the industry and the federal government regulatory bodies tends to be rather formal and cooperative. This has resulted in rules that are precisely formulated and implemented with little flexibility or agency discretion. Environmental advocates have been less active players in this cooperative approach.

Yet, Germany has a long tradition of environmental and public health activism. The German Green Party is the oldest, largest, and most effective of the European national green parties. Since its founding, the Green Party has maintained a steady interest in national and European chemicals policy as a means of protecting the German and European environment and public health. German trade unions are also well organized and politically influential. They have a long history of promoting occupational safety and health. In addition, environmental advocacy organizations such as Bund fur Umwelt, Naturschutz Deutschland and Greenpeace have a broad membership base and are able to mobilize effective political support throughout much of the country. Of particular note is the popular support given to the German animal rights advocacy movement, which has long opposed the use of animal testing in assessing the effects of chemicals and pharmaceuticals.

It is because of these influences that the German federal government has thus been particularly active in European Union policies on chemicals.

Structure and Governance

The basic structure of German environmental policy is laid out in Article 20a of the German Constitution, however environmental legislation is integrated into a wide array of federal statutes. Implementation of the statutory regulations and regulatory enforcement and compliance are exclusively the responsibility of the sixteen federated states, the Lander, even where legislative authority belongs to the federal government. In order to coordinate information management on chemicals, the Lander maintain a Joint Lander Database on Hazardous Substances (GDL) which contains substance specific data on over 24,000 chemical entries. Because resources, traditions, and commitments vary significantly among the Lander, this delegated authority results in a somewhat varied pattern of regulatory compliance – for example, one Lander might regulate a substance much more stringently than another.

The primary federal agencies responsible for implementing environmental policy include the Federal Ministry of Environment, the Federal Environmental Agency (UBA), the Federal Institute for Health Protection for Consumers and Veterinary Medicine (BgVV), and the Federal Institute for Occupational Safety and Health (BAuA). The Federal Environmental Agency was created during the 1970s but its powers are actually quite limited. Although, the UBA does

participate in international negotiations it has neither domestic regulatory responsibilities nor in-house research capacities. Nonetheless, there is a detailed process for assessment and regulation of chemicals between several ministries and agencies.

The regulation of workplace conditions is divided between the Federal Ministry for Labor and Social Affairs (BMAS) and various sector-specific workplace insurance institutes (Berufsgenossenschaft, BG). The labor ministry, with advice from the BAuA, is responsible for setting general regulations, including workplace exposure standards for hazardous chemicals, while the BGs set specific plant requirements, conduct inspections, maintain records, provide trainings and administer insurance claims.

Federal Statutes

The basis of German chemicals policy is laid out under the German Chemicals Act of 1980 (ChemG) which authorizes regulatory action where there is "substantial hazard to human life or health or the environment." The Chemicals Act lays out by regulation both the various duties regarding new and existing chemicals and the control of toxic substances in the workplace. This includes the requirements for pre-market testing, notification, and, if necessary, the labeling of new chemical substances. Notification on new substances must be made to the special Notification Unit (Amst ChemG) which was established under the Chemicals Act as a subdivision of the Federal Institute for Occupational Safety and Health (BAuA).

Chemicals Regulation

Regulations on new and existing chemicals are authorized under the Chemicals Act and closely parallel, but do not go beyond, the European Union directives (described in Section 5). However, Germany is strongly committed to full implementation of European Union requirements. Compared with government activity on new chemicals, which is quite extensive, the initiatives on existing chemicals have been more limited. Germany participates in the OECD high production volume chemicals program and has conducted systematic risk assessments on several of the high priority existing chemicals under the EU's existing chemicals regulation.

The responsibility for implementing these risk assessments is regulated by the Administrative Provision for Existing Commercial Chemical Substances (ChemVwV-Altstoffe) and is the responsibility of the UBA, BgVV or BAuA with advice from the Notification Unit and the Advisory Committee on Existing Chemicals of Environmental Relevance. This Advisory Committee is comprised of experts from the scientific fields, industry, and the authorities.

While any chemical testing is harmonized with the OECD SIDS (Screening Information Data Set) protocol, in order to minimize the use of animal testing, all testing protocols create a Prior Inquiry Duty to determine whether existing test data will suffice and animal testing is, therefore, unnecessary. Germany has been a leader in Europe in requiring test data and cost sharing among manufacturers.

Voluntary Agreements

Because the German chemical industry carries so much political influence, German authorities often rely on cooperative and voluntary agreements with industry to achieve environmental objectives, rather than confront the industry directly with aggressive regulations that phase out the use of chemicals of concern. In many cases these cooperative agreements have been followed up with more formal government rules after several years of voluntary performance.

Both the VCI and BDI have been avid proponents of various voluntary agreements negotiated between industry and government on a substance-by-substance basis where particular chemicals have been found to be particularly concerning. Over the years various voluntary approaches have been used to reduce the use of the chlorofluorocarbons in aerosols, asbestos in construction applications, alkyl phenol ethoxylates, several solvents in paints and lacquers, wood preservatives, and the use of leaded gasoline. For example, the 1986 agreement on alkyl phenol ethoxylates resulted in commitments to reduce their use in textiles and leather, cleaners, and anti-freezing agents, though there are several exemptions such as pesticides and cutting fluid additives.

Another case of German voluntary approaches to regulation is the work of the Advisory Committee on Existing Chemicals (GDCh). During the 1980s and 1990s the Committee collected and evaluated data about existing chemicals and wrote more than 200 reports about chemicals of concern, including levels of risk concern and risk reduction measures. Some observers have noted that these publicly available reports did have an influence on risk reduction efforts and regulation. The impacts were studied in a 2000 report available only in German.

German Use of Precautionary Risk Assessment and Substitution of Chemicals

German environmental law is acknowledged as the point of origin for the precautionary principle, or "Vorsorgeprinzip". Roughly translated as the "foresight" principle, the idea first emerged during the 1970's development of water protection law as a means to forestall damage to environmental resources by "forward-looking" planning. Since those early days the precautionary principle has been elaborated to focus on protective actions that can be taken in the face of the uncertainty of potential risks and to place the burden of demonstrating the absence of potential harm on those who propose new developments or technologies. The Vorsorgeprinzip has been invoked to justify the implementation of vigorous policies to tackle river contamination, acid rain, global climate change and North Sea pollution.

More recently, the UBA, in a far reaching proposal on "Precautionary Risk Assessment and Risk Management of Chemicals" has laid out a ambitious process for integrating the precautionary approach into chemical hazard assessments. This process is driven by five "substance related environmental action targets". These include:

1. The irreversible damage of persistent and bioaccumulating, or persistent and highly mobile, xenobiotics into the environment is to be avoided completely, irrespective of their toxicity.

2. The irreversible discharge of xenobiotics with carcinogenic, mutagenic, or reproductive effects (CMR substances) into the environment is to be completely avoided.
3. The anthropogenic release of persistent and bioaccumulating, persistent and highly mobile, carcinogenic, mutagenic or reproductive toxic natural substances into the environment must not lead to an increase in geogenic or biogenic background concentrations.
4. The anthropogenic release of other (eco-)toxic substances (including naturally occurring substances) which do not fall into the above categories into the environment is to be reduced to the technically unavoidable level.
5. An increase in chemical discharges into environmental media is to be avoided, regardless of the effects known so far and other intrinsic properties, where high distribution and/or low exchangeability makes recovery practically impossible.

Based on these five targets, the process includes a broad array of risk assessing and risk managing instruments that permit groups of chemicals to be managed or discouraged according to their intrinsic properties. Although work has proceeded on refining and preparing this proposal for adoption, the process has been slow and no date has been set for formal proceedings.

However, German government agencies have used their regulatory authorities to actively promote the substitution of dangerous substances. The legal basis for determining substance hazards and finding substitutes is provided in the Hazardous Substances Ordinance of 1999 (Gefahrstoffverordnung). This legislation provides embodiment for the commonly accepted "substitution principle" that requires that if a safer substitute to a hazardous substance exists at comparable cost and performance it should be used. Under the statute it is the responsibility of the BAuA to draw upon the chemical notification documents to periodically develop lists of safer substitutes by use category. Of particular note has been the BAuA success in promoting various chemical substitutions through the publication of a "positive list" of safer dyes and colorants (ie, a list of safer substitutes). This commitment to substitution is credited with encouraging the development of a wave of safer chemistries and various changes in production that reduce chemical exposure and hazards.

The focus on substitution has encouraged university and technical assistance centers to develop protocols for substitution decision making with government funding. For instance, the Berufsgenossenschaftliches Institut fur Arbeitssicherheit has developed a matrix model for rating chemicals as safer substitutes and the Institut fur Okologie und Politik (Okopol) of Hamburg has developed a five phased assessment strategy for assisting in chemical substitutions. These procedures, like the precautionary risk assessment program, remain in development, but all of them suggest that Germany continues to seek more far-reaching and systematic procedures for managing industrial chemicals. It also suggests that the German approach is to encourage development and integration of safer substitutes for problematic chemicals in industry, which is a less confrontational approach than that of restricting chemicals.

Part of the substitution approach of the German government has been to sponsor research on the impacts of regulation in stimulating innovation in the chemical industry, as well as strategies for

encouraging innovation. A 2002 report by the UFZ Centre for Environmental Research on innovation impacts of REACH has played an important role in debates over the impacts of the proposed European policy.

The German Role on Chemicals Policy within the European Union

Germany has maintained a dominant role in shaping European Union chemicals policy. For instance, Germany was a principal proponent of a common Europe-wide approach to pre-market notification procedures during the negotiations over the European Commission's Sixth Amendment to the Dangerous Substances Directive. And it was the German government (along with the UK Government) that initiated a discussion about the lack of effective chemical testing at an informal meeting of European Environmental Ministers in 1998. This was the discussion that led the European Council of Ministers in 1999 to call for a new European chemicals policy.

This is not particularly surprising. The German chemical industry has long held a deep concern about the effects of government policies on innovation and product marketing. Of particular concern has been the proliferation of incompatible national chemical management policies. With large international chemicals markets and subsidiary firms throughout the world, the German chemicals industry has been a strong supporter of cross-national policy harmonization. Recognizing that over 50 percent of the domestic chemical industry's foreign chemical sales goes to European countries German government authorities have taken a major role in pressing for policy coordination within the European common market.

The result has been that Germany's national chemical laws and the directives and regulations of the European Union are quite similar. Only on occasion do European Commission initiatives on chemicals directly confront Germany's well-integrated policies. Instead, where other member countries seek to advance European Union chemicals policies, they work hard to coordinate with and respect the powerful interests of Germany and its chemical industry.

Concerns over the proposals in the European Union "White Paper" have been growing among German industries. In March of 2002 the Chemical Industry Association, industry unions, and German government published a position statement on the White Paper entitled a "Joint Position of the German Government, the Association of the German Chemical Industry (VCI) and the Mining, Chemical and Energy Industrial Union (IG BCE) on the European Commission White Paper 'Strategy for a Future Chemicals Policy'".

While applauding the objectives of the White Paper, the statement called for a more simplified and less burdensome approach stressing an increased focus on chemical exposure rather than inherent properties of chemicals, an exemption for intermediates used in contained applications, a phased transition to the new system for smaller volume chemicals and small and medium-sized enterprises, and more European Commission responsibility for chemical testing. However, the statement does suggest some recommendations for strengthening the White Paper, for example including additional substances under the authorization process. Although, this joint position has been presented as a caution about Germany's enthusiasm for the proposed REACH system, it was not presented as an opposition to the White Paper.

Officials from the Federal Ministry for Environment, including Uwe Lahl, a Ministry General Director, consider that the willingness of the industry to critique features of the White Paper without opposing the broad concepts to represent a tacit endorsement and a willingness to go along with the prospects of European Union legislation. While the joint statement was criticized by NGOs for being too weak and conciliatory to industry, the German government believed that this was the only approach to diffuse the opposition of the powerful chemical industry and its unions, allowing the government to support the REACH program. The German government believes it was successful in convincing industry that the German industry that the government would be unable to stop the White Paper legislation; thus, the most industry and unions could hope for would be to present concerns about the proposal and try to influence its details. The success of the statement, according to Ministry of Environment officials is that they have been able to survive both the intragovernmental political battle on REACH (for example between the trade, economic affairs, and environmental ministries) and the complicated political problem of industry and labor opposition. With the relative success in calming down industry, officials in Brussels can move forward to achieve their goals.

Despite this agreement, the German chemical industry and its trade unions have maintained a critical stance towards the REACH proposal and have offered separate statements. A more critical German industry response has come from the German industry association Bundesverband der Deutschen Industrie (BDI). In a September, 2002 position paper the BDI offered a defense of existing chemicals regulations and a strong critique of the REACH system. In addition, the BDI presented an economic analysis prepared by the consultancy, Arthur D. Little (ADL), that outlined potentially massive economic and job loss effects of implementing the REACH system (with as much as a value added loss of 6.4% to the German Economy and 2.4 million jobs). A meeting of leading economists hosted by the German government to review the ADL study found it to be not economically sound and that it far overstated the costs of the implementation of REACH.

It is interesting to note that small- and medium-sized companies as well as downstream users of chemicals and retailers in Germany have been generally absent in chemicals policy discussions to date, this despite their influence and efforts already underway in some sectors to substitute problem substances. Further the German environmental movement has been relatively quiet in responding to domestic industry opposition to REACH, as compared to advocacy groups in other countries.

As the REACH legislation is being drafted, the German Ministry of Environment is playing a central role in advocating for its adoption nationally, within Europe, and internationally. It is likely that the German government will continue to seek consensus from industry and trade unions so that Germany puts forward a supportive position on EU-wide chemicals legislation. For example, in September, 2003, the German government, industry, and trade unions issued a consensus statement on the May, 2003 draft REACH legislation that supports most of its components. German trade unions, other than the chemical workers union, have also issued statements of support for the REACH legislation.

4. INTERNATIONAL INFLUENCES ON EUROPEAN CHEMICALS POLICIES

As a result of the strong leadership of northern European countries, the REACH program has, to a great degree, been shaped by obligations resulting from international treaties and agreements. While some of these obligations are regional – such as the Oslo and Paris Convention (OSPAR) – others are international in scope, such as the United Nations Environment Programme's Stockholm Convention. Whereas Northern European countries have used these venues to advocate a European Union chemicals policy that is as close to their own as possible and to provide further protections from specific substances, the European Union has used the international venues as a means to harmonize international standards upwards. Such upwards harmonization provides a mechanism to "pull along" less advanced or more reactive European countries as well as protect the European Union from potential trade-related disputes as a result of chemicals restrictions. International treaties, agreements, and programs have played an important role in shaping European chemicals policy and the REACH proposal (and its impacts on international policy) for the following reasons:

- They have provided a mechanism for Northern European countries (and the EU) to go beyond national measures to protect health and the environment, particularly with regards to chemicals in products. As chemicals, particularly persistent and bioaccumulative ones, can travel long distances, efforts to control emissions at the national level will often only provide minimal gains. Thus, it is critical that controls be placed at the international level on particular substances. Further, Northern European countries have advocated for international action on chemicals of concern, particularly chemicals used in products, to avoid being challenged at the EU or international level for interrupting free trade.

- They have provided an opportunity to shape and influence a strong EU policy. The goal of most European countries concerning REACH has been to influence the final structure of the EU program as it will directly impact Member State industry and efforts to control chemicals. The Northern European countries and some others have sought to use international treaties such as the Oslo and Paris Convention to shape the content of the REACH program. Obligations established under these international treaties, agreements, and programs will for the most part have to be incorporated into the REACH proposal. Thus, the international programs provide one additional venue for countries to influence the shape of EU-wide policy.

- They provide a means to influence upwards harmonization of chemicals assessment and management. The EU has been sharply criticized by some countries for the trade implications of the REACH proposal. By focusing efforts on pushing for a high international standard in chemicals assessment and management, the EU can limit trade challenges. As noted above, because of the globalization of chemicals, an internationalized system is critical to the success of REACH in speeding action on problem chemicals and reducing risk. International venues also provide the EU an opportunity to diffuse opposition and to create new alliances with countries, such as those in the developing world, who could pose strong opposition to the EU policy.

This section analyzes six particularly important international agreements/efforts that have influenced EU chemicals policy (and have been influenced by EU policy): (1) the Stockholm Convention on Persistent Organic Pollutants (POPS); (2) the North Sea Conferences; (3) the Oslo and Paris Convention (OSPAR); (4) the Rotterdam Convention on Prior Informed Consent and several United Nations Environment Programme initiatives that provide additional platforms to promote European policies; and (6) the Organization for Economic Cooperation and Development. Other initiatives, such as the International Maritime Organization's Convention on the Control of Harmful Anti-Fouling Systems on Ships—which institutes a ban on the new use of organotin compounds in anti-fouling systems on marine vessels as of January 2003—are not discussed.

The Stockholm Convention on Persistent Organic Pollutants

The Stockholm Convention on Persistent Organic Pollutants, signed in May 2001, was the outcome of several years of intense negotiations to establish a legally binding means to address threats to health and the environment caused by Persistent Organic Pollutants (POPs). These substances, travel long distances through air currents to northern locations, persist in the environment for long periods of time and biomagnify through the food chain. They have been substances of highest concern for many years for Northern European countries. The Stockholm Convention calls for an international production phaseout (except in particular circumstances, for example DDT use to control malaria) of 12 substances: pesticides (many of which are already restricted); polychlorinated biphenyls; and dioxins and furans. The Convention provides for financial and technical assistance to developing countries so that they can inventory and destroy existing stocks of POPs, as well as transition away from POPs. It also provides for international research and monitoring of POPs. Finally, the convention provides for a "precautionary" addition of new POPs to the Convention's list, based on evidence of risk and long-range transport.

The Convention still must be ratified by 50 countries before it can enter into force, although it is expected that it will be in force by 2004. Meanwhile, the Intergovernmental Negotiating Committee (INC) parties are meeting to chart out specific implementation aspects (operational rules) of the Convention, including how additional chemicals can be added. However, there is general opposition to the addition of new chemicals until the Convention is ratified and in force.

While the Stockholm Convention mainly addresses pesticides and chemicals that are production by-products or that have already been phased out of production, the European Union and particularly northern European Member States, see the ratification of the Convention as successful internationalization of their substitution approach to a set of chemicals that they view as highly problematic. The ability for a "precautionary" addition of new POPs (despite opposition from some countries, such as the U.S.) provides an opportunity for European countries to extend the reach of the Convention beyond a relatively "easy" and non-controversial set of problem pollutants. For example, the Nordic Council has issued a report proposing the addition of polybrominated diphenyl ethers – PBDEs, similar in structure to PCBs – to the list of POPs.

As for its influence on the REACH program, POPs have been non-controversial as chemicals to be included in the authorization process. For the Northern European countries, the Convention provides another pressure point to ensure that substitution of hazardous chemicals is included in the EU REACH program. For the European Commission, the ratification of the Stockholm Convention—while not a direct influence on REACH—provides another avenue for the EU to press for a stronger chemicals policy (including the authorization process) and to bring in those European countries that have been less supportive or apathetic about the European chemicals reforms.

North Sea Conferences

The North Sea Conferences, held approximately every 3-5 years (there have been five so far) are intergovernmental meetings of officials responsible for the protection of the marine environment and surroundings of the North Sea (not just involving toxic substances), as well as some other countries. These include: Belgium, Denmark, Sweden, France, Germany, the Netherlands, Norway, Sweden, Switzerland, the UK, and the European Commission. The Conferences work closely with commissions set up to address pollution of the Wadden Sea, as well as the Rhine and Elbe. The Conferences involve a broad cross-section of government officials, NGOs (which have strong influence in the Conferences) and industry officials. Since 1984 the North Sea Conferences have served as a means for Northern European countries to advance a precautionary chemicals agenda. The first international application of the precautionary principle to toxic substances occurred with the Second North Sea declaration of 1987.

Each conference issues non-binding statements of aspirations and intentions of North Sea countries in terms of marine protection and evaluation of progress made in implementing recommendations from earlier conferences. Since these are non-binding statements, country ministers can be more free-thinking and issue broader, stronger recommendations than in binding agreements. Recommendations for action are made to government bodies, intergovernmental agencies, and often to industry - for example requesting that industry use safer substitutes or develop them when they are not currently available. The recommendations of these declarations are also integrated into political initiatives to turn them into compulsory provisions of international and European Union law. Since the North Sea Conferences serve as a "process within a process" of OSPAR (see below), North Sea Ministers often attempt to use the North Sea Declarations to move action within that binding agreement.

The North Sea Conferences have served as an important international driver for the scope and goals of the REACH program. In the 1995 Esbjerg Declaration from the 4th North Sea Conference, North Sea Ministers agreed to what has been termed the "generational goal":

> "This implies the prevention of pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim of concentrations in the environment near background values for naturally occurring substances and close to zero concentrations from man-made synthetic substances."

The generational goal calls for the phaseout of the release of all highly dangerous chemicals in one generation. It was originally established to ensure a clean marine environment for forthcoming generations but has since been expanded and supported by ministers of environment to be more generally applicable to protecting human health and ecosystems from priority chemicals (the UK government expressed reservations about the generational goal as it was not restricted to the highest priority substances). As a goal, the generational goal was vague and easy enough for politicians to agree to. NGOs, some government officials, and others have now called on governments to develop policies to implement this goal. As noted earlier, the Danish government has defined the generational goal as follows:

> "Discharges and losses of environmentally-hazardous chemicals into the sea must be reduced, so that they can cease entirely before 2020, with the ultimate goal of reducing the concentration in the marine environment to near background levels, for naturally occurring substances, and to near zero, for man-made substances…By 2020 no products (or goods) on the market contain chemicals that have severely problematical effects on human health and the environment."

The ministers of environment involved in the North Sea conferences have further noted that generational goal should be achieved through development of clean technology, substitution, safer use practices, and a lifecycle approach to chemicals. In the declaration the ministers promoted a strategy for hazardous substances that includes establishment of best environmental practices, use of various regulatory and voluntary tools in achieving goals, research and monitoring (particularly on mixtures of chemicals and endocrine disruptors), and immediate action on priority substances, such as heavy metals, dioxins, chlorinated short chained paraffins, nonylphenols, brominated fire retardants, and musk xylenes.

The 2002 Bergen Declaration of the Fifth North Sea Conference specifically notes the importance of an EU chemicals policy and further supports the one generation target. It notes that this goal can only be achieved by examining diffuse pollution from consumer products throughout their lifecycles. The Declaration calls on the EU to integrate lifecycle product exposure concerns into its chemicals policy. Further, it emphasizes the importance of substitution and the need for initiatives on substitution that involve a broad range of stakeholders, calls on industry to seek safer alternatives to hazardous substances, promotes the identification and development of alternative materials and processes, and calls for governments to ensure publicly available data on risks and alternatives. Chemicals policy, according to the declaration must be highly integrated with product policy. Finally, the Declaration notes the need for OSPAR to develop effective and efficient monitoring and assessment processes for priority chemicals so as to measure progress towards the generational goal.

Oslo and Paris Conventions (OSPAR)

The OSPAR Convention for Protection of the Marine Environment of the North-East Atlantic was adopted in 1992 and entered into force in 1998. The Convention unifies two previous conventions dealing with marine pollution in the Northeast Atlantic: the 1972 Oslo Convention for the Prevention of Marine Pollution by Dumping from Ships and Aircraft and the 1974 Paris Convention for the Prevention of Marine Pollution from Land-Based Sources. The OSPAR

Commission administers the Convention and develops policy and international agreements, though the parties to the Convention generally bring forward proposals for action. This convention of Northeast Atlantic nations, including the European Commission, can adopt binding decisions addressing protection of the quality of the marine environment by preventing pollution from: (1) land-based sources; (2) from dumping and incineration; and (3) off-shore sources. The overarching goal of the Convention is prevention of degradation and restoration of the marine environment (and human health), through application of three principles: the precautionary principle; the polluter pays principle; and the principles of clean technology.

The 1998 Sintra Declaration of the OSPAR Ministerial meeting sets forward the generational goal as the basis of its hazardous substances strategy and notes the need for progressive action with well-defined intermediate targets, starting with priority chemicals. At the Sintra Ministerial meeting, parties agreed to an OSPAR strategy with regard to hazardous substances to direct future work on chemicals that focuses on substitution and exposure reduction. The strategy calls for:

- Development of tools for assessing risks of potential hazardous substances in the marine environment. OSPAR has a strong focus on more effective characterization of risks, particularly those associated with endocrine disrupting chemicals, as well as means to characterize sources of contaminants, identify and assess alternatives, and measure impacts of preventive actions.

- Identification of chemicals of concern and tools to identify and prioritize such chemicals. The OSPAR process consists of an initial screening step whereby substances are screened based on their intrinsic hazardous properties of persistence, bioaccumulation and toxicity (PBT). When experimental data are not available, substances can be characterized using quantitative structure activity relationships and other tools. Substances meeting hazardousness criteria (meaning they persist, bioaccumulate and are toxic or those with equal hazard concerns – a "safety net" procedure) are listed on the OSPAR List of Substances of Possible Concern. Substances on this list are placed on the OSPAR website and organizations are invited to submit toxicity information on them, leading to the development of data sheets for each substance. Afterward, the level of concern is assessed through an examination of production, exposure, occurrence and effects in the marine environment. Substances of highest concern based on analysis and expert judgment are placed on a List of Chemicals for Priority Action. An OSPAR working group has developed a substitution decision tool to support these efforts.

  The OSPAR Lists of Substances of Possible Concern and List of Chemicals for Priority Action are regularly updated based on evolving scientific understanding. The 1998 strategy identified fifteen substances for priority action and approximately 250 substances and groups of substances (pesticides and industrial chemicals) as substances of concern, identified through various international lists of substances of concern. As of 2002, there were 45 substances or groups of substances (such as brominated fire retardants) on the List of Chemicals for Priority Action and about 400 on the List of Substances of Possible Concern.

- Development of action plans on priority substances. Once a substance has been identified as of possible concern or one for priority action, an action plan is developed for the substance. Based on background documents, measures to address concerns about the substance are debated and adopted. In cases where a substance enters the marine environment from outside the OSPAR region or is already restricted in the region, the OSPAR Commission works with international bodies to promote broader international measures to reduce exposures.

The OSPAR Convention has set an international precedent in noting the need for prioritization of chemicals of concern and substitution of a broad range of hazardous substances as critical to protection of the marine environment. Parties to the Convention however vary in their efforts to implement the Convention's generational goal and action on priority chemicals – which is binding at the international level but not in national law. Countries such as Sweden and Denmark introduced the one-generation concept and have taken national steps through various tools to address priority chemicals. Other countries such as the UK and France see the generational goal as a target that they should work towards but they also must balance chemical restrictions with economic concerns. For example, in 1995 OSPAR parties for the first time agreed to phase out a substance, short-chained chlorinated paraffins. By 2000 only some countries had implemented the phase out through national legislation.

The European Commission is a contracting party to the OSPAR Convention, and currently there is debate as to whether European Commission decisions or OSPAR decisions have supremacy. Nonetheless, the OSPAR process has served as an important influence in the development of the EU White Paper on chemicals. As a result of the OSPAR Convention, the generational goal is a centerpiece of the EU proposed policy as is substitution of harmful substances based on inherent hazardous properties. The Convention has served as a binding process to ensure upwards harmonization of the EU policy and another venue for the Northern European countries to advocate a proactive chemicals strategy. Further, the OSPAR list of priority substances has served as the basis for the EU's Water Framework Directive (see analysis in Section 6). As the European Union's REACH program is developed, it is quite possible that the OSPAR process will increasingly be superseded by EU actions

Parallel to the OSPAR process is the Helsinki Convention on Protection of the Marine Environment in the Baltic Area, which was signed in 1992 and entered into force in 2000. Signatories include Baltic countries (Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia, Sweden) and the European Community. The implementation of the Convention is heavily influenced by Sweden and Finland, and as such, has taken on many of the same hazardous substance goals as OSPAR, though implementation and action occurs to a lesser degree due to the presence of Eastern European nations.

Rotterdam Convention on Prior Informed Consent (PIC)

The Rotterdam Convention has provided another, more indirect route, for European countries to influence international chemicals control efforts. The Rotterdam Convention was adopted in 1998 in response to concerns over the international trade of restricted chemicals, and has since been ratified by 30 of the necessary 50 countries for its entrance in force. The Convention

facilitates information exchange about hazardous chemicals, restrictions on their use, and in particular, protects developing countries from trade in hazardous chemicals. The Convention establishes the principle that the export of a chemical (pesticide or industrial chemical) covered by the Convention can only take place with prior informed consent of the importing country. For the prior informed consent procedures to go into effect, a notification of a national ban or severe restriction must be received from two countries representing two PIC regions (ie Asia and Europe), and a review on the science and risk reduction potential of the restrictions must take place. Once in effect, a "decision guidance document" is sent to importing countries, which can then allow the import (with or without restrictions) or not allow it, what has been termed a "first line of defense". Exporting countries are then required to ensure that companies within their jurisdictions comply with the decision of importing countries. The Convention also requires parties to inform each other of national bans and restrictions, that exporting countries provide hazard safety data information to importing countries, and that countries exporting substances banned or restricted within their territories notify importing countries. The original PIC list contains 22 pesticides and 5 industrial chemicals (including mercury compounds and PCBs), including 8 POPs.

While not necessarily a risk reduction treaty, the Rotterdam Convention provides northern European countries another avenue to place chemicals of concern on the international agenda for reduction measures. Countries (or the European Union) can obtain the support of a country in another PIC region to place a specific chemical on the PIC list, and once approved can use the PIC listing as a de facto ban to imports without violating international trade rules. The Convention also provides an opportunity to internationally promote lists of chemicals of concern, indirectly influencing international chemicals markets. Thus, the Rotterdam Convention provides another international impetus to the EU's efforts to increase information on as well as encourage substitution of chemicals of concern.

Other United Nations Initiatives

In addition to its effort to influence global chemicals treaties, the European Commission and particularly Scandinavian Member States have actively participated in a number of UN Environment Programme initiatives. These serve as mechanisms to forward European goals, bring international support, particularly from developing countries for European chemicals policy efforts, and to build international harmonization of their proposed policies.

The signing of the Rio Declaration on Environment and Development in 1992 set the stage for a more coordinated international approach to chemicals management. The Rio Conference established the Intergovernmental Forum on Chemical Safety and the Inter-Organization Programme for the Sound Management of Chemicals (an inter-agency United Nations effort to coordinate activities on chemicals) to develop international voluntary (and in some cases leading to mandatory) approaches to reduce health risks from the production and use of chemicals. The Declaration from the 2002 World Summit on Sustainable Development (WSSD), builds on the 1992 Rio Declaration, by calling for promotion of clean production and sustainable product design, as well as implementation of the Rotterdam and Stockholm Conventions and an international strategic approach to chemicals (see below). Most notably, parties to the WSSD agreed on an internationally-acceptable variation of the generational-goal, which states:

"Renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their lifecycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment, inter alia, aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures, and science-based risk management procedures, taking into account the precautionary approach."

Some of the particular initiatives that are influencing or are influenced by the EU White Paper process, include:

- Intergovernmental Forum on Chemical Safety (IFCS). The IFCS consists of 120 countries, as well as non-governmental organizations (public interest, industry, science and labor) and intergovernmental organizations, though only governments have voting rights. It is a non-binding effort whereby stakeholders meet to discuss and develop action plans to address various aspects of the assessment and management of industrial chemicals and pesticides, including capacity building. The IFCS provides policy guidance, identifies priorities, develops strategies and makes recommendations to government, industry, international organizations, and non-governmental organizations for collective action. It also operates through regional sub-groups established to address regional concerns in chemicals assessment and management. While poorly funded, the effort has been important to identifying international priorities on chemicals and building consensus on "low hanging fruit" actions on chemicals management, such as destruction of obsolete stocks of pesticides. Broader statements, for example, on substitution of harmful chemicals have been more difficult to achieve due to the consensus nature of the Forum.

  The IFCS takes a broad approach to chemicals management, including safety concerns, chronic risks, assessment, and risk management. In particular, the IFCS has been a useful mechanism for European nations to interact with and build capacity and vision on chemicals with developing countries. European influence is demonstrated in the 2000 Bahia Declaration on Chemical Safety from the Third Meeting of the Intergovernmental Forum on Chemical Safety. The Declaration sets timelines for specific actions of different actors and calls for finalization, ratification, and entry into force as soon as possible of all international treaties addressing chemicals management; promotion of global cooperation for chemicals management, pollution prevention and cleaner processes, materials and products; right to know on chemicals; and an international approach to sound management of chemicals. The Bahia Declaration was adopted into a set of Priorities for Action Beyond 2000 which includes: expanding and accelerating the international assessment of chemical risks; harmonization of classification and labeling of chemicals through a Globally Harmonized System; restricting the illegal trafficking of chemicals; information exchange on chemicals and their risks; strengthening capacity in developing countries; and establishing risk reduction programs.

- Strategic Approach to International Chemicals Management. Based on efforts of the IFCS and the IOMC, the UNEP Governing Council in February 2002, adopted a decision to establish a "Strategic Approach to International Chemicals Management," an integrated international approach to chemicals management for chemicals of global concern such as POPs. It aims to build bridges across various agreements and conventions on chemicals. The concept was later that year endorsed by the World Summit on Sustainable Development in Johannesburg. The initiative begins with the Bahia Declaration goals and aims to link capacity building, analysis of chemical impacts and tools to safely manage chemicals and develop safer alternatives. The initiative is the result of seven years of UNEP discussions, as well as a survey completed by governments and other organizations on the need for a strategic approach and to identify main issues, needs and opportunities. Most governments supported an international strategic approach, particularly for upwards harmonization and capacity building, and noted the need to integrate many on-going efforts and initiatives, including: right to know, cleaner production, illegal trafficking in chemicals, labeling, assessment, classification, and substitution. Since the effort is only just getting underway, it is unclear what its impacts on integrated chemicals management will be, though its initial approach appears to be holistic in nature, integrating safety, toxicity, assessment, and lifecycle concerns. One potential outcome is an international framework convention on chemicals management.

- Regionally Based Assessment of Persistent Toxic Substances. Building on the Stockholm Convention and concerns about persistent toxic substances, funded by the United Nation's Global Environment Facility and several donor states, UNEP initiated a Regionally Based Assessment of Persistent Toxic Substances (PTS), which consists of the collection, assembly and evaluation of data on sources, environmental levels and impacts of PTS chemicals across the globe. The Assessment has been conducted through integration of twelve regional assessments using existing data and consultations. The goals are a comprehensive regionally-based assessment of the damage, threats, and concerns posed by persistent toxic substances including an understanding of the root causes of problems and capacity to manage them, as well as to evaluate and agree on priorities for intervention. It is expected the assessment will identify a list of priority candidates for addition to the Stockholm Convention list of Persistent Organic Pollutants.

- Global Mercury Assessment. In 2001, the UNEP Governing Council called on UNEP to undertake a global mercury assessment, including a summary of toxicity, characterization of sources and exposure pathways, and prevention and control options. A working group report and outline of risk management options were presented in February 2003. The group noted that mercury contamination presented a significant global threat to humans and wildlife. The report noted that mercury travels through the earth at a far greater rate than was previously known and ends up in regions where the metal was never released. At the UNEP conference to discuss the report, delegates agreed that there is sufficient evidence of global adverse effects from mercury to warrant coordinated international action.

Organization for Economic Cooperation and Development (OECD)

The European Union has been an important actor in advancing international action on chemicals through the Organization for Economic Cooperation and Development. The OECD is an intergovernmental organization in which representatives of 30 industrialized countries in North America, Europe, and the Pacific, and the European Commission, meet to coordinate and harmonize environmental, economic and social policies. The OECD works though committees and sub-groups. An important area of work for OECD is that of harmonization of chemicals regulation. Given the global nature of the chemical industry and increasing concerns about non-tariff barriers to trade, as well as the global marketing of chemical products, OECD has placed a strong focus on strong, harmonized chemicals testing and control approaches, which can reduce duplicative activities and reduce costs for government and industry. OECD aims to bring together experts from many countries to develop innovative instruments and approaches and to share the burden of similar efforts.

The vast majority of OECD chemicals program is dedicated to harmonization of testing and assessment methods, including the following:

- *Development of test guidelines and methodologies*. OECD has taken a central role in the development of methods for toxicity testing, including international standards for good laboratory practice. This includes setting standards for hazard assessment, such as defining persistence and bioaccumulation. The goal of this initiative is to work towards mutual acceptance of data globally. Two areas of particular effort currently include: development of test methodologies for endocrine disrupting chemicals, and development of alternatives to animal testing, including development of acceptable uses of structure activity data. OECD issues guidelines and guidance documents to harmonize international testing efforts.

- *Development of harmonized classification and labeling schemes*. Because of the global nature of chemicals, OECD has been a central actor in the development of a Globally Harmonized System for classification and labeling, as well as development of classification endpoints.

- *Coordination of new chemicals review*. In 1982, an OECD expert group developed its Minimum Pre-Marketing set of data which defines a minimum base set of data needed for an initial assessment of the potential effects of chemicals on health and the environment. OECD's work in this area has been to compare and develop standardized systems for new chemicals submissions (that respect different systems for managing chemicals) that do not hinder. The effort has consisted of development of standardized notification forms; establishment of criteria for chemicals exempt from new chemicals reporting; and establishment of multilateral arrangements for reducing duplicative testing and assessment.

- *Coordination of existing chemicals review*. The existing chemicals program of OECD has been one of the largest part of the organization's chemicals program in recent years. In 1987, the OECD Council issued a Decision that Members should strengthen programs

to systematically investigate existing chemicals. A subsequent 1990 OECD Council Act, established a program to investigate risks of existing chemicals. Given the sheer number of chemicals in commerce, OECD identified a limited universe of chemicals of concern, the approximately 5,000 High Production Volume (HPV) chemicals – those produced over 1,000 metric tons in one OECD country or the European Union. The main objective of the existing chemicals program is to undertake an initial screening of the potential risks of HPV chemicals. To achieve this, OECD identified a minimum package of information to undertake an initial assessment on chemical characteristics and effects. The OECD SIDS (Screening Information Data Set) data set consists of the following elements:

- General information on the chemical, including use patterns, sources of exposure, and structure;
- Physiochemical data;
- Environmental fate and pathways;
- Ecotoxicity – acute toxicity to fish and algae; and
- Human toxicity – acute toxicity, genetic toxicity, repeated dose toxicity, and any available human exposure data.

Under the initiative, Member States proportionately (according to chemical production) take leadership ("share the burden") on investigating chemicals in conjunction with the country's industry. The country prepares a SIDS dossier and Initial Assessment Report, including recommendations for follow-up actions on the chemicals, which is circulated to other Member countries and peer reviewed. The chemical is then discussed and the assessment agreed to at an Initial Assessment meeting where recommendations for future testing and management are discussed (post-SIDS efforts). The results of the SIDS dossiers are then made available on the Internet.

While an ambitious program, OECD has noted that progress is slow. After ten years only 200 assessments have been agreed upon, constrained by limitations in resources as well as differences between nations. Thus, the initiative has been refocused, in recent years, to concentrate on initial hazard assessment of HPV chemicals (so as to have basic information on a wider range of chemicals rather than extensive information on few chemicals), prioritization of assessments (such as for chemicals which have wide dispersive uses), and development of a framework for consideration and assessment of groups or clusters of chemicals that are related by structure, use, or other parameters. Also the organization of the assessments has been streamlined and as a result the output has increased substantially. OECD hopes that voluntary programs such as the U.S. High Production Volume Challenge and the International Council of Chemical Association's HPV initiative will fill in gaps and is coordinating its activities with such programs

- *Development of additional assessment methods*. OECD has a small program to develop standardized methodologies for chemicals risk assessment, exposure assessment and emissions scenarios, and is beginning to develop methods for lifecycle assessment of chemicals in products.

- *Risk management efforts*. While the majority of OECD's efforts are focused on harmonizing chemicals testing and assessment, OECD has a small program on risk management. OECD is developing guidance documents on market-based incentives and socioeconomic analysis for lifecycle management of chemicals; it is also working on harmonized systems for integrated product policy, extended producer responsibility, and eco-labeling. OECD is also a central organizer of international efforts to establish pollutant transfer and release registries. Finally, OECD has taken an international role in development of sustainable chemistry (or green chemistry) efforts. The effort is designed to help countries integrate sustainable chemistry into chemistry training and to promote information exchange and development of guidance on sustainable chemistry internationally.

The 2001 OECD Environmental Outlook for the Chemicals Industry provides projections of trends in production, consumption and health and safety of chemicals that are likely to affect the direction of OECD's efforts in the future. Three main areas of particular concern are identified: the continuing lack of data on toxicity and exposure to existing chemicals in commerce; the growth of chemical production and consumption in non-OECD countries; and tools for addressing risks from chemicals in products. However, the focus of OECD efforts is likely to remain technical and expert driven in nature – focused on assessment and testing, even though these have policy ramifications of their own. Since OECD works on consensus, and even consensus on chemicals assessment has been slow and arduous at times, consensus on risk management measures is even more difficult. One observer active in OECD discussions noted that the expert committees could not even reach consensus that lead was bad in the environment. As such, OECD is likely to be most successful in advancing an upwards harmonization in testing of chemicals.

Through the OECD program, the EU has been able to promote an international standard for assessment of new chemicals, as well as its goal that all chemicals in commerce have basic screening data. Because of the importance of the OECD to international harmonization of chemicals assessment, the EU has used the OECD as a means to promote its policies for alternatives to animal testing, minimum datasets, classification and labeling, and when discussed, risk management. The OECD's 2001 Environmental Strategy may provide an additional tool to expand the influence of European chemicals policy globally.

5. THE EUROPEAN UNION'S CURRENT APPROACH TO CHEMICALS POLICY

The REACH program builds on, integrates and replaces a series of four cornerstone European Union Directives and Regulations on chemicals that have been in place since the late 1960s. The successes and limitations of these existing pieces of legislation form an important rationale for the establishment of REACH. Further, the disparate oversight of chemicals control to date (by different countries and for new and existing chemicals) is a critical impetus for the more integrated approach proposed under REACH. In addition to the influences of the current four central pieces of EU chemicals legislation, REACH has been influenced by a series of other pieces of chemicals legislation addressing particular chemicals, industries, media, and exposures. These are discussed in the section after this.

In this section, we first present an overview of the European Union's legislative process, an understanding of which is critical to understanding the process and development of legislation to implement the REACH proposal (for more information see http://europa.eu.int/eur-lex/en). Following this introduction, we examine the four pieces of EU legislation and discuss their impacts to date, as well as their strengths and limitations.

The European Legislative Process

The legislative process can be viewed as an interaction among three main legislative institutions of the European Union:

The European Commission. The European Commission is the administrative decision-making body of the European Union. It is organized into 24 directorates general (DGs) responsible for various policy areas. Each directorate general is headed by a commissioner (appointed for five year terms by Member States), whose role is like that of a government minister. The European Commission initiates all European legislative proposals. Responsibility for current and proposed chemicals legislation is shared between DG Enterprise and DG Environment. These Directorates General work with other DGs in developing and implementing policy.

The European Council. Composed of ministers from the governments of Member States, the Council meets in different formations depending on the subject matter. The two key Council formations for chemicals policy are Environment and Competitiveness. The Member State Ministers on these Councils are supposed to represent the positions of their entire Government, and positions are often extensively debated by the permanent representatives that each Member State has in Brussels. The agendas of Council meetings (what legislation or proposals will be discussed) are set by the nation that holds the Presidency, which rotates every six months. The nation that holds the Presidency drafts and negotiates the positions agreed by Council. Primary debate on chemicals legislation will probably happen in the Environment Council, though it is possible that it may be transferred to Competitiveness council – the decision is up to the current Presidency. Most Council votes on environmental legislation are by qualified majority vote, a complex system that gives large Member States more votes than smaller ones. While the Council and Parliament have equal power in theory, the Council often is the more important of the two legislative bodies because of having greater expertise.

The European Parliament (EP). The Parliament is the popular legislative body, comprised of 626 Members of Parliament (MEPs) from all EU Member States with elections occurring every five years (June 2004 is the next election). Most of the EP work is done in what are called Standing Committees, with final positions voted on in plenary session. Some issues can be voted through by simple majority - a majority of those present in the chamber; but final resolutions on legislation must be carried by an absolute majority of all MEPs, i.e. with a typical turnout of 75%, a 67% vote is needed to pass legislation. The Committee on the Environment, Public Health and Consumer Affairs is usually the lead for the environmental legislation. A Rapporteur for the piece of legislation is chosen on the basis of a complex point system whereby political parties 'buy' leadership over a particular piece of legislation. Shadow Rapporteurs from the other party groups are also chosen. The Rapporteur drafts the committee's report on the legislation, then the committee as a whole votes on amendments to this report and the shadow Rapporteurs lead the discussion in their party groups. The chemicals review will probably also be considered by the Committees on Industry, External Trade, Research and Energy and on Legal Affairs.

Based on a request from the Council of Ministers or the Parliament, or internal interest, the European Commission writes a white paper, green paper, or communication that outlines a proposed policy. These papers are establish general policy directions of the European Commission. Once a white paper is written, it is generally assumed that legislation will follow at some point. The paper is aired internally first within the Commission Directorates drafting it and then within all Directorates (called "inter-service consultation") to find common ground before a Commission "public" position is presented. These policy papers are usually a compromise of positions. White papers are then debated by the Council of Ministers and the Parliament, each of which offer recommendations/conclusions for legislative proposals. While the Commission is not required to integrate the Council and Parliamentary conclusions into its drafting process, it tends to thoroughly consider their advice.

The Commission then drafts legislation, which is debated within the Lead Directorates and then is published by the Commission following internal (inter-service) consultation. In the case of the chemicals legislation, it is undergoing an Internet Consultation, a notice and comment process in which stakeholders, including governments, can provide comments on the proposal's workability. The Commission is not required to respond to comments, but given the scope and contentiousness of some proposals, such as REACH this process could result in more than minor changes to the draft legislation (the timeline for the REACH proposal is discussed in the section after this).

After this consultation legislative proposals then enter the Parliament for 1st reading. Parliament's Environment Committee would probably be the lead and there is no time limit for the first reading. After the Environment Committee agrees on its report (e.g. suggesting amendments to the legislation), the report is discussed, amended and voted on (simple majority) by the full parliament in plenary session.

The Council will then receive Parliament's text. By the time they receive Parliament's text they usually have been discussing the Commission's draft legislation and will often have reached a political agreement prior to the Parliament's 1st reading vote. Once the Council has received the

Parliament's text they will finalize their Common Position, which usually involves a series of amendments to the Commission's proposed legislation, which may or may not reflect the Parliament's amendments. This Common Position is agreed to by qualified majority vote, though there is a tendency for the Council to try to reach consensus. This Common Position is sent to the Parliament.

When the Parliament receives the Council's Common Position, a 2nd reading begins. This is time-limited, and the parliament has 3 months to decide whether to amend, accept or reject the Council's common position in a plenary vote. As before, discussion starts in the committees and ends in a plenary vote. Amendments to the Council's position must be carried by an absolute majority of all MEPs, which means approximately 60% of the number of MEPs normally present in the chamber.

As with the 1st reading, the Commission then has the opportunity to state whether it accepts or rejects Parliament's amendments, then resubmits the legislation to the Council, which then has 3 months to reach a view on it (voting by qualified majority voting if the amendment has been accepted by the Commission, and by unanimity if the Commission rejected the amendment). If the Council accepts every European Parliament amendment then the legislation will become law. Otherwise the legislation enters Conciliation.

If Conciliation is necessary, the Presidency convenes a Conciliation Committee, made up of 15 members from Council, 15 members from Parliament and 1 non-voting member from the Commission. The Conciliation Committee must reach agreement on a Joint Text within 6 weeks, by qualified majority vote of the Council representatives and a simple majority of the Parliament representatives. If a Joint Text is not agreed upon within 6 weeks, the legislation fails.

The Joint text must then be voted on and adopted by the Council and the Parliament (by qualified majority vote and absolute majority respectively). Then it becomes the final text of the legislation, though there are delays before it is published in the official journal, at which point it becomes law – these delays include further formal procedures and translation into all the EU's languages.

It is important to note that once a white paper is written by the Commission, it is very likely that legislation will come afterwards. Also, once legislation is drafted by the Commission, it becomes even more likely that legislation will come, though details may differ in some ways from the Commission's proposals. However, legislation drafted by the Commission is generally very structurally similar to that which is finally passed by the European Council and Parliament. Legislative debates have timelines in the European Union, so it can be expected in most cases that legislation will be passed within a 3-5 year period. This is important because the publishing of a White Paper and subsequent legislative drafting provide important signals to regulated industries of what is likely to come in the future. In this way, industry can prepare to a great degree for upcoming requirements while debate on legislation is occurring. One important example is that while debates were underway in the EU on the Waste from Electronic and Electrical Products Directive, manufacturers began on their own to reduce and eliminate their use of targeted toxic substances as well as to work on take-back systems.

Legislation on the environment takes the form of either a:

- Directive – which provides the framework for legislation that each Member State must draft, debate, and implement; or
- Regulation – which is automatically binding on the Member States and is implemented as ordered from the Commission. These have the advantage of specificity and full implementation but take longer to develop, as they are more centrally debated.

In both cases, legislation in Europe is a hybrid of what would be considered in the United States as a statute and a regulation. European directives and regulations tend to be more prescriptive than U.S. statutes, but less prescriptive than a regulation. The working details of European regulations or directives are often worked out in a process called "comitology."

The four current cornerstones of chemicals regulations in the European Union (described below) consist mainly of directives and one regulation (on risk assessment and risk reduction of existing substances). As such, implementation varies widely by Member States. The REACH legislation will be implemented most certainly as a regulation to ensure harmonized compliance across Member States.

Current EU Legislation that Forms the Basis for the REACH Proposal

Under current legislation, the European Union has achieved some limited successes in controlling chemicals of concern. However, information on the toxicity of most chemicals in commerce is still missing and only a limited number of chemicals have been subject to risk assessment and risk management procedures. The four pieces of legislation that form the backbone of the REACH program are:

- Directive 67/548/EEC on the Approximation of the Laws, Regulations, and Administrative Provisions Relating to the Classification, Packaging, and Labeling of Dangerous Substances (the Dangerous Substances Directive).

- Directive 88/379/EEC on the Approximation of the Laws Regulations and Administrative Provisions Relating to the Classification, Packaging, and Labeling of Dangerous Preparations, subsequently amended by Directive 99/45/EC and Directive 2001/60 EC which extend the scope of the earlier directive (the Dangerous Preparations Directive).

- Regulation EEC 793/93 on the Evaluation and Control of the Risks of Existing Substances (the Existing Substances Regulation).

- Directive 76/769/EEC on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations (the Limitations Directive).

Some aspects of these four pieces of legislation include:

- The requirement that manufacturers and importers of all new chemicals that have come into commerce since 1981 notify authorities and conduct basic toxicological testing and risk assessment prior to marketing.

- The requirement that manufacturers, importers, and distributors of chemicals and chemical preparations assess whether substances or preparations they are selling meet hazard criteria and if so to label the substance or preparation, including a danger symbol, standard phrases on the nature of the risk, and safety precautions related to risk.

- The requirement that European authorities undertake a process for data collection, priority setting, risk assessment and risk management of existing chemical substances on the market before 1981.

- The establishment of marketing restrictions or bans on chemical substances and preparations that could pose substantial risk to consumers.

These pieces of legislation lay the foundations of EU chemicals policies and have been amended on several occasions to change procedures and add new chemicals to lists (of classification or restrictions). Major modifications to these laws or additions of chemicals to lists have been implemented through the legislative process (Commission Proposal, Council of Ministers and Parliamentary debate), whereas minor changes in response to updated scientific or technical information (called adaptations to technical progress) can be achieved more quickly through expert group discussions leading to a Commission directive. Two of these pieces of legislation – the Dangerous Substances Directive and the Existing Substances Regulation – are implemented by DG Environment, while the Dangerous Preparations and the Restrictions Directives are implemented by DG Enterprise, as they are more related to marketing of chemicals, while the others focus on assessment. It is interesting to note that, under current legislation and the proposed REACH policy, DG Enterprise has a unique role as both proponent of enterprise/ businesses and risk manager. The implications for this unique role in chemicals management are unclear.

While some parts of the existing legislation are related to chemical testing, assessment and labeling, there are some provisions related to risk management as well. They all share similar overarching goals of protection of health and the environment, while reducing non-tariff barriers within the internal market. Legislation in force up until 1979 dealt primarily with harmonization and not disrupting the internal market, rather than environmental and health protection.

All four pieces of legislation were evaluated in 1998 as part of a Commission Working Document spurred by the Council discussions that launched the White Paper discussion process. The White Paper responds to many of the issues raised in this evaluation. Three particular overarching concerns in all four pieces of legislation include: (1) concerns over varying and limited compliance and enforcement in Member States (responsible for implementation of the pieces of legislation for the most part); (2) the slow speed of assessment, classification, and risk management decisions, many of which must go through the EU's co-decision-making process

between the Council of Ministers and Parliament, and (3) and the lack of adequate monitoring and analysis to measure the impacts of policies in reducing chemical risks.

The Dangerous Substances Directive

The 1967 Dangerous Substances Directive was the first EU legislation with regards to chemicals control and has since had several amendments and changes to its annexes. Until its sixth amendment of 1979, the directive only covered classification and labeling of dangerous substances (defined under the law by types of toxicity). The Directive now contains two main parts: classification and labeling; and new chemicals review, described in detail below.

The Sixth Amendment in 1979 established the distinction between new and existing substances. New substances were those placed on the market after September 18, 1981, while existing substances (defined later in the Existing Substances Regulation) were all those on the market prior to that date. All existing substances were to be placed on the European Inventory of Existing Commercial Chemical Substances or EINECs, a static inventory which contains some 100,000 chemicals. The classification and labeling requirements apply to both new and existing chemicals, though somewhat differently.

Classification, packaging and labeling.

The first part of the Dangerous Substances Directive involves classification, packaging, and labeling requirements. The goal of these requirements is to harmonize EU procedures. Substances (defined as chemical elements and their compounds) that are designated as dangerous must be labeled for their hazardous properties. Dangerousness is defined according to fifteen classes of danger, including flammable, explosive, toxic (very toxic, harmful), carcinogen, mutagen, reproductive toxicant, and more recently dangerous to the environment, etc. Recently, the definition of dangerous has been updated to consider "weaker" or "moderately harmful" effects – such as dizziness. The Commission is considering classifications that include new effects of concern such as immunological, neuro-developmental and endocrine disrupting effects.

When a manufacturer, importer or distributor sells a chemical that is known or suspected to be "dangerous," they are responsible for assessing whether it is dangerous according to the Directive. If the substance fits the definition of "dangerous" the company is responsible for appropriately labeling the substance, including a danger symbol, standard phrases on the nature of the risk, and safety precautions related to risk. The manufacturer, distributor or importer is also required to provide a safety data sheet to industrial users. The Directive outlines the content requirements for labels and the requirements for packaging so that users are protected (e.g., child proof fastenings). Annexes outline the testing methods required to determine potentially dangerous properties of substances. If the substance is not known or suspected to be dangerous, it can circulate freely, until otherwise classified by the European Community and placed on the European Community List of Dangerous Substances.

Through a working group of Commission and Member State experts (along with the participation of industry and trade unions) as well as various sub-groups, the Commission has developed a harmonization procedure for classification and labeling. To date, classification and

labeling have been agreed on Community-wide for some 5,000 new and existing industrial chemicals, listed in an annex to the Directive, of which about 3,000 have been classified as dangerous.

Implementation of classification, packaging and labeling provisions

The process of classifying the 100,000 chemical substances on the market as of 1981 has been slow due to the consultative process for harmonizing classifications. Even for new chemicals (see below) for which classification and labeling is more informal within the Commission, it is expected that 1-2 years will pass before official Commission classification and labeling requirements are detailed, meaning that the substance can be used without labeling if the company determines that it is not dangerous.

There is concern that the classification and labeling provisions are not sufficiently applied and enforced in all Member States. As a result, some substances may not be labeled when they should be, whereas others might be labeled in disparate ways. Self-classifications are often found to be wrong, even for new substances already registered as dangerous under the Directive. Since responsibility for enforcement rests with the Member States, it is important to ensure that national implementing legislation and enforcement are sufficient to rectify these limits (including for example, restricting substances not classified or labeled according to the directive or liability for damage arising from "uninformed use.") Another concern is lack of tracking of substances classified as dangerous.

A limitation of this part of the Directive is that it does not technically focus on risk management, but rather simply classification and labeling. However, classification of substances as dangerous according to the Directive can have repercussions on the marketing and use of the chemical. These include the Limitations Directive; occupational health directives regarding carcinogens, mutagens, and reproductive toxicants; a directive on volatile organic compounds, which has specific provisions for carcinogens; the cosmetics directive; and directives on toy safety which requires that toys not contain dangerous substances or preparations in amounts that may harm children's health.

New Chemicals Notification

The second part of the Dangerous Substances directive is the new chemicals notification process. The goal of the EU new chemicals notification program is to provide for the development of data on new chemicals to support the existing and future chemical regulatory programs of 15 different nations in such a way as to avoid non-tariff trade barriers that might result from 15 different notification schemes. The program represents primarily a standardized notification, classification, labeling, and reporting system for substances that might be hazardous to human health or the environment rather than a comprehensive chemical review program for protecting against unreasonable risks. The latter is the responsibility of individual Member States. The new chemicals notification requirements were established in 1979 with updates to the Dangerous Substances Directive. The Directive was again updated with the 7th Amendment in 1992, which requires authorities to prepare risk assessments for each new chemical.

The Directive requires that *each* company or importer bringing a "new chemical" to market must submit a pre-market notification package to the Member State Competent Authority sixty days before marketing the chemical. New chemicals are considered new chemicals for life and thus the directive applies to all subsequent manufacturers of the substance. The threshold for notification is 10 kg per year per chemical though there are many exemptions (see below).

"Pre-market" is defined in the Directive as "supplying or making available to third parties." Adopting pre-market regulation reflects EU thinking on the need to protect and enhance innovation in the common market. The assumption is that existing worker protections and laws to protect from accidents are adequate to protect from manufacture-related risks of a new chemical. The EU Directive does not provide for specific control actions prior to a new chemical's arrival on the market, although Member States may choose to require pre-manufacture submission of information.

Pre-market testing, with the burden on industry, represents a central part of the EU program. The battery of tests required is the OECD Minimum Pre-Market Dataset (a screening level dataset). The choice of testing requirements represented the need for a common system among Member States with clearly defined responsibilities, rather than a flexible case-by-case decision making system. The system provides flexibility in the choice of tests to fulfill requirements, and a manufacturer to petition a Member State for a specific test exemption, upon demonstrating why the test is not needed. For chemicals placed on the market in quantities over 1,000 kg per year, the notification required under the Directive must include the following data: chemical identity; information on manufacture, use, and exposure; hazardous effects during use; data on toxicokinetics; the planned classification, packaging, and labeling; recommendations as to precautions to be taken during use and emergency measures; the amount of the chemical that will be marketed or imported per year; procedures for the proper disposal, reuse, or rendering the substance harmless; the results of testing on physical chemical and physico-chemical properties.

The Directive contains exemptions from reporting requirements for various types of chemicals. For chemicals marketed under 1,000 kg per year, there are reduced reporting and testing requirements. Other exemptions, requiring a limited announcement with no test data, exist for polymers, research substances, and low-production-volume chemicals. Once a chemical is on the market, the manufacturer must notify authorities of any changes in production and the availability of any new risk data. Authorities may also request additional data at any time if they feel the substance may pose a high risk. More detailed chronic toxicity testing is required as production level increases (e.g., at 100,000 kg per year and 1,000,000 kg per year), serving as a safety net. Submitters must also propose a classification and labeling for the substance according to the Directive's definitions.

Once a pre-market notification is received, authorities in the Member State where the notification was received review the validity of the test data and conduct a risk review of that notification substance. The authorities designated for such review differ by country, as does the exact nature of the review or actions following review. The quantitative or qualitative risk review, described in the 7th Amendment to the Directive, includes an estimation of risks to workers, consumers, and the environment throughout the whole lifecycle of the chemical (production, storage, use, and disposal). The results of the risk review include one of four outcomes: the substance is of no

immediate concern and need not be considered again until further information is made available; the substance is of concern and the country authority shall decide whether additional information is needed once the next use threshold is reached; the substance is of concern and further information should be immediately requested; the substance is of concern and the authority should immediately make recommendations for risk reduction, which may include restrictions on use and marketing, modifications to classification, packaging or labeling, or precautions or production controls. The acceptance of the dossier in one Member State makes the notification valid in all Member States, allowing Community-wide marketing. The substance is placed on the European List of Notified Chemical Substances (ELINCS).

Implementation of New Chemicals Notification

As of 1998 a total of 2,109 new chemicals were reviewed in the EU (3,793 notifications), with about half being submitted in the UK and Germany and 30 percent in the Netherlands, France and Italy. Of those, non-European manufacturers accounted for about 60 percent of all notifications (Switzerland, the United States and Japan), which indicates their ability to adapt to EU testing requirements. Three new chemicals were banned in the EU on the basis of this review and approximately 70 percent were labeled as hazardous as defined by the Dangerous Substances Directive.

Through 1998 only 87 notifications reached an annual threshold of 100,000 kg and 9 reached 1,000,000 kg. From the establishment of risk assessment review requirements of the 7th Amendment in 1993, through 1998, only 400 chemicals were subjected to risk assessments (with an estimate of 1-2 years to complete each assessment). No or low concern was concluded in over 70 percent of the cases where risk assessments were conducted, and less than 30 percent required additional testing or recommendations for risk reduction.

The often burdensome testing requirements for new chemicals have been one of the main criticisms of the new substances requirements. Some industry observers argue that the requirements starting at 1,000kg stifle innovation in new chemicals. Additionally, because of the differing levels of enforcement of each Member State, research indicates that a potentially large percentage of new chemicals may have been marketed without prior notification (and are thus, illegally marketed). Further, because of concern and protection of confidential business information, distribution of new substance dossiers to authorities in other Member States may take as long as a year. Lastly, while required to be updated yearly, ELINCS has only been updated two times since its inception.

A 1999 review of the Dangerous Substances Directive concluded that the Directive is an important platform for a wide range of downstream EU risk management legislation. However, there is a serious need to update the directive for greater clarity, speed, and efficiency, including: more rapid classification; improved exemptions for new chemicals reporting to facilitate innovation; simplification of notification requirements; reallocation of responsibilities to improve enforcement; and reduction of unnecessary animal testing.

The Dangerous Preparations Directive

The 1988 Dangerous Preparations Directive, updated in 1999, is similar to the classification, labeling and packaging requirements of the 1967 Dangerous Substances Directive but applied to preparations, defined as mixtures or solutions of two or more substances, one of which is classified as dangerous. The directive sets out harmonized rules for classification, packaging, and labeling that apply to manufacturers, distributors and importers. These companies have the responsibility for classification, labeling and packaging of preparations, though there is no pre-market notification requirement for new preparations. Once a preparation has been classified, packaged and labeled by the producer or importer and notification has been made to Member State authorities according to the Directive (which have authority for its implementation), it can be marketed throughout the EU without any obligation to supply information to other national authorities. There is no distinction between new and existing preparations under the Directive.

Between 90 and 95 percent of all chemicals on the European market are preparations. Because of the sheer number of preparations – estimated at about one million on the EU market (including solvents, coatings, lubricants, agricultural chemicals, and consumer products, such as detergents and disinfectants but not medicines, cosmetics and foodstuffs) – and the amount of testing that would be required (a burden for small- and medium-sized companies and incompatible with animal welfare concerns), the EU had to develop a method for assessing and classifying preparations. Through this method, called the "conventional" method, the classification of a preparation can be calculated from knowledge about the classifications of the component substances and their concentrations (including their additivity). However, a manufacturer, distributor or importer can also choose to conduct testing. For all preparations, however, basic information on physio-chemical properties must be submitted (e.g., explosivity, flammability, etc).

The Dangerous Preparations Directive is closely linked to the Dangerous Substances Directive. The directive uses the substance classifications of the Dangerous Substances Directive, as well as the same criteria for labeling, the same labeling scheme, the same test methods, and the same packaging rules. Thus, modifications to the Dangerous Substances Directive have consequences for the Preparations Directive. Additionally, the Preparations Directive has been updated to include gaseous preparations as well as to require safety data sheets for industrial users, for preparations both classified as dangerous and for those that may pose dangers to health or the environment because they contain more than 1 percent of a substance classified as dangerous. The 1999 changes to the Directive, which were to be implemented in Member State law by 2004, includes dangers to the environment and sensitizers in the classification and labeling requirements, as well as the inclusion pesticides and biocide preparations.

Implementation of the Dangerous Preparations Directive

Similar to the Dangerous Substances Directive, the Preparations Directive, while successful in its goal of reducing barriers to the free circulation of dangerous preparations, has been limited in enforcement, which varies by Member State. Some preparations have not been classified and some are classified in different ways by different manufacturers, particularly due to differences in how dangerousness is calculated. Also, while the Directive calls for uniform labeling, it may

be necessary to have different labels for different types of users. Nonetheless, the directive has extended the traditional focus on substances alone to the preparations in which they are most often used.

The Existing Substances Regulation

The Existing Substances Regulation was passed in 1993 as a response to the lack of risk assessment and action on chemicals on the market before the 1979 new substances amendments under the Dangerous Substances Directive came into effect. The 1987-1992 Fourth Community Action Programme on the Environment noted the need for procedures to prioritize chemicals and evaluate risks to the environment and human health posed by "existing" chemical substances. The Regulation's goal is to identify and reduce risks related to the production and distribution of existing chemicals, including to workers and consumers, not just communities impacted by point source emissions. One goal of the Regulation was to ensure that each chemical is assessed on the basis of the same criteria. The regulation states that controls on hazardous chemicals should be based on an assessment of actual risk to human health and the environment, rather than simply the hazardous properties of the substance. It aims to ensure that a Member State would not notify its intention to restrict marketing and use of a substance without carrying out a risk assessment according to principles agreed to by all Member States.

The act envisions a four step process for risk assessment: (1) data collection; (2) priority setting; (3) risk assessment; and (4) risk management. Implementation of the Regulation is coordinated by the European Chemicals Bureau, a European Union research body, located in Ispra, Italy.

The Regulation requires that manufacturers and importers provide specific information on EINEC-listed (the European Inventory of Existing Commercial Chemical Substances) chemicals produced or imported in volumes above 10 metric tons per year (starting with HPV substances produced over 1,000 tons per year), including production quantities, classification and labeling information, reasonably foreseeable uses, and toxicological information (data requirements are reduced for substances produced under 1,000 metric tons per year). Companies are allowed to submit data jointly. As of 1998, data on approximately 2,500 substances was received with data on about 15,000-20,000 chemicals expected. The data received as of 1998 indicate about 2,500 HPV Chemicals (above 1000 tons production per year) and 15,000-20,000 low production volume chemicals (between 10 and 1,000 tons per year). Data are collected in the International Uniform Chemicals Information Database (IUCLID) managed by the Commission.

To harmonize the risk assessment process, a Commission Regulation of 1994 lays down the principles for assessment of risk, and a 1996 Technical Guidance Document provides detailed instructions on performing the assessment. The scope of the risk assessments should cover emissions and consequent environmental impacts and human exposures at each stage of the lifecycle of a chemical. Exposure of humans from all relevant sources should be considered, including exposures from consumer products, ambient air, food, drinking water, and in the workplace.

Each risk assessment ends up with one of the following conclusions for each of the various protection goals (human health, aquatic organisms, atmosphere, mammals and birds, etc): need

for further information or testing to assess risks; no present need for further information or risk reduction measures beyond those currently applied; there is a need for limiting the risks.

Because of the sheer number of substances to assess, the Regulation calls for prioritization (though it does not specify how this should be achieved) to determine which chemicals should be assessed first. So far, 141 priority substances have been identified on four lists, which should be regularly updated. The lists are chosen based on high production, dispersive use, high toxicity, and lack of information on effects. A priority setting scheme called the EU Risk Ranking Method, was developed for identifying substances for the priority lists. Substances that have undergone an equivalent assessment under other EU legislation are not assessed under this Regulation.

Each substance on the priority list is formally assigned to Member State "Rapporteurs" on a proportionate, voluntary basis who perform the risk evaluation on behalf of the EU. Member States often volunteer to conduct risk assessments on chemicals of concern within their borders. The burden is on the Commission and Member States to conduct the assessment. In conducting the assessment the Rapporteur should incorporate existing assessments to avoid duplicative work. The Rapporteur sends out a draft risk assessment report for consideration by Member States (including requests for additional data). Other Member States have the opportunity to comment and final acceptance of the conclusions of risk assessments is agreed to in meetings between Member State competent authorities.

If the risk assessment concludes that risk reduction measures are needed, the Member State is required to propose a risk reduction strategy. The risk reduction strategy should consider economic and social impacts, monitorability, and availability of alternatives. This strategy can consist of voluntary measures, measures within the context of the Limitations Directive or other legislation, recommendations of exposure or permit limits, or the development of new legislation to address the chemical's risks. Thus the Regulation establishes a close link between risk assessment activities and risk management actions.

Implementation of the Existing Substances Regulation

As of late 2002, Member State Rapporteurs have completed the first draft Risk Assessment Reports on 96 out of 141 priority substances listed on the first four lists. Conclusions have been agreed to for 64 of the 96 substances. The following conclusions were drawn for the 64 substances: 51 required risk reduction measures; two required more information before final conclusions could be reached; 11 concluded that there is no need for further information or risk reduction. Member States have developed proposals for risk reduction strategies for 25 of those 51 substances, ten of which have resulted in European Commission recommendations on measures, which then must go through EU regulatory/legislative processes.

It has been estimated that the time from publication of a priority list to the circulation of the first draft of a risk assessment report is about 18 to 29 months. A further 9 to 25 months are needed from the circulation of the first draft until agreement is reached on the risk assessment report (though the speed is increasing, with increased experience in the risk assessment process). The

timescale for determining risk reduction strategies depends on the availability of the Rapporteur's resources.

A 2002 Dutch government review of the first 41 completed risk assessments under the Regulation found that 34 resulted in a conclusion of either more data needed or risk reduction needed. The researchers found that for most chemicals, the OECD minimum screening data set for HPVs is insufficient to complete a risk assessment, particularly with regard to reproductive toxicity. Further, risk assessments often found risks associated with a variety of use patterns (consumer use, intermediates, etc.); as such, the researchers recommended that risk assessments be expanded to include unforeseen downstream user and consumer risks.

The limited implementation of Existing Substances Regulation, enacted to deal with weaknesses in the regulatory structure for existing substances, has highlighted current problems in chemicals policy and has been an important driver for the REACH program. While envisioned as a risk management regulation, in practice it has been mired in risk assessment. In particular, the process of conducting risk assessments and then agreeing on and enacting risk reduction measures in response has been extremely slow and costly. Because of the voluntary nature of the Regulation's risk assessment provisions, there has been a disproportionate lack of commitment on the part of Member States. In part this is due to underestimation of the resources needed to conduct the risk assessments.

The consultative process for each risk assessment and set of risk management measures, combined with the legislative steps necessary to enact these measures, means that it can take years before action is taken on a particular chemical. Long debates often take place on the strengths and weaknesses of the data in the risk assessments. For example, 4,4'-methylenedianiline was first placed on a priority list in 1994 and by 1995 a draft risk assessment was prepared by Germany and discussed with industry and updated; the risk assessment was not discussed in the Commission until 1997 with revisions agreed on in 1998. As of 2000, risk reduction measures were still under discussion. As the Regulation places the burden on governments to collect data, assess risks, and demonstrate danger before preventive action can occur, industry has an incentive to slow down the process and has not been forthcoming with data to support risk assessments.

The Limitations Directive

The Limitations Directive is arguably the most important chemicals risk management policy currently in force in the European Union. While originally adopted to harmonize Member State's controls on dangerous substances and preparations, allowing the free flow of goods through the EU, the Directive has been an important tool for restricting the use of harmful substances – particularly carcinogens, mutagens, and reproductive toxicants – in consumer available preparations. The Directive was introduced in 1976 to address situations in which individual Member States were introducing national restrictions on marketing and use of chemicals (in response to limitations of classification and labeling) that might disrupt the EU internal market.

The Directive establishes rules for harmonized restrictions on use and marketing of hazardous substances and preparations in Member States, but does not apply to transport of hazardous substances or preparations, those exported to non-member countries, or to products covered under other pieces of legislation such as cosmetics, medicines, and pesticides. The Directive creates a framework for restrictions by means of an annex where controlled substances and preparations are listed – these can only be placed on the market subject to specified conditions. Enforcement is up to each Member State. The Directive mainly applies to substances and preparations (mixtures or solutions comprised of two or more substances) sold to consumers, with their use in particular types of products also being controlled.

Proposals for restrictions on substances and preparations generally originate under a separate directive (83/189) which requires that Member States notify the Commission of their intention to unilaterally introduce national level limitations. However, proposals also have come from European Council resolutions, OSPAR Convention restrictions, New Substances Notifications, risk management actions from the Existing Substances Regulation (though this has happened only one time in the case of short chained chlorinated paraffins), and other Directives and Regulations.

Because restrictions are established often in response to notifications of Member State unilateral actions to protect health, decisions must be made quickly under the Directive. Once a proposal is made to add a substance to the restrictions list, an independent consultant prepares targeted assessment of risk (limited in scope and based on available data) as well as an analysis of the social, economic, and health and environmental advantages and drawbacks of the restriction, according to a Commission guidance. This process usually occurs in consultation with stakeholders. Once completed, the Commission develops a proposal for amendments to the Directive, which are debated and adopted following the co-decision procedure between the European Parliament and Council of Ministers (essentially a legislative process). However, modifications on restrictions of substances already included under the Directive, as a result of new scientific knowledge or evidence of less dangerous substitutes, can be made through Commission Directives (essentially a rule making procedure), whereby proposals only have to be approved by a qualified majority of Member States. Once a substance is added to the Directive, Member States must adopt the restrictions through their own legislative processes within a specified timeframe.

The Directive provides for two types of restrictions on substances and preparations and their use, which depend on the type of risk—bans with exemptions or controlled use. Restriction decisions are generally made on a case-by-case basis though some may be done for classes of chemicals. A ban with exemptions means that marketing and use of the substance is prohibited except for specifically approved uses for which there are no alternatives or risk is not deemed as great. Exemptions may be for specific periods of time. Controlled use means that marketing and use of a substance and the preparations containing it are allowed except those specifically prohibited that present a special risk and where safer substitutes exist. Most restrictions are "controlled use." They may consist of concentration limits in a preparation or product, as well as labeling, exposure limits and other safety measures. For example, marketing and use may be banned for the general public but professional users may be permitted to continue using the substance for specific applications or as an intermediate. In other cases uses may be restricted in certain

products (such as textiles) or for certain uses (such as treating water). Restrictions can be made for protection of consumers, workers, or the environment.

In response to a European Council of Ministers resolution on cancer prevention, in 1994, an amendment was made that prohibits the sale to the general public of all substances and preparations (but not final products) classified under the Dangerous Substances Directive as known or probable carcinogens, mutagens, or reproductive toxicants (CMRs), making a direct link between these two directives. Such substances must be labeled as "restricted to professional users." This blanket marketing ban contains exemptions if the substance is present at very low concentration. Despite this amendment to the Directive, marketing bans on CMRs are not automatic and each new substance has to be included in an amendment to the Directive, adopted by the Council and the Parliament through the co-decision procedure which usually takes between 18 and 24 months (though a full impact analysis is not required for each). A CMR market restriction can be extended to products through a separate discussion and listing of the substance.

Implementation of the Limitations Directive

To date, the Directive has resulted in restrictions of 42 substances and groups of substances covering some 900 chemicals, including approximately 850 substances labeled as carcinogenic, mutagenic or reproductive toxicants. Among these are several hundred complex substances derived from coal and petroleum. As a result some observers have argued that the 900 restrictions have created a "façade" of action. About 15 percent of the restrictions are to protect children's health. Bans with exemptions have been issued only for PCBs, some PCB substitutes, and pentachlorophenol.

Some of the restrictions include most uses of asbestos, tris(2,3 dibromopropyl phosphate) in textiles, benzene in toys and preparations (excluding gasoline), polybrominated biphenyls in textiles, cadmium as a colorant in plastics, in pigments, and as a stabilizer in many uses, nickel in jewelry, and trichloroethane and tetrachloroethane. More recent restrictions include a ban on the sale of copper chromium arsenate and creosote treated wood to consumers (though some industrial uses are still allowed), a ban on the use of hexachloroethane in the manufacturing or processing of non-ferrous metals, a restriction on organotin compounds in treating the hulls of boats, a restriction on azo dyes in textiles, and a restriction on short-chained paraffins in metal working and leather production.

The European Parliament and Council recently finished negotiations on restrictions on polybrominated diphenyl ethers (PBDEs), used as fire retardants, which were approved in February, 2003. The restriction imposes an immediate marketing and use ban on pentabromodiphenyl ether and octabromodiphenyl ether and a commitment to rapidly take appropriate measures when a risk assessment and risk reduction strategy is completed for decabromodiphenyl ether (the most widely used PBDE). Also, restrictions have recently been passed on nonylphenols used in detergents and other products and hexavalent chromium in cement. A proposal for restrictions on the use of phthalates in products intended to be put in the mouth of children under three is still under debate.

In general, the Limitations Directive has been viewed as successful in its goal of preserving the internal market and in terms of toxic substances management. Some observers have noted that the CMR provisions have put in legislation the principle that chemicals should be restricted on the basis of their inherent hazardous properties, not their risk. Other observers note that the Limitations Directive is a "sweeping up" directive to take action on substances not restricted under other legislation. Member States – which have been the motivating force behind restrictions under the Directive, can use it as a tool to initiate EU debate and action on a particular substance through notification of their unilateral action to restrict it (such as Sweden's effort to institute an EU-wide ban on mercury).

Nonetheless, in all cases, particularly for CMRs where the decision to ban consumer-available preparations and substances is automatic, the co-decision process can take a long period of time until restrictions are in place, as this is done on a case-by-case basis. The burden to act is on the Commission. Debates often occur on the risks of a particular chemical use, such as azo dyes in carpets hung on walls. The process of adding substances to the Directive is also hampered for those substance for which testing methods must be developed by the European Standardization Organization to enforce restrictions – for example in the case of restrictions on the marketing and use of nickel in jewelry. In the case of substances for which restrictions might cause economic impacts for certain countries or substitutes are limited – such as asbestos – the process of agreeing on restrictions can take even longer. The concerns are particularly evident when a substance is found to pose an immediate acute risk to health. Efforts to modify the procedures under the Directive to accelerate the decision-making process have failed to date.

The CMR provisions of the Directive apply only to consumer available substances and preparations, not final articles and products, to which consumers are often exposed. In 2002, some Members of Parliament proposed an amendment to the Directive extending the scope of the ban on the sale of CMR substances and preparations to articles. However, both the Council of Ministers and the Commission have rejected this proposal.

Enforcement is the responsibility of Member States and thus differs by location and company. This poses a problem when a restriction includes many exemptions, as in the case of cadmium where there are exemptions of 40 application areas. The Commission does not keep data on impacts of the restrictions – whether the use of restricted chemicals has been reduced, whether substitutes are safer, or the economic impacts – which limits the ability to measure the success of the Directive to date. It is likely that implementation has varied across countries and companies. Larger companies, such as Procter and Gamble argue that they take the CMR restrictions seriously and none of their products contain such substances.

6. OTHER EUROPEAN CHEMICALS LEGISLATION THAT HAS INFLUENCED OR WILL BE AFFECTED BY REACH

The four pieces of legislation evaluated in Section 5 form the foundations of the EU's REACH program. However, there are several other pieces of EU legislation on chemicals that have influenced and have been influenced by the debates on a new EU chemicals policy. In many ways they present an overlapping and complicated web of obligations and authorities to control chemicals that could complicate efforts to establish an integrated approach to chemicals management. For example, occupational health protections are not explicitly included under REACH but current occupational health directives may present an indirect means to control problem chemicals, particularly CMRs, as there is a specific substitution requirement. How the REACH program will interact with controls on chemicals in cosmetics or biocidal products, for example, is unclear at this point, though it is likely that such products will be explicitly exempted to one degree or another under the REACH legislation.

The various directives provide a myriad of authorities and programs to restrict harmful substances, opening doors to additional routes to address chemicals of concern. For example, many chemicals related directives take their definition of "hazardous" from the Dangerous Substances Directive. Thus, any changes to augment or modify the definition of hazardous will likely have implications for all of the other directives employing that definition. This multi-law approach to hazardous substances control – while complicating compliance, may lead to greater successes (synergies) in restricting dangerous chemicals. It is not clear yet how these potentially overlapping obligations will be addressed through the REACH process.

Nonetheless, it is clear that many of the directives currently in force have greatly influenced debates leading to the REACH proposal. They have established in law the concepts of substitution of harmful chemicals. They have provided an impetus for adding certain hazardous substances such as PBT chemicals and endocrine disruptors into the authorization process.

Those directives of most interest in chemicals control because they restrict a class of problem chemicals or could directly interact with REACH include: (1) the Water Framework Directive; (2) the Waste from Electronic and Electrical Equipment and Restrictions of Hazardous Substances in Electrical and Electronic Equipment Directives; (3) occupational health regulations; (4) the Cosmetic Products Directive; and (4) the Biocidal Products Directive.

European Legislation on Chemicals

* Dangerous Substances Directive (1967)
* Limitations Directive (1976)
* Dangerous Preparations Directive (1988)
* Existing Substances Regulation (1993)
* Cosmetic Products Directive (1976, 2003)
* Occupational Health regulations (1990,1998)
* Biocides Directive (1998)
* Water Framework Directive (2000)
* Waste from Electronic Products/ Restrictions on Hazardous Substances (2003)

Water Framework Directive.

The 2000 Water Framework Directive (2000/60/EC) is a broad piece of legislation aimed at maintaining and improving the aquatic environment including inland surface waters, transitional waters, coastal waters, and groundwater (though not the open sea). The aquatic environment includes water, sediment and biota. While the Directive has numerous provisions relating to aspects of water quality, its measures with regards to hazardous substances in production and products represent some of the most far reaching requirements in EU chemicals policy to date.

The Directive calls for the European Parliament and Council to adopt "specific measures against pollution of water by individual pollutants or groups of pollutants presenting a significant risk…for those pollutants measures shall be aimed at progressive reduction." The first step in the strategy against pollution of water is for the Commission to establish a list of "priority substances" (substances of concern) selected amongst those that present a significant risk to or via the aquatic environment. The priority substances are identified and prioritized using: risk assessments conducted under the Existing Substances Directive; other targeted risk assessments; evidence on the intrinsic hazard of the substance; evidence from monitoring of contamination; and other factors, such as use and exposure patterns. To establish the priority list, the European Commission, developed a method called "combined monitoring-based and modeling-based priority system (COMMPS)". Using this method, the Commission evaluated some 310 substances and its first priority list in 2000 contained 32 substances. The priority list is subject to consultation with governments, industry, and NGOs. While the Directive does not require a specific number of chemicals to be added to the priority list, the list is to be updated every four years.

The Directive also calls on the Commission to establish a list of "priority hazardous substances" (substances of very high concern) based on the list of "priority substances." The Commission developed a procedure for identification of such substances according to their level of hazard, which includes hazard assessments carried out under the OSPAR Hazardous Substances Strategy and inclusion on EU and international lists of dangerous substances, as well as information on production, use, and socioeconomic impacts of actions on such substances. Substances can be classified as hazardous based on their inherent characteristics, such as persistence, bioaccumulation, and toxicity. Of the original 32 substances included in the 2000 list, 11 were labeled as priority hazardous and 11 were designated as priority substances under review for listing as hazardous. The 11 priority hazardous substances include industrial chemicals, pesticides, and combustion by-products: pentabromodiphenyl ether; short chained chlorinated paraffins; cadmium and its compounds; hexachlorobenzene; hexachlorobutadiene; hexachlorocyclohexane; mercury and its compounds; nonylphenols; polyaromatic hydrocarbons; and tributyl tin compounds. The to be reviewed list includes several pesticides of concern, such as atrazine, chlorpyrifos, and endosulfan, as well as lead and lead compounds.

For each of the substances on the priority substances list, the Commission is required to propose EU wide standards to control and reduce emissions of each substance including: environmental quality standards (EQS) applicable to concentrations of the substance in surface water, sediments and biota; and product and process controls for point and diffuse sources. These should

progressively over time result in the reduction of discharges, emissions and losses of the substances. Proposals should be developed within two years of inclusion on the list of priority substances and product. Process controls should be established under appropriate EU legislation. The Council and Parliament must adopt measures likely through "daughter directives" for each substance or group of substances. If the EQS and control measures are not agreed on within six years, Member States are required to establish their own measures.

For priority hazardous substances, the Directive calls the Commission to propose controls for "the cessation or phasing-out of discharges, emissions, and losses" not to exceed 20 years after the adoption of those proposals by the European Parliament and Council. *This is the first time a phaseout on inputs of certain chemicals into surface waters has been made a legal requirement.* Controls can include bans, use restrictions, and requirements for zero-emission facilities and must be agreed upon on a case by case basis by the Parliament and Council co-decision procedure.

To date, the priority substance list has been developed by the Commission and the Commission is now in the process of developing proposals for EQS and control measures which together should be published by the end of 2003. While the priority list and priority hazardous substances list were supposed to be completed and sent to Parliament and the Council by the end of 2002, assessments on the substances under review for the priority hazardous substances list (particularly pesticides for which the pesticide industry has pursued legal action to avoid their listing) have not been completed, so the list has not been finalized as of yet.

Waste from Electronic and Electrical Equipment (WEEE) and Restrictions on Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directives.

The Waste From Electronics and Electrical Equipment Directive places responsibility on producers for collection of end-of-life electronic waste and sound treatment. It applies to a broad range of products including large and small household appliances; information technology equipment; lighting equipment; electrical tools; toys; and medical devices. It specifies the type of recovery required for certain types and components of products.

To address concerns over hazardous substances used in electronics and electrical equipment and exposure through waste, a separate Directive, RoHS, was established (which was originally part of the WEEE directive). The Directive requires the substitution in all new electrical and electronic equipment from July 1, 2006 of the use of mercury, cadmium, lead, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers in electrical and electronic equipment and the periodic review of other substances used in such products for substitution. The Directive provides for exemptions from substitution if it is not possible from the technical point of view or it costs are too high with respect to potential benefits. Substitution should ensure health and safety of users of such equipment. Exemptions currently in the Directive include mercury in fluorescent lamps, lead in glass of cathode ray tubes, lead in some soldering (to be reviewed for restriction), lead in electronic ceramic parts, chromium plating (except where restricted under other legislation) and hexavalent chromium use as an anti-corrosive of cooling systems in absorption refrigerators.

Both directives were finalized by the Parliament and Council of Ministers in January 2003.

Occupational Health Regulations.

While the White Paper on chemicals does not specifically mention or integrate occupational health, and occupational health authorities have not been actively involved in the development of the REACH legislation, there are several existing occupational health directives that either influence or would be influenced by REACH. These include: the Occupational Carcinogens Directive; the Chemical Agents at Work Directive; and the Directive to Encourage Improvements in Safety and Health at Work of Pregnant Workers and Workers who Have Recently Given Birth or are Breastfeeding.

The Occupational Carcinogens Directive (90/394/EEC) of 1990 provides a step-by-step approach for minimizing and controlling workplace risks from exposure to substances and preparations which meet the criteria for known and probable carcinogens and mutagens as defined in the Hazardous Substances and Hazardous Preparations Directives. The directive applies not only to substances produced or used in the manufacturing process but also intermediates and production by-products. Under the directive, firms must assess risks of exposure (types of exposures, duration, etc.) on a regular basis. If a risk to health is identified, there is a general duty of reduction and replacement of carcinogens and mutagens in the workplace. "The employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety." The assessment of alternatives should be submitted to authorities. Where substitution is not technically feasible, the firm is required to use the substance under closed loop conditions to eliminate exposure. If this is not feasible, the firm is required to reduce exposure as much as is technically feasible through engineering measures. As a last resort, personal protective equipment may be used. The directive also requires surveillance of exposed workers and categorization of workers job tasks. Finally, it requires the European Commission to establish binding limit values for carcinogens for instances when substitution is not feasible. To date, in addition to the substances and preparations already listed under the Dangerous Substances and Dangerous Preparations directives, the directive lists several processes that can lead to carcinogenic emissions or byproducts exposure to which should be minimized.

The Chemical Agents at Work Directive (98/391/EEC) of 1998 consolidates several earlier directives and outlines minimum requirements for work with hazardous chemical agents. Hazardous chemical agents include any chemical substance or preparation which meets the dangerousness criteria in the Dangerous Substances and Dangerous Preparations Directives, even if not on the annexes to those directives. It also applies to any chemical substance that may present a risk to safety and health due to its physiochemical or toxicological properties but does not apply to substances and preparations that are only dangerous to the environment. The directive establishes a framework for establishing binding and recommended occupational exposure limits for such substances. Member States must set their own limit values based on the European values. Employers are required to assess worker risks from exposure to hazardous substances, including consideration of multiple chemical exposures. The Directive establishes a hierarchy of workplace controls to minimize exposure to the extent feasible, including

substitution as the preferred method, followed by design changes, workplace organizational changes, reductions in chemical use, and personal protective equipment. It allows certain substances and activities to be prohibited altogether to protect workers, permitting countries to go around the Limitations Directive as long as the internal market is not affected. The Directive also establishes surveillance regimes for workers exposed to hazardous substances. As of 2002, binding occupational exposure limit values had been established only for lead. Only some benzidine compounds and other aromatic amino compounds have been completely restricted under the directive.

The Directive to Encourage Improvements in Safety and Health at Work of Pregnant Workers and Workers who Have Recently Given Birth or are Breastfeeding of 1992 (92/85/EEC) requires that employers assess exposure of pregnant workers and those who have recently given birth or are breast feeding to all classes (known, probable, suspect) of carcinogens and mutagens. For all activities liable to involve a risk of exposure to agents, processes, and working conditions listed in an annex to the Directive (including carcinogens, mutagens, mercury, antimitotic drugs, carbon monoxide, and substances that can be absorbed through the skin), employers must develop measures to reduce or eliminate exposures. These measures must be undertaken according to the Directive on Improvements in the Safety and Health of Workers (89/391/EEC) the framework legislation that establishes the general principles of workplace prevention. The pregnant worker's directive also prohibits exposures of minors to all hazardous substances as well as exposures to specifically listed substances for pregnant and breastfeeding women. To date, lead and lead compounds are the only substance listed as prohibited for pregnant and breast-feeding workers.

These occupational health directives incorporate the concept of substitution where feasible for hazardous substances that are listed under the current hazardous substances and preparations legislation. However, their implementation to date has been limited due to weak and varied enforcement and the difficulties for small- and medium-sized companies to comply with the risk assessment and risk reduction measures.

The Cosmetic Products Directive.

The Cosmetic Products Directive (76/768/EEC) of 1976 establishes rules to harmonize European regulation of cosmetic products including their marketing and labeling. The Directive sets forward a general condition that cosmetic products may not be hazardous to health under normal and foreseeable use and that industry must ensure this. The Directive lists substances restricted and banned as well as substances that may be used as coloring agents, preservatives or UV-filters and establishes a process to add additional substances to the list. To date, several toxic substances of consumer concern have been restricted in cosmetics as a result of the Directive.

The Directive has been important in shaping the EU REACH policy in two ways: first, efforts to successfully minimize animal testing of cosmetics under the Directive have been directly applied as rationale to minimize animal testing under REACH. Second, in 2001 the European Scientific Committee on Cosmetics and Non Food Products called for a blanket ban on all known and probable CMRs in cosmetic products without any prior assessment of their exposure-related risks. This fundamentally challenged the Cosmetics Directive, which regulates based on risk

(inherent hazard plus exposure). In February 2003, the European Parliament and Council passed an amendment to the Cosmetics Directive that restricts CMRs in cosmetic products. The amendment states: "Given the special risks that substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1, 2 and 3, pursuant to Directive 67/548/EEC may entail to human health, their use in cosmetic products should be prohibited…A substance classified in category 3 may be used in cosmetics if the substance has been evaluated…and found acceptable for use in cosmetic products." The directive is important because it extends restrictions on CMRs in products for the first time to Class 3 (possible carcinogen). The amendment text also includes requirements for labeling hazardous substances in cosmetics.

Biocidal Products Directive.

The Biocides Directive of 1998 (98/8/EC) integrates several earlier pesticide directives and aims to minimize barriers to trade in biocidal products while maintaining a high level of protection. It provides a framework of rules concerning the authorization of pesticides and the mutual recognition of pesticides within the EU, as well as establishment of Community level lists of approved active ingredients. In addition to the list of active ingredients, the Directive establishes a list of "low-risk" products. These products are not allowed to contain active ingredients listed as carcinogenic, mutagenic, toxic for reproduction as defined under the Dangerous Substances Directive, that or are sensitizing or bioaccumulative. The Directive further states that biocidal products containing known or probable CMRs may not under most cases be authorized for use by the general public. Finally, active substances can be denied approval if they pose a risk to health or the environment or if there is another active substance permitted for the same product type which poses significantly less risk to health or the environment. Thus, the directive contains a substitution requirement and is important as it is the first full inclusion of comparative assessment in substance legislation. While not fully implemented yet, the Biocidal Products Directive is expected to build on the powers under the Limitations Directive, in that both can be used to restrict pesticides in consumer available products.

7. THE EUROPEAN WHITE PAPER ON CHEMICALS AND THE REACH PROPOSAL

The development of legislation to implement the REACH (Registration, Evaluation, and Authorization of Chemicals) process is the result of five years of complex debate and discussion among the European Commission and Member States. This section provides in-depth examinations of the White Paper on Chemicals (the policy paper which established the need for a new approach to chemicals management) and the REACH proposal. The examination is based on the White Paper, discussions from working groups established by the European Commission to assist with technical aspects of the REACH proposal, and draft legislative building blocks from 2002, interviews with Commission staff, and other materials collected through March, 2003.

A legislative proposal to implement the REACH system was presented by the European Commission for comment on May 7, 2003. At the end of this section we provide an overview of the draft legislation. While specifics of the REACH policy have changed through discussion and lobbying from stakeholders, the general principles and framework have remained the same since the White Paper on Chemicals was published in 2001.

The REACH legislation will replace three of the four existing cornerstones of European chemicals legislation and modify the fourth (the Dangerous Substances Directive). It is important to note that the REACH proposal is the farthest reaching proposal for chemicals regulation since the enactment of early chemicals legislation some twenty-five years ago. Thus, there are many difficult aspects of the program's implementation that have been debated. This section details some of the issues in those debates.

The process of developing the REACH proposal consisted of a series of key steps. Given the far-reaching change envisioned in the White Paper, the European Commission has been particularly careful to engage stakeholders in discussions on developing the legislation, as well as undertaking thorough impact assessments (discussed in Section 8):

- In 1998, at an informal meeting of environmental ministers, concerns were raised (primarily by Germany and the UK) about the lack of testing of chemicals;
- In November 1998, the Commission issued a report on the implementation of Community regulation on chemicals, resulting in the European Council of Ministers (environmental ministers from Member States) recommending the need for an integrated and coherent chemicals policy for the Community.
- In May 1999, following a stakeholder conference on chemicals policy (in February), participants at an Informal Meeting of EU Environment Ministers, issued a statement on deficits and needs in chemicals policy. This statement – called the Weinmar Statement – in particular notes the need to link product-related environmental policy and chemicals policy in a coherent and integrated approach.
- In June 1999 the Council of Ministers published a statement recommending that the European Commission develop a strategy by 2000 to reorient chemicals policy. The statement contained recommendations as to content of the new policy including filling

data gaps, placing responsibility on industry, substitution of substances of highest concern, and grouping of substances for accelerated action.

- The European Commission held discussions with stakeholders, including another stakeholder conference in December 1999 to develop its new policy proposals on chemicals.
- Following drafting by Directorate General (DG) Environment and DG Enterprise, the Commission worked with other DGs on a final text – the February 2001 White Paper – Strategy for a Future Chemicals Policy. This text represents the Commission's position on the directions that should be taken in a future chemicals policy.
- Following the publication of the White Paper, it was debated by the Council of Ministers and the European Parliament (as well as a stakeholder debate in April, 2001). These two legislative bodies then issued recommendations for the development of legislation.
- The European Council's conclusions, published in June 2001, reaffirm its support for the White Paper and legislation to implement it, note the need for innovation in new chemicals and alternative technologies as well as integration with integrated product policy, and call on the Commission to:
    - Work with stakeholders on exploring ways of taking action on priority substances before legislation comes into force.
    - Consider measures to integrate and avoid duplication with other pieces of chemicals related legislation.
    - Develop criteria and procedures for identifying and prioritizing chemicals of concern.
    - Simplify the legislation to the extent feasible.
    - Include in the authorization procedure persistent, bioaccumulative and toxic chemicals (PBTs), very persistent and very bioaccumulative substances (vPvBs) and known endocrine disruptors once screening methods have been developed.
- The European Parliament issued several reports on the White Paper including: one (October, 2001) a report from the Committee on the Environment, Public Health and Consumer Policy, which argued for strengthening the White Paper proposals, and the other from the entire Parliament (November 2001). The Parliament's report notes concerns over the potential economic implications of the proposed REACH proposal. It recommends:
    - Data collection for analyzing reductions in high priority substances.
    - Development of an efficient system that is not overburdensome for small- and medium-sized companies. Technical and financial assistance should be provided to such firms. Demonstration projects should be undertaken to test the policy.
    - Authorization should only include known and probable Carcinogens, Mutagens and Reproductive Toxicants (CMRs classes 1 and 2).
    - The REACH process should support global harmonization of chemicals regulation.
- Following the White Paper's publication, the Commission established 7 multi-stakeholder working groups to provide advice on technical aspects of the proposed legislation. These working groups issued reports on their deliberations on issues ranging from classification and labeling to criteria for identification of priority substances.
- Based on input from the Council, Parliament, the working groups and stakeholder (including Member State) lobbying, the DG Environment and DG Enterprise developed a

legislative package for implementing REACH which was presented to other Directorate Generals for Interservice Consultation (discussion between leaders of DGs) in April 2003.

- Following internal Commission debate, an Internet Consultation (a notice and comment period) was initiated in May 2003 with a two-month timeline for submitting comments on the workability of the REACH proposal.
- Based on comments from stakeholders and the other Commission offices, the two lead Directorate Generals are expecting to formally issue the legislative drafts in late October, 2003. It is then up to the country with the Council presidency to place it on the legislative calendar for debate. A first reading of the legislation could take place by spring 2004, though this is unlikely. The accession of ten new Central European nations to the EU in summer 2004 could affect this legislative timetable.

A Long and Transparent Process Leading to Reach

* 1998 Council of Ministers concern/request for report on status of chemicals policy
* 1999 Stakeholder conferences and additional consultations
* 2001 Comments by Council and Parliament
* 2001-2002 Stakeholder Working Groups
* Other stakeholder conferences, Member State meetings and informal discussions on business impact, workability, etc.
* 2003 Draft Legislation for Comment
* 2003 Final Draft Legislation

It is likely that the legislation will leave many issues undecided in detail, and these issues will continue to be developed in Commission-led committees (called 'Comitology'), involving Member State and Commission experts and stakeholder participation.

Goals of the White Paper

The White Paper on a Strategy for a Future Chemicals Strategy, the outcome of more than two years of stakeholder and internal European Commission discussions, provides the foundation for the Commission's approach to a new integrated chemicals strategy. The White Paper outlines the problems of the current regulatory system and sets forward a series of political objectives for a new chemicals policy. These include protection of health and the environment as a priority; avoiding fragmentation of the internal market; maintenance and enhancement of the competitiveness of the European chemical industry; increased transparency; and integration with international efforts while avoiding unnecessary barriers to trade. An additional political objective is minimization of animal testing through use of alternative test methods (see below).

The White Paper focuses both on increasing information about the hazards of chemicals and management of particular high hazard industrial chemicals. It proposes a new integrated policy for chemicals embodied in the Registration, Evaluation and Authorization of Chemicals process. The REACH process would, to a great degree, centralize the European chemicals management system through the establishment of a new chemicals agency or "central entity." Specific objectives outlined by the Commission include:

- A single system for new and existing chemicals. A centerpiece of the Commission's proposal is bridging of knowledge and management gaps between new (usually more thoroughly tested and managed) and existing chemicals (which represent more than 90 percent by volume of chemicals on the market) by eliminating this distinction.

- Deadlines for providing information on chemical toxicity and use. After a certain date, chemicals lacking basic information would not be allowed on the market.

- Industry responsibility. The White Paper proposes that industry now has responsibility for developing information on toxic substances, for assessing risks, and for ensuring safe use of substances, and that this responsibility should be extended along the manufacturing chain to downstream producers and users.

- Substitution of high hazard chemicals. Substances with certain hazardous properties that give rise to very high concern should be substituted wherever possible and only be permitted for specific uses.

- Stimulate innovation. By placing the burden on industry and having strict but realistic timelines, it is hoped that the policy will shape innovation behavior in firms leading to safer chemicals.

- Provide public information. The White Paper notes the importance of public access to information on chemicals (while protecting trade secrets) so that they can make informed choices, avoid products with harmful chemicals and place pressure on industry to develop safer substitutes.

- Fulfill international obligations. The proposed policy would support the European Union's compliance with the Oslo and Paris and Stockholm Conventions, provide support to developing nations, as well as avoid trade barriers by proposing a system that applies to both domestic and imported products. The proposal would also allow for use of data collected under international efforts such as the OECD program, thus minimizing animal testing.

Below, the REACH proposal and some of the key debates in its development are examined. The REACH policy represents as big a change in chemicals regulation as the initial chemicals regulations of the 1970s and 1980s. REACH creates a single European system for chemicals regulation of both new and existing substances and extends responsibility along the supply chain. In essence it expands chemicals regulation beyond the small number of new substances that have been much more scrutinized as of the 1980s to the other 99 percent by volume of substances that received much less attention and represent the bulk of profits of the chemical industry. Many highly complex details need to be elaborated and debated in order to ensure a workable system that supports both health and environmental as well as competitiveness goals. Following an examination of the components of REACH, some of the main points of difficulty and, often, of contention, in developing a new chemicals policy are explored.

After, the legislative proposal that was put forward by the European Commission for comment in May 2003 is detailed. This draft is likely to change somewhat once the final legislative draft is issued in October 2003.

Registration

The starting point for the REACH proposal is the registration process. According to the White Paper, all industrial chemicals marketed over one ton per year must be registered. This includes development and submission of basic information (toxicological, physiochemical, production, exposure) on chemicals. The registration process establishes government oversight of all industrial chemicals in commerce, eliminating any distinction between new and existing substances.

The White Paper states that "registration requires a manufacturer or importer to notify an authority of the intention to produce or import a substance and to submit a dossier containing the information required by the legislation. The authority puts this information into an electronic database, assigns a registration number and performs random spot-checks and computerized screening of the registered substances for properties of particular concern." According to the White Paper by 2012 (with shorter timeline for highest production volume chemicals), all chemicals in commerce produced over one ton per year must be registered (this has changed as a result of the various debates in the legislative drafting). Registration is the responsibility of manufacturers and includes testing and lifecycle risk assessment. It covers each specific use of the chemical up to the final product stage (i.e., chemical formulations such as paints would be covered but not when the paint is applied, for example, to a table). This is similar to the requirements under the new substances notification requirements currently in force (under ther Dangerous Substances Directive) where each manufacturer/importer of a "new substance" is required to submit a notification dossier.

Manufacturers and importers will be required to submit a registration dossier for substances produced in volumes exceeding one metric ton (about 30,000 substances). The registration dossier would include the following information: data on identity and properties of substances; intended uses and exposures; production quantity; hazard classification; safety data sheet; preliminary risk assessment for intended uses and disposal (with Commission guidance); and proposed risk management measures.

Required ecological and human toxicity testing would be tiered by volume: for substances produced/imported in quantities between 1 and 10 tons, in-vitro testing would be required on basic toxicological properties; for substances produced/imported between 10-100 tons, the OECD Screening Information Data Set (SIDS) base testing would be required; for substances produced/imported between 100-1,000 tons, substance specific chronic testing would be required; and for substances produced/imported over 1,000 tons, additional chronic testing would be required. Companies would be permitted to enter into consortia for testing and preparing data and they would be encouraged to create linkages with downstream users to collect data. Sanctions would be developed in cases of non-compliance or poor quality data. In hopes of stimulating innovation in new chemicals, the registration proposal would increase the threshold for new chemical substances testing from the current 10 kg to 1 ton.

A July 2002 draft of the registration legislation provides some insights into the process and how the legislation has developed from the White Paper. First, the draft places a general duty on manufacturers, importers and downstream users to "ensure the safe manufacture and/or use of the substances they manufacture, place on the market, or use by identifying their hazards, assessing their risks in normal use and by putting in place appropriate risk management measures". This 'duty of care' includes provision of information to users of substances and is implemented through the registration process. The registration process applies to manufacturers and importers of substances marketed on their own or in certain articles or preparations. Substances cannot be imported or manufactured unless they have been registered. Manufacturers of preparations, as opposed to substances, are considered downstream users and subject to different requirements.

The registration process would apply to the manufacture or import of substances in quantities over 1 ton per year (as well as to imported preparations where a substance is present above tonnage thresholds). The registration dossier (which could be preferably submitted electronically to ensure data quality) would include a base set of information identical for all substances and then various types of information depending on chemical use, type, and production. This information would include: identity of the manufacturer or importer; identity of the substance; information on the production and uses of the substance; all relevant information on the human health and ecological hazards of the substance; proposed classification and labeling of the substance; a full assessment of the risks related to the manufacturing and processing of the substance, as well as a preliminary assessment of risks from intended uses and disposal; and recommended risk reduction measures. In annexes, the legislation would spell out information requirements as well as the relevant testing/information required based on quantity of the substance manufactured or imported in the Community by a single manufacturer or in total. This tiered testing is likely to follow proposals in the White Paper (above 10 tons per year; above 100 tons per year; above 1000 tons per year). From 1-10 tons per year, the dossier would likely include just in-vitro testing and a summary of the studies on the substance's risks.

In the case of a substance manufactured or imported by several companies, companies would be able to jointly submit some data for the registration or to submit on behalf of others, though basic substance information would be required of all companies.

Once a dossier is received from a company, the central entity would assign a number to the registration and forward information to the Member State responsible for the registration (the one where the manufacturing takes place or the importer is established). The central entity would perform a completeness check, though not assess the quality or adequacy of the data or any justifications) of each dossier before forwarding it to Member State authorities. The Member State authority then has 60 days from the registration date to inform the registrant that a dossier is incomplete. In the absence of any indication to the contrary from the Member State, manufacture or import can proceed after the 60 day registration period or 60 days after submitting any supplemental information. Thus, while data collection and guidelines for testing/registration, etc. would be centralized at the registration stage, implementation and review would be conducted at the Member State level.

The draft sets out timelines for implantation of the registration provisions, including: 2-3 years for substances listed as CMRs categories 1 and 2 that are manufactured or imported over 1 ton on any occasion; 2-3 years for substances manufactured or imported over 1,000 tons per year per manufacturer or importer (and possibly produced above 5,000 tons per year for all manufacturers); 5-6 years for substances manufactured or imported in quantities over 100 tons per year; 10 years for substance produced or imported over 1 ton per year (though DG Environment would like to see a 2012 deadline). Notifications for new substances submitted under the Dangerous Substances Directive would count as registrations (which would be covered immediately under the REACH proposal); however, as production increases (to the next tonnage threshold) these substances would fall under the requirements of the registration process.

The draft legislation also includes an obligation for registrants to notify the central entity of any changes in manufacture quantities, new information on the health or ecosystem effects of the substance, or new uses of the substance.

Exemptions. The legislation excludes medicinal products, plant protection products, food additives, mixtures of substances in waste, substances exclusively produced for export outside the community, substances in transit, possibly crude oil and other substances excluded from the European Inventory of Existing Chemical Substances (EINECs) reporting requirements, and other explicitly indicated substances. The legislation would exempt substances manufactured or imported for process-oriented research and development with a limited list of customers up to a certain amount of years subject to specific requirements; substances uses in scientific research and development; and some intermediates (see below). Addressing polymers has been an area of debate in the REACH process. Polymers are likely to be subject to reduced requirements or exemptions in some cases.

Data requirements. The White Paper notes the need for flexibility in the test package so as to not unduly affect certain chemicals, companies or markets. The draft legislation notes that tests should be done according to OECD methods but that test data need not be generated by specified methods if equivalent and reliable data are available. It allows for waiving of certain tests if not necessary or if the substance would be used under strict controls. Submitters would be required to justify deviations and the adequacy of the test data would be examined on a case-by-case basis. The first goal is information on chemicals, according to the Commission, not testing per se. A second goal is avoidance of animal testing (see below). As alternative test methods are validated, test requirements are likely to change. Such alternative methods would likely be less time and resource intensive. For substances produced under 1 ton per year, only in-vitro testing would be required. There have been some debates in the European Union over the past several years about the use of surrogate measures for tests, such as Quantitative Structure Activity Relationships (QSAR). The Danish and Dutch governments are highly supportive of using such information to prioritize chemicals for risk reduction; however, the European Union has been less supportive of use of QSAR, instead advocating testing on particular substances.

Pre-Registration. While not covered in the White Paper or the draft legislation, there have been discussions about the establishment of a Pre-Registration phase for REACH. Such a Pre-Registration would make very basic information available to enable producers and importers to form consortia for data collection for Registration, in order to reduce animal testing and testing

costs. Pre-Registration could be conducted on a strict timeline to ensure preparation of registration dossiers. The central entity would manage this information.

Downstream users of chemicals. The role of downstream users of chemicals has been a contentious issue in the REACH debate, due to the potential increased requirements for a variety of industries. Many downstream users feel that having to fulfill the requirements of registration would be an economic burden and hinder innovation, particularly in industries with rapid development of products (see below). Chemical producers, however, are interested in increasing the responsibility of downstream users to provide data, so as to reduce their burden in implementing the registration process.

The White Paper on Chemicals notes that "downstream users must assume responsibility for the safety of their products". This general duty is further elaborated in the draft legislation. The role of downstream users is unclear in the White Paper. It states responsibilities but does not prescribe what downstream users should do in terms of testing, registration or authorization. It states that authorities should be empowered to require downstream users to carry out additional testing where uses and exposure patterns differ from those originally envisaged by manufacturers or importers. In this sense downstream users should provide information to authorities about any downstream use which has not been envisaged by a manufacturer or importer (including non-intended uses) and which has not been addressed in the preliminary risk assessment. Downstream users should also be required to participate in the preliminary risk assessment process with manufacturers.

Downstream users may often be manufacturers of substances themselves, formulators, or product producers. A Commission working group on risk assessment noted that downstream users should be defined broadly under the REACH program. It concluded that the downstream user risk assessment should cover those who use a substance or preparation to provide a product or who incorporate it in a product. However, given the large number of downstream users – most of which would not handle the original substance itself but rather preparations – a reduced requirement under REACH would seem reasonable.

According to the draft legislation, the registration requirements would apply only to the manufacturers and importers of substances. However, the general duty to provide data and ensure safe use would apply and authorities could act based on that duty. One option that has been discussed is that downstream users prepare risk assessments on their particular use but only submit an electronic postcard providing information on any use not envisioned in the registration dossier. This postcard would not constitute a registration but rather would serve as additional information to inform the registration decisions and for the evaluation stage of the substance. Downstream users could be required by Member States to provide information during the review of the Registration Dossier or at the Evaluation phase. They could also be required to implement risk reduction measures identified by manufacturers or importers in their registration dossier.

Information sharing. An important goal of the Commission's White Paper is the sharing of information throughout product chains, to improve lifecycle understanding of chemicals as well as risk management. It is expected that this sort of information sharing will improve supply chain connections and product management. By requiring that registration dossiers contain

information and a preliminary risk assessment on intended uses and disposal, manufacturers and importers are obligated to make contact with downstream users to collect critical data. Manufacturers and importers must also provide information to downstream users on safe chemical use, including labeling and classification. Downstream users also have a duty to provide information for risk assessment, particularly on non-intended uses.

A working group on information through the supply chain examined means to improve supply chain information. They noted that market forces alone may not be enough to facilitate the flow of information, therefore some regulatory means are necessary. An important conclusion of the workgroup is the need for improved databases to facilitate information flow throughout the supply chain. An identifier (the coverage of the substance under REACH) on safety data sheets of REACH registered substances may also help facilitate information flow far down the supply chain. While the main responsibility at the registration phase would apply to manufacturers and importers of chemicals, the workgroup noted the importance of determining duties throughout the supply chain in the REACH legislation. As a first step, a categorization of uses and steps in the supply chain should be developed. These might include: producers, distributors/traders, formulators, users of chemicals (industrial and professional – i.e.. automotive and construction), retailers, and consumers.

A second aspect of information sharing is between manufacturers themselves. The concept of pre-registration is to help manufacturers and importers establish consortia to share registration responsibilities. While the Commission will encourage the formation of consortia, it will not play a role in making such links happen. Such sharing of data between companies is already encouraged under the Dangerous Substances Directive and the Existing Substances Regulation.

Two issues arise in the context of data sharing: cost sharing and confidentiality of information. While the draft registration legislation allows the sharing of information and consortia in registering chemicals, it does not provide any requirement for cost sharing. Cost sharing becomes more complicated as downstream users become responsible for providing data. Issues of confidentiality are discussed below.

Substances in articles. Another contentious issue in the REACH debate has been whether substances in final products should be included under the REACH system (particularly at the registration stage). Under current legislation, notification for new substances applies only to the substance itself or as a constituent of a preparation. Substances used in products have been exempted from notification, though restrictions on substances in products have been covered under the Limitations Directive and other pieces of legislation. The White Paper notes that in most cases, substances found in products would be subject to registration because they are marketed as substances or preparations before being integrated into products. However, this might not be the case where the manufacturing process has occurred outside the EU.

Given the potential health risks from chemicals in products, the White Paper recommended the development of a working group to examine product categories and relevant exposure situations which would require inclusion of substances in articles in the registration process. The draft legislation also notes that registration would apply to manufacturers and importers of substances used in certain articles, though it does not provide an indication of what those articles would be

(including imported ones). Substances in articles would also be covered under the authorization procedure (ie authorization would be required for use of high concern chemicals in products, see below).

The working group on substances in products focused on the key issue of imported products that may contain untested and unregistered substances. Substances manufactured and used in products sold in the EU would more than likely fall under registration. While there was no general agreement of the working group one proposal put forward was that REACH should apply primarily to substances and preparations but that the registration process should consider risks from use in products. It should also contain a general duty for importers and manufacturers of products to control risks where dangerous substances might be released during normal use.

The registration and authorization of substances in imported articles has been another important issue of concern. Some governments and industry have raised the potential for violation of World Trade Organization (WTO) rules if the EU were to discriminate against products on the basis of the chemicals they contain (being a Technical Barrier to Trade). However, the EU is concerned that if they do not include imported articles under the REACH system EU companies would be penalized. Violation of WTO rules is less of a concern with regards to chemicals used in production processes.

Classification and labeling. The White Paper on Chemicals proposes to leave essentially intact the classification and labeling requirements under the Dangerous Substances Directive. Based on evaluation of new chemical submissions, it is expected that a large percentage of registrations for existing chemicals will require classification as dangerous. Based on the draft registration legislation, it appears that the harmonized classification and labeling process would occur separate from the registration process. The White Paper recommends that industry provide a list containing comprehensive information about the classification and labeling of all dangerous substances on the market and that this list be publicly available.

Classification and labeling are critical in the REACH process because classification as a known or probable CMR (and possibly as a PBT or vPvB) will force a substance to enter the authorization process. Since the process of Community agreement on each classification and labeling proposal is slow and time consuming, the Commission has suggested the development of a separate official classification for chemical substances, particularly for identification of substances of very high concern (that would be covered under authorization), whether or not the substances have been listed on the industry classification inventory or existing annex to the Dangerous Substances Directive. Much of the discussion on classification and labeling has focused on European adoption of the Globally Harmonized System for classification and labeling which is currently being developed by the United Nations.

Evaluation

The Evaluation phase of the REACH proposal has changed significantly since the White Paper. Below we describe the evolution of this phase and then later in this section present Evaluation as elaborated in the draft legislative proposal. Following the registration phase, this phase would consist of an in-depth evaluation by a Member State Competent Authority of risk data for

chemicals exceeding a production volume of 100 tons (about 5,000 substances) or lower volumes for chemicals of particular concern (persistent, mutagens or highly toxic substances). Thus, all high production chemicals as well as a smaller number of chemicals of concern will go through the evaluation phase. Criteria will need to be developed to identify which are chemicals of high concern, though Member States believe the list should be non-exhaustive. Chemicals could also enter the evaluation phase as a result of spot checks on registration dossiers. The evaluation would not apply only to the individual registration dossier but rather the substance itself.

In evaluation, manufacturers or importers would be required to submit all available hazard, exposure, and risk information to authorities as well as to propose a strategy for further testing to fill in data gaps (the latter in conjunction with authorities). Member States authorities would be allocated evaluation responsibilities on a proportional basis. The process and responsibilities for evaluation would be similar to those under the current system for reviewing new chemical substance notifications. Multi-disciplinary teams in authorities would review the industry provided data, testing plan and require substance-tailored testing, as needed. For chemicals of high concern, authorities could require immediate safety measures.

To respond to the slow process of establishing additional testing requirements under the Existing Substances Regulation (which is decided through Commission Committees), under the REACH proposal, Member States would be responsible for deciding on additional testing. The number of substances that will undergo evaluation will depend on the resources of Member States, and thus evaluations will need to be prioritized.

Once a Member State reviews the full industry risk assessment and test data (authorities would not be conducting their own risk assessment), it would issue conclusions and recommendations for mandatory risk management measures. The adoption of the risk management measures would occur through the Accelerated Risk Management Process (below). It also is possible that a Community-wide risk assessment will be called for by a Member State Rapporteur or consultant.

A Commission working group on risk assessment noted the need for guidance on criteria for reviewing risk assessments as well as a review of the relationship of REACH risk assessments to ones performed under other legislation. Industry would have responsibility for risk assessments but should be given some flexibility, based on community guidance. Where possible, targeted risk assessments (focused on key outcomes of concern) should be conducted. Also, for chemicals having diffuse sources and emissions, community risk assessments would be conducted starting with industry-provided data.

Given the decentralized approach proposed in the White Paper, a mechanism would need to be set up for resolving disagreements between Member States at the EC level. This could be organized by the central entity. Several Member States have indicated their preference for a more centralized evaluation process, where the evaluation process occurs within the central entity, using expertise provided by Member States. There are pros and cons to both options. A centralized process would not fully use the greater resources available in the Member States, while a centralized process may be more consistent and rapid. If there are few expected disagreements between Member States on evaluations, then the decentralized approach may be

more effective. In either case, the central entity would need to develop criteria and guidance for undertaking the evaluation process so that it is consistent.

Accelerated Risk Management.

Similar to the process under the Existing Substances Regulation, the risk evaluation can lead to a risk management plan. The White Paper envisions an Accelerated Risk Management process to ensure rapid implementation of recommendations. According to the White Paper, "specific uses of substances which do not have one of the properties listed under the authorization system but for which restrictions are needed should be addressed in an improved and accelerated procedure." The White Paper notes that the preliminary risk assessments under the registration process will provide information on whether a substance can be handled without posing unacceptable risks to workers, consumers or the environment. There is, thus, a need for rapid targeted risk assessments for a small percentage of chemicals to identify needs for risk reduction measures and would occur during the evaluation phase.

While not providing specifics of how Accelerated Risk Management would be undertaken, it is likely that it would be achieved through a revision of the existing decision-making process for restrictions under the Limitations Directive. Currently, restrictions under the Limitations directive require the lengthy Parliamentary/Council co-decision procedure. The process could be accelerated if risk management powers were delegated to the Commission and then disagreements addressed through a committee process.

A July 2002 draft building block of the REACH legislation on "restrictions on the production, marketing, and use of certain dangerous substances and preparations" provides an indication of the Accelerated Risk Management Procedure being proposed by the Commission. The draft repeats the duty of care and the need to ensure a high level of protection for health and the environment. According to the draft, a substance on its own, or in a preparation or article listed in an annex to the regulation cannot be placed on the market or used unless it complies with the conditions of that restriction. These restrictions can range from prohibiting the sale or production of the substance (or its use in articles), specifying particular approved uses or requirements for workplace or other controls. The decision to place a substance on the list would occur when it is deemed that there is unacceptable risk to health or the environment which must be addressed on the community level. The draft also places a ban on all substances which meet the criteria for persistent organic pollutants (no specific use authorizations would be allowed). It also incorporates all existing restrictions under the Limitations Directive.

According to this draft, the restrictions process begins with a Member State proposal resulting from the evaluation process. The legislation would specify criteria for risk assessments. Member States could base their decisions on risk assessments prepared under REACH or other relevant risk assessments. The central entity would review the Member State risk assessment within 30 days for its conformity to requirements. The Commission can also initiate this process if it considers that a substance poses an unacceptable risk. In this case, the central entity would appoint an expert to prepare a risk assessment. The central entity would then publish all risk assessments and the Member State and Commission suggested restrictions on its website and

invite all interested parties to provide comments on the risk assessment and proposed restrictions as well as to provide data on the socioeconomic impacts of the proposal.

Based on a Rapporteur's report, the central entity committee on risk assessment would then formulate an opinion on the suggested restrictions within nine months. Simultaneously, within nine months, the central entity committee on socioeconomic analysis would prepare a report and opinion on the potential impacts of the proposed restrictions. The opinions would be submitted to the Commission which would prepare its own proposed amendments to the regulation's annex within three months. Final decisions on the amendments would be conducted through a committee process of the Commission and Member States within three months.

The draft contains sanctions for non-compliance with the regulation's provisions and a "safeguard" clause whereby a Member State can take emergency temporary action to restrict a substance if it poses an immediate risk to health or the environment. The Member State would be responsible for notifying other Member States and the Commission would be required to adopt a community-wide decision within 90 days.

Distinctions would need to be made between restrictions under Accelerated Risk Management and the authorization process, below, which are not presently clear.

Authorization

The authorization process is a centerpiece of the REACH proposal and perhaps its most controversial part. It is also potentially the most resource-intensive part of the REACH process. The notion behind authorization is that substances of very high concern, on the basis of their intrinsic properties, should require a specific permission before they can be used for a particular purpose. This permission should only be given if the substance can be used safely. This is similar to the positive listing concept of pharmaceutical regulation. Authorization addresses limitations in the current system in which government must prove danger before preventing exposure and industry has an incentive not to provide risk data. This shifts the burden of proof and encourages industry to develop data to show the relative safety of substances or uses.

Under the White Paper proposal, all new and existing chemicals which are known or probable carcinogens, mutagens or reproductive toxicants and all substances with characteristics of persistent organic pollutants (POPs) will be progressively subject to the authorization procedure, unless the producer demonstrates that a use poses no risk to health or environment. This would include approximately 1,400 chemicals. Industry has generally accepted the inclusion of these chemicals as they are already included under existing legislation.

Much debate has occurred, however, on the inclusion of additional types of substances in the authorization procedure. The Directorate General for Environment, environmental organizations, and Scandinavian countries have argued that authorization also be applied to Persistent, Bioaccumulative and Toxic Substances (PBTs) as well as Very Persistent, Very Bioaccumulative Substances (vPvBs). It is likely that these substances, numbering about 100 according to research by the European Chemicals Bureau, will be included in the authorization process.

Two other categories of substances have also been suggested for the authorization procedure – endocrine disruptors and sensitizers. Since many endocrine disruptors are reproductive toxicants or carcinogens, in many cases this would automatically trigger authorization. However, until a more accepted definition of endocrine disruption has been developed, it is likely that they will be addressed on a case-by-case basis under REACH. For sensitizers, criteria for defining what constitutes a sensitizer would need to be developed before their inclusion in the authorization process.

Authorization would occur after registration and evaluation, though it was envisioned that substances could undergo authorization prior to registration and evaluation. The authorization process would be implemented in a progressive way (starting with substances of highest concern) and the White Paper proposes a two step decision-making procedure:

In step 1 - the substance or particular uses that would be subject to Authorization are identified and a precise date when all unauthorized uses are prohibited is established as well as types of uses that would be exempted from authorization.

In step 2 – particular uses of the substances will be authorized on the basis of a risk assessment submitted by the applicant to the authorities. The assessment would include the entire substance lifecycle. Applications for the use of several substances could be submitted simultaneously. Authorities could request further exposure data to determine the safety of a particular use and then could grant authorization if that use presents a negligible risk. Conditioned authorization could be allowed if justified by overall socioeconomic benefits or the lack of safer feasible alternatives. The process would allow case-by-case exemptions to authorization requirements to ensure flexibility. Authorizations for use would be granted by Member States or the Commission depending on the potential impact of the substances (i.e., is the impact on workers and a local environment or community-wide). Authorization of a chemical in products would generally be granted at the Community level. A committee procedure would be applied for all Community level decisions.

Based on the White Paper discussion and Council and Parliament conclusions, the Commission working group on Substances of Very High Concern (SVHC) discussed several critical aspects of the authorization process:

- Prioritization of SVHCs and phasing them into the authorization process. The workgroup determined that substances should be prioritized based on their intrinsic hazard, types of use, types and magnitude of potential exposures, and European or international commitments. The workgroup noted the need for expert judgment and prioritized POPs, PBTs and vPvBs as categories of highest concern for authorization. However, indications of high exposure potential might be enough reason to prioritize. In some cases, substances could be grouped for authorization to accelerate the process.

- Criteria for Substances of Very High Concern - CMRs, POPs, PBTs, and vPvBs. In its review of the Commission's White Paper, the European Council requested that criteria be developed for identifying high concern chemicals that might be subject to authorization.

The working group noted that criteria for PBTs and vPvBs exist that could be used and that because of their small numbers, decisions could be made about their addition to the authorization list on a case-by-case basis. Decisions on CMRs would be made based on existing lists but criteria would need to be developed for identifying new ones. In the absence of data, decisions on categorization could be made using quantitative structure activity relationships.

- The workgroup discussed inclusion of endocrine disrupting chemicals at length and determined that they should be addressed on a case-by-case basis and that tools for identification are needed.

- Inclusion of other SVHCs in the authorization process. The workgroup debated the idea of a "safety-net" to include substances that might not fit any of the categories of substances included under the authorization scheme but might be of concern due to their intrinsic hazards or use patterns. These include: immune system toxicants, sensitizers, and other extremely toxic substances. However, criteria to define these substances should be developed and it would be important to not overload the system.

The Commission's Working Group on Accelerated Risk Management and Authorization 2002 report provides indications of the challenges in implementing the authorization process. The Working Group noted that the process of authorization should apply only to substances of very high concern and that procedures should be quick and efficient, with strict timetables and an initially small number of substances. The group preferred that the central entity prepare the case for authorization, which only manufacturers and importers would apply for, and that group applications should be encouraged to avoid overloading the process. According to the report, the process should include an automatic exemption for research and development and the possibility of exemptions for low exposure, protection under other legislation or other reasons. Authorization decisions should consider specific uses, costs and benefits to stakeholders and options for reducing exposure with the goal being substitution and exposure reduction. The Commission would need to develop guidance for consistent socioeconomic analyses. The goal should be substitution and exposure reduction. Some working group members felt that authorization should be automatically given if the risk of a use does not pose an unacceptable risk, with the option for further review and consideration of alternatives. The group noted concerns about requiring risk assessment of alternatives since information may be lacking and this could slow the authorization process; such assessments could be considered during periodic reviews of authorizations.

Several debates about the implementation of the authorization procedure have arisen. One key question is whether the authorization requirement is a substitution requirement or will it have "loopholes" that would allow exemptions. For example, will the burden be on industry or government agencies to prepare socioeconomic analyses and risk assessments for authorizations? Will exposure controls be considered sufficient to allow authorization despite the availability of suitable alternatives? Will authorization apply injudiciously to everyday substances, such as alcohol? Another important question is the timing of authorization. The Commission has noted in response to these concerns that the goal is progressive implementation with realistic timeframes.

The July 30, 2002 draft regulation for the authorization procedure provides some insights as to the Commission's thinking. There is debate between DG Environment and Enterprise on whether authorization should be extended beyond CMRs and POPs. DG Environment argues that PBTs and vPvBs should be included as well as substances that may not fall under these categories but that due to their intrinsic characteristics and use patterns pose a serious long term risk. Criteria for defining substances of high concern would be included in an annex to the legislation. The draft exempts motor fuels, mineral oil products used in combustion plants, fuels sold in closed systems, substances exclusively produced for export outside of Europe, food additives (and substances used in animal feed), medicinal products, and cosmetics, though there is some debate over the exclusion of fuels or mineral oil products.

The draft notes that the production, placing on the market, or use of a substance subject to authorization is prohibited unless it is authorized and placed on the market according to authorization requirements (there is some debate between DG Environment and DG Enterprise as to whether authorization would apply to production). The central entity would maintain a list of substances subject to authorization including the uses for which they have been registered, including information on the manufacturer or importer and uses. Additional substances could be added to the list as they are assessed in the registration process.

Based on the authorization list, the central entity would propose a prioritization scheme for examination – starting with those substances with widely dispersive uses (including consumer use). Deadlines would then be set for authorization requests after which all unauthorized uses would be prohibited. Decisions on authorization would be included in an Annex to the legislation including uses and conditions under which authorizations can be granted and maximum time periods for authorizations.

According to the draft, the Commission can exempt certain uses or categories of uses if they present a negligible risk, specific EU legislation is in effect, or the substance is being used under controlled conditions, though these can be repealed pending additional information. The draft allows for two types of authorizations – community authorizations (granted by the EU), where the applicant places a substance on the market; and Member State authorization (granted by the Member States) where the substance is not used in products that cross Member State borders. Depending on the type of authorization sought, application by the manufacturer, importer, or downstream user of the substance would be made to either the Community or Member State authorities. The application would include: contact information, information on the use of the substance, an assessment of risks to health and the environment, detailed information about production procedures, use and disposal as well as exposures (including potentially a mass balance), an assessment of potential accidents, a socioeconomic analysis (including implications if authorization were refused) and information on health and environmental risks of alternative products.

Authorizations can be justified by the overall socioeconomic benefits from use of the substance. An authorization which covers the use of a substance in an article would also cover the production and placing on the market of that article. There is some debate between DG Enterprise and DG Environment as to whether authorizations are time limited and whether

availability of viable alternatives is sufficient to deny an authorization. Manufacturers, importers or downstream users placing a substance on the market or using a substance that has already been authorized can inform the Commission of their intentions to fulfill the conditions of authorization. They will not need to apply for authorization unless notified by the Commission within 30 days.

In the case of Community authorizations, the central entity would issue an opinion based on the application within 12 months of receipt. Once its opinion is developed (considering risk, socioeconomic factors), the applicant would have the option to appeal within 7 days of notice of the opinion. Within 3 months of receiving an opinion from the central entity, the Commission would prepare its decision based on a committee procedure. Member State authorizations would follow a similar process, though with relevant appointed Member State authorities. The Member State would set out its opinion and make copies available to the central entity and other Member States; it would also be published on the central entity's website.

Distribution of Responsibilities between the Commission and Member States

Current European chemicals regulations have generally been implemented at the Member State level. This has led to different approaches and levels of implementation and enforcement. An important goal of REACH is the establishment of a single coordinated, coherent approach to chemicals assessment and management. The European Commission Environment Directorate is interested in as strong a centralized role in the REACH program as possible to ensure consistency and harmonization. This means that countries with lower levels of environmental enforcement (such as Greece and Portugal) raise standards, while ensuring that countries with more aggressive chemicals policies (such as Sweden and Denmark) cannot disrupt the internal market with stricter policies. This is particularly important because the 2004 accession will bring ten new countries into the European Union, some of which with very limited chemicals management resources. This centralization must be balanced with Member State powers in the European system and the fact that technical expertise and resources generally come from Member State authorities.

According to the White Paper on Chemicals Strategy, Member State authorities would broadly retain their current responsibilities under the REACH proposal. Evaluation and authorization would likely be implemented at the Member State level with direction from the Commission (chemical registration dossiers would be allocated to Member States on a proportionate basis). A committee procedure would be put in place to address circumstances where agreement cannot be reached among Member State authorities. The draft regulations will state clearly the particular role of Member State authorities and a central entity in the REACH process. While the decentralization of review would continue, the development of a new centralized data collection and decision-making structure is critical to the Commission's goal of a strong integrated policy and also important to other countries, such as the United States, which view disjointed European chemicals requirements as problematic.

Central Entity

Given the broad scope of the REACH initiative, a key consideration is how the program will be coordinated. In the White Paper on Chemicals Strategy, the European Commission proposes the establishment of a "central entity" for administration of the REACH system. This would mark the first centralized approach to chemicals management in the European Union and would follow the approach taken in the case of pharmaceuticals with the establishment of the European Agency for the Evaluation of Medicinal Products and the European Food Standards Agency. The establishment of a new entity presents a large challenge for the Commission.

The Commission's proposal in the White Paper is to extensively expand the European Chemicals Bureau (now an office with a staff of 40), a part of the European Union's Joint Research Centres, currently charged with developing toxicological testing and risk assessment methodologies as well as administering the evaluation program for existing chemicals under the Existing Substances Directive. The White Paper proposes that the central entity would carry out the following tasks: (1) serve as a receiving body for the registration dossier and forward copies of the dossiers to Member State authorities; (2) establish and maintain a comprehensive central database on all registered chemicals; (3) ensure data quality and perform spot-checks and screening of registered substances for properties of concern; (4) support Member States in the evaluation of substances; and (5) establish an efficient and secure data exchange network. The entity would also provide public access to non-confidential data in the dossiers, would coordinate classification and labeling, would facilitate circulation of information through supply chains, and would develop an operational framework for the evaluation, authorization, and accelerated risk management processes to ensure a coherent approach.

To understand the resource needs and feasibility of establishing a central entity, the Commission commissioned a report prepared by Deloitte and Touche and published in June 2002. The report reviewed two potential structures for the new central entity: an enlargement of the European Chemicals Bureau (ECB), which is part of the Commission; or an independent agency set up under its own regulation with its own legal identity. There are some differences between these. An entity under the Commission would be more advisory and technical, directed by input from Member States. An independent agency could have financial independence (it could seek fees from industry), the ability to make quicker decisions, and greater ability to issue risk management recommendations. Further, a new agency would require legislation to begin its duties whereas the ECB could be expanded almost immediately.

The Deloitte and Touche report reviews several scenarios for registration (inclusion of intermediates, possibility of pre-registration), evaluation, authorization, and accelerated risk management based on the Commission's Business Impact Assessment (an economic impact analysis of the proposed REACH process – see next section) to understand the potential costs and workload of a new agency. It estimates total staffing for the new agency ranging from 220 to 420 individuals. Yearly staff costs could range from 20 to 40 million euros for the agency (with an approximately 80 million additional euros over ten years for overhead), for a total of about 340 million euros over the next 10 years (excluding costs to Member States for their work

on evaluation and authorization). Depending on the inclusion of intermediates and manual checks of dossiers, this number could increase significantly. These review times and figures were gathered through interviews with Member State competent authorities, industry, and the Commission. However, they do not reflect the potential for institutional learning through review of dossiers, which could reduce review times and increase knowledge on chemicals as well as other possible models for rapid chemicals assessment such as that undertaken for new chemicals by the U.S. EPA under its Toxics Substances Control Act.

Envisioned in the White Paper is the possibility of a fee-based system for registration, evaluation, and authorization to offset government costs. This system would apply to both domestically produced and used substances as well as imported ones. For a scenario of mid-range number of registrations, including intermediates (25,000 registrations and 55,000 intermediates), the cost per substance for registration is estimated in the Deloitte and Touche report to be about 700 euros. This would include pre-registration, registration, classification and labeling. The evaluation and accelerated risk management process (for about 34,000 substances) would cost approximately 3,200 euros per substance, independent of the tonnage per year used (given that evaluation would be similar regardless of production). If 1,470 substances go through the authorization process in a 10 year period, it is estimated that the cost will be approximately 74,000 euros per substance (or 148,000 if Member State authorities receive the same fee). If less registrations are submitted, the fee for registration and evaluation could increase to up to 26,600 euros per substance, while authorization could increase up to 180,000 Euro per substance. These fees would cover about 80 percent of the central entity's costs, the other 20 percent of which are general administrative and research staff costs would need to come from the Commission's budget.

The report makes several conclusions. Resources and costs for the central entity will depend greatly on the total quantity of substances, the timing of substances' arrival, and the responsibilities of the entity – though there would be little difference in costs between an independent agency and expansion of the Current European Chemicals Bureau. To make the review system as efficient as possible, leaving out processes such as manual checks of registration dossiers, would reduce costs significantly. Further, distributing the amount of authorizations over a longer period (50 a year versus 147) would reduce costs and resources. Finally, the report notes that start up of the new entity and staffing with sufficient qualified, experienced scientists will be a challenge. One way to address this is to place Member State experts on detail to the entity until the system is fully operational.

Building on the Deloitte and Touche report, a June 2002, European Commission internal draft regulation outlines the consensus being reached on a central entity. It highlights the careful balance in Europe between centralized authority and Member State powers. The draft establishes a new independent agency called either the European Agency for the Safety of Chemicals or the European Chemicals Agency, as well as a set of new committees and administrative procedures. This independent agency will be responsible for "coordinating the scientific and technical resources put at its disposal by the competent authorities of the Member States for the registration, evaluation, authorization and restriction of substances, including in preparations and/or articles." The agency is modeled after the European Agency for the Evaluation of Medicinal Products and its relationship to Member State competent authorities.

The draft establishes the relationship between this agency, other agencies (for example on food safety and medicinal products), and the Commission.

According to the draft regulation, the Agency would be composed of several committees, a secretariat, and management and advisory boards. The regulation proposes a centralized administrative process that is also highly Member State driven. It expands centralized coordination of chemicals management but maintains the Member State-coordinated decision-making processes of earlier chemicals policy. These include:

- The Committee for Risk Assessment. Composed of one expert from each Member State, it would be responsible for preparing the Agency's opinion on human health or environmental risks.

- The Committee for Socioeconomic Analysis. Composed of one expert from each Member State appointed for renewable three-year terms, it would be responsible for preparing the Agency's opinion relating to the socioeconomic analysis of the effect of possible legislative action on substances. This is particularly important in the authorization stage.

- The Forum for Exchange of Information on Enforcement. Composed of one expert in chemicals management and enforcement from each Member State appointed for three year renewable terms, this group would coordinate a network of authorities responsible for enforcement of the REACH system.

- A Management Board. Consisting of 14 members with broad geographic distribution and with at least one member of industry, labor, consumer groups and environmental groups, the board would be responsible for the agency's budget and operations.

- An Advisory Board. Consisting of one expert from each Member State authority, this board would provide non-binding technical and scientific advice to the agency.

- A Secretariat. The Secretariat would serve as the day-to-day operational body of the Agency in charge of procedures for pre-registration, registration, and mutual recognition by Member States of evaluation as well as preparation of guidance, data maintenance and information provision. It would coordinate databases on all registered substances as well as the classification and labeling inventories, and ensure all non-confidential data are publicly available. It would also provide operational guidance for companies and others on REACH, as well as support to Member State authorities and technical and scientific support to improve coordination between the Commission, Member States and international organizations. Finally, it would work with the Forum on information exchange, training, and stakeholder relations.

Committee and Forum members would be supported by Member State resources and would be responsible for coordinating efforts between the Member State, the Agency, and the Commission. These are technical and not political positions. Each of the two committees, when issuing an opinion is to appoint a Rapporteur, who are to be appointed in proportion to the

Member State's population, though exceptions are possible. According to the regulation, the Committees and Forum could establish working groups consisting of governmental and non-governmental stakeholders.

The draft regulation notes that Agency revenues should consist of funding from the European Community as well as industry fees though it does not provide information on the extent of fees or how they will be collected.

Alternatives to Animal Testing/Validation of Alternative Methods

The issue of alternatives to animal testing has become critical in the development of the EU REACH proposal. The REACH program will likely entail a significant increase in testing requirements. Estimates of the increased number of animal tests range from 77,000 to 12 million. This projected increase has engendered opposition to REACH by some animal rights groups, particularly in the United Kingdom. This powerful constituency is an important factor in development of the new policy, raising questions about a number of policy elements affecting animal tests. The chemical industry has also been able to raise concerns about animal testing in their critiques of the REACH program.

The UK Medical Research Council's Institute for Environment and Health (IEH) has produced several reports on the REACH program for the UK government. Their initial report estimated that the White Paper program would require 12 million animal tests. IEH produced a follow-up report with revised scenarios, apparently under pressure from environmental groups and some government officials who stated that their estimates were grossly overestimated.
In its analysis of the IEH study Friends of the Earth, an environmental advocacy group, noted that estimates do not account for several other factors that will further reduce the amount of animal testing. They provide a lower estimate of 77,000 tests per year, based on the assumption that 25 percent of chemicals will be withdrawn from the market under the new regulations, and that the number of tests will be reduced by 50 percent due to grouping of similar chemicals. They consider these assumptions to be "conservative." They also state that the IEH assumptions about the testing requirements are possibly too high.

The large variation of these numbers reflect the enormous uncertainty involved in understanding the amount of animal testing that will occur as a result of REACH. There are several variables which remain unknown quantities, making the process of estimation vulnerable to varying interpretations.

Several Member State governments have also raised animal testing as a key concern in the development of the REACH process. For example, the UK House of Lords released a report in March 2002 urging the UK government to demand that the EU legislation minimize animal testing. Denmark, Sweden, the Netherlands, Austria, and Germany have also raised concerns about animal testing requirements under REACH. It is very clear that the new chemicals policy will have to include mechanisms to substantially reduce the number of animal tests.

The EU White Paper lists minimization of animal testing as a goal, but does not include any specifics on mechanisms for reducing animal tests through data sharing or alternatives to animal

testing. The European Commission has seen fit, due to the "very large amount of correspondence" on animal testing, to provide a short response to these concerns that reiterates the White Paper's attitude on animal testing. This states that:

- "For substances produced/imported in quantities between 1 and 10 tons, testing should generally be limited to in vitro methods;
- Existing information on the toxicity and ecotoxicity of substances, including epidemiological studies, will be taken into account;
- The general testing requirements will be modified to incorporate exposure-driven testing where appropriate;
- Tailor-made testing programmes for substances will be developed under the control of authorities for testing of higher production volume chemicals;
- The development of further alternative testing methods, using fewer or no animals, will be fostered;
- Existing substances will be grouped to minimize testing, where appropriate."

The European Centre for the Validation of Alternative Methods (ECVAM) was established in 1991 by the Commission to assess the state of the technology on alternatives to animal testing, with the goal of making alternative tests more useful and broadly available. ECVAM has established a set of priorities. The short-term priority is to identify alternative methods already adequately validated or most promising. In the mid-term, the priority is to quickly pre-validate and then fully validate the most promising methods identified at the initial stage, and develop new methods for hazard assessment. The long-term priority is to further evaluate validated alternatives for use in risk assessment.

ECVAM circulated a draft report summing up their progress in the first stage, dated May 2002. This report makes it clear that many endpoints lack good alternatives, and makes recommendations for the chemicals policy. The basic recommendation is to review all of the information available on alternatives to assess their relevance and reliability as well as possibilities for refining current animal-based methods and reducing their number. This review should then be used to prioritize work on methods, allowing resources to be put into developing and validating the most promising alternatives. Methods for the endpoints with the worst prospects for alternatives should be refined and reduced (decrease the number of animals used) until alternatives can be developed.

In addition to the work underway by ECVAM, the European Chemicals Bureau is working to validate quantitative structure activity relationships (QSAR) as a way to rapidly screen chemicals for hazards. The QSAR approach has been strongly supported by the Danish and Dutch governments, though the Commission has been less supportive to date of using QSARs and other structural information in place of actual test data.

There may be two ways to reduce the amount of animal tests required. Animal tests can be replaced with non-animal tests, or the amount of data already available may prove to be larger than expected.

The EU White Paper states that testing of chemicals produced or imported in quantities of 1-10 tons should be limited to in vitro testing. For at least some of the basic tests envisioned in this

tonnage range – mainly physiochemical tests – in-vitro tests already exist. However, validated in-vitro tests do not exist for all of the endpoints envisioned. There seem to be two major problems with the technology – lack of investment in research of alternatives, and slow speed of validation and cross-national acceptance of alternatives. The OECD is working to harmonize national chemical testing requirements, including validation of alternatives, but progress is very slow.

The second key problem with determining the amount of additional animal testing is that neither governments nor industry know exactly how much data already exists on chemical toxicity. In some cases, toxicity data may already exist and neither animal tests nor alternative methods will be necessary. The REACH legislation will likely include mechanisms to encourage and require companies to reveal as much data as possible. The legislation could ensure that companies cannot benefit from using data produced by other companies. One way to address this problem is to encourage submission of all data that companies have and to establish means to avoid duplicative testing in different countries, either by encouraging consortia or setting up programs by which companies can use previously developed data by paying a premium to the company that conducted the original testing (an approach favored by Germany).

Intermediates

How intermediates (and polymers) should be included in the REACH process has been an area of contention since the White Paper was released. Chemical intermediates are defined by the European Commission as "a chemical substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another chemical substance(s)." Some intermediates arguably do not result in human or environmental exposure and inclusion of all intermediates could seriously overload an already ambitious system. It has been estimated that as many as 40,000-60,000 intermediates could fall under the REACH system. However, in Germany where there is some experience with tracking intermediates, authorities have estimated that approximately 3,000-4,000 have been produced and could fall under the REACH system.

Industry groups and some Member States, such as the UK have offered proposals for addressing the issue of intermediates in the REACH proposal. In January 2003, the European Joint Research Centre (JRC) Directorate issued the report of an Expert Group on Chemical Intermediates established to help inform the REACH debate. The working group defined four types of intermediates:

Type 1: Non-isolated (not leaving a closed production system)
Type 2: Isolated intermediates stored and used on-site (which can be operated by one or more legal entities)
Type 3: Isolated intermediates transported between or supplied to a limited number of sites under strict contractual control (including contract manufacturers)
Type 4: Isolated intermediates supplied other than with strict contractual controls between the original supplier and recipient

Under the JRC proposal, type 1 intermediates would not be included under REACH and type 4 intermediates would be treated as normal substances subject to REACH as they are being placed

on the market. Based on industry data, the JRC workgroup estimates that about 29,000 intermediated might fall under type 2, 10,553 under type 3, and 5,812 under type 4. They estimated that about 1,700 intermediates of type 3 would be produced over 1000 tons per year. However they note that these estimates are highly uncertain.

The JRC expert group determined that there was a reasonable rationale to distinguish between type 2 and type 3 intermediates on the grounds that there would be less opportunities for non-occupational exposure if the substance was handled on site (occupational exposure is already addressed through occupational health directives). Thus, the group determined that type 2 intermediates should be registered under REACH with a minimal dataset comprising identity and volume information. Duty of Care provisions under the REACH program would apply and national authorities would be allowed to request additional information on a case-by-case basis. Some participants noted that additional data (beyond the minimal data proposed) would be useful on type 2 intermediates, in particular on physio-chemical properties and hazards, as well as potential exposures, and classification and labeling. For type 3 intermediates, the group agreed that tiered testing requirements should be developed, based on the transported volume of the substance and control conditions applied. Low-volume type 3 intermediates would be treated like type 2 intermediates; intermediates transported in 10-1,000 tons would require information on chemical properties and for more than 1,000 tons some base set testing of would be required. These requirements could be waived on a case-by-case basis provided the registrant demonstrates that the use is strictly controlled. The group noted the need for flexibility in addressing intermediates as well as using information on toxicity from surrogates such as quantitative structure activity relationships.

While the debate on intermediates continues, evidence indicates that the Commissioners of the Environment and Enterprise Directorates have accepted the JRC group proposal as reasonable for the REACH proposal and are likely to exclude non-isolated intermediates from the process, while leaving open the possibility of more aggressive regulation of type 2 and type 3 intermediates.

Access to Information

Increased transparency – both in public access to information as well as a clearer regulatory system – is an important goal of the REACH program as outlined in the White Paper on Chemicals. The Commission notes that "the public has a right to access to information about the chemicals to which they are exposed. This will enable them to make informed choices and to avoid products containing harmful chemicals, so creating pressure on industry to develop safer substitutes." Yet, according to the Commission, this public information must be balanced with adequate protections for confidential industry data.

The White Paper and draft legislation include a duty to inform – that industry should develop and provide information to authorities and downstream users about chemical risks. It places the responsibility on industry to provide information on chemical risks and instructions for safe use of chemicals. But the Commission notes that there is currently no tracking system for the public to determine whether there are regulatory measures in place or in progress for individual

chemicals as well as information on chemical toxicity, classification, authorized uses, and other information.

The White Paper proposes the establishment of a central REACH database to collect submitted information, with easy-to-read substance summaries. Substance labels could provide information that would lead consumers to additional information. This database would be administered by the central entity and accessible via the Internet as a single source of chemical information. Details of the extent of information made available under the program are unclear – for example, information on chemicals in products – and are likely to be areas of strong debate. Information such as chemical waste and emissions accounting have not been discussed in the context of REACH.

An important industry concern for REACH is disclosure of confidential business information – to either consumers or competitors. While the White Paper only briefly discusses protection of confidential information, it does note the need for property rights for data produced under REACH. It states that those who generate data under the system should be encouraged to share them, and those who use the data should be obliged to pay a fair and equitable contribution to the generator of the data.

The Commission's Working Group on Information through the Supply Chain struggled with the balance between right-to-know and protection of confidentiality. Some members of the workgroup were concerned about disclosure to manufacturers' markets of the full composition of formulations or articles, the exact annual production of a single manufacturer or importer, and in some cases the exact chemical formula. Such disclosure needs to be considered in the context of potential impacts on European competitiveness and innovation. Fair competition needs to be balanced with provision of information, the group concluded. Other group members noted that while confidential information is important, REACH provided the opportunity to provide users of chemicals and the public new information on chemicals and their risks that would result in greater accountability on manufacturers to develop safer products.

The group discussed the need for different levels of confidential information: non-confidential; confidential information shared between manufacturers on a bilateral or multi-lateral basis; and confidential information shared between Member States and the central entity. In order to facilitate consortia and supply chain information sharing, there needs to be some level of protection for firms, so that they are not put at a competitive disadvantage as well as to ensure that costs for data collection are shared. In the case of downstream users, who may not want to disclose product composition to suppliers, some opportunity for them to provide data for registration or authorization separately from manufacturers would be important.

The group agreed that clear definitions of what is confidential information (and what information is necessary to support confidentiality claims) as well as binding regulations are needed to ensure consistent and centrally harmonized, though flexible, application of confidentiality requirements. Further there must be means for sharing information among authorities and with health care providers in the event of emergencies and with health and safety professionals for workplace or consumer protection.

Workability of the REACH proposal

The REACH proposal presents an enormous change in chemicals regulation in Europe. It is a response to the limitations of the current system to adequately manage chemical risks. Thus, an important concern for all stakeholders is a workable system that actually changes chemicals management practices. The implementation of REACH must broadly address the limitations of the current system in terms of resources, timing, data gaps, and enforcement. Of particular concern is how the system will be implemented and the division of labors between the Commission, central entity, and Member States. The Commission understands the challenges that lie ahead and wants a successful system that starts off slow, addressing priority substances, while making any mid-course corrections before more substances are brought under the system. This will help demonstrate that the worst fears of industry are not realized and help to address potential problems, particularly for small and medium-sized companies. An overloaded and unworkable system would damage the Commission's credibility and ability to effect change.

As described in previous sections, the Commission has taken several steps to improve the workability of the system:

- Exempting certain substances from the registration or authorization processes. By exempting many polymers and intermediates, as well as substances for research and development and some others, the Commission expects to substantially reduce the number of registrations and authorizations.
- Flexibility in data and other requirements. While there will be minimum information requirements under the new policy, the Commission expects some decision-making on testing to be done on a case-by case basis. The goal is the best possible information to make chemicals management decisions. For low volume production chemicals, only in-vitro testing will be required. Data produced outside the EU, including under programs such as the U.S. Environmental Protection Agency's High Production Volume Challenge program should be used. Similarly, the Commission expects to allow grouping of substances of similar structure/use for the registration process to reduce data requirements. Electronic data submission possibilities would be important to improve data quality and expediency of submissions.
- Allowing consortia for registration and authorization. By allowing companies to form consortia among producers and downstream users, the Commission believes it will reduce the workload on companies and improve supply chain information sharing. However, the ability to form consortia must avoid the "free rider" syndrome where some companies do all the work on testing but others use the data without having to pay for it.
- Increasing testing thresholds for new chemicals. For new chemicals, the threshold for testing has been increased from 10kg to 1 ton, which the Commission hopes will stimulate innovation in new chemicals.
- Prioritizing registration and authorization processes. To address the large workload envisioned under REACH, the Commission has proposed that the registration and authorization processes give highest priority to chemicals of highest volume and highest concern. This will allow some testing of the functioning of the system as well as modifications to improve its efficiency. Prioritization likely will need to be carried out at

the Community level to ensure coordination across Member States. Criteria for prioritization will also need to be developed.

An important concern regarding workability is the relationship between the Commission and Member States in the process. A November, 2002 meeting of Commission and Member State chemicals authorities outlined some specific concerns regarding implementation of REACH. The Member State authorities noted several important areas of concern for success of the REACH legislation: capacity and workload; enforcement; and credibility.

The primary concern for authorities is how they will deal with many more substance dossiers than they currently handle under new substance notification requirements and the Existing Substances Directive without additional resources. However, an analysis by the Dutch government indicates that dossiers for priority substances in that country could be handled with current staffing, with some adaptation in working processes. Operational guidance would be important for registration, as well as substance identity checks and other measures to avoid duplication of work. At the evaluation stage there needs to be an efficient distribution of the burden of reviewing dossiers and flexible priority setting.

The Member State authorities outlined the need for collecting fees to ensure sufficient resources to implement the requirements. The level of resources is key to the level of credibility of the process, as is the level of workload. Prioritization is key, particularly for authorization. Resources must include training and education in new aspects of the REACH process, in particular the socioeconomic analysis which is not currently conducted and could slow the regulatory process.

Similarly, given the under-resourced and poor enforcement of existing regulations and the lack of enforcement harmonization across authorities, they note the need for improved enforcement at the Community and Member State levels. The success of REACH will depend on strong enforcement – both quality and level of expertise. Enforcement would include checking compliance of dossiers as well as whether industry properly identified and implemented risk reduction measures. It is also necessary to ensure that authorizations are being sought and mandatory restrictions are being implemented.

The authorities noted that high quality data is critical for success of the program (and the workload of authorities). Thus some step in the system to verify data quality – for example random spot checks - would be useful. If high quality data are available, some Commission officials expect that risk reduction will be achieved through the registration and evaluation procedures with minimum agency efforts. They note that given experience with new substance notifications, if industry generates good data and risk estimates which indicate concern, it will self-regulate the risk. Thus, an important part of the REACH proposal should be to ensure that good data are developed to promote voluntary action by firms. The implementing legislation should ensure a framework that enables and encourages industry to take responsibility as a precursor to regulatory action.

Thus, three key issues in the workability of REACH will be establishing a clear, yet flexible division of labors, ensuring that adequate resources and training are available to implement the system at the Member State Level, and establishing a consistent system of enforcement.

The May 7, 2003 Draft European Commission REACH legislation

On May 7, 2003 the European Commission reached a milestone in its development of the REACH process: the publication of draft chemicals legislation. The legislation, which was leaked a month earlier to most stakeholders, reflected the political compromises that had to be made to institute the type of fundamental change in chemicals regulation embodied in the White Paper on Chemicals. The publication of the draft legislation followed debate and compromise between DG Environment and DG Enterprise, the legislation's "sponsors" and a month long consultation between European Commission directorate generals. Publication of the legislation was widely covered in the trade press and concern about its contents emerged almost immediately. At the time of publication of the draft, the European Commission opened the legislation up for a two-month public consultation process, allowing stakeholders to submit comments on the proposal's workability and content. More than 6,000 comments were submitted through an Internet-based process, representing a wide range of opinions and positions. While many of the comments on the draft legislation were similar, it would be impossible to analyze the scope of them in this paper – the comments are available on the DG Environment Website.

In the months since the publication of the draft legislation, the European Commission has dedicated extensive staff resources to reviewing the comments and proposals for changes in the legislation and stakeholder groups (as well as European governments and others such as the United States) have lobbied extensively to ensure that their concerns are reflected in the final legislative proposal which is likely to be very similar to the final European legislation (after debate by the European Parliament and Council of Ministers). The European Commission expects to release that final legislation at the end of October 2003.

The May 7, 2003 legislation maintains the general goals and structure of the 2001 White Paper on Chemicals, though reflects the dialogue and outreach of the European Commission with experts and stakeholders. While some commentators have argued that it was a 1,200 page piece of legislation, the main new parts of the legislation amount to less than 200 pages with technical annexes (such as on risk assessment) filling the rest of the pages. The draft legislation, however, is necessarily very complicated, difficult to follow in places and perhaps overly vague in some parts and detailed in others. A review of key components of the draft legislation is provided below.

The draft legislation includes a long preamble and legislative history section. It begins by instituting what is termed a "duty of care" on all manufacturers, importers and users of chemicals to ensure that substances are used safely at all stages in their lifecycle. The duty of care is similar to a general duty on manufacturers, importers and users to develop and provide information and to take all reasonable steps to prevent impacts from their use of chemicals. It includes a responsibility to pass information on chemical use, exposure, and toxicity down supply chains. This general duty is implemented through the preparation of what are terms in the

draft "chemical safety assessments." All manufacturers, importers and users of chemicals, not matter what the amount of use, are required to prepare a chemical safety assessment which identifies potential hazards, exposures, and risk management measures. This assessment should not be burdensome according to the legislation and be based only on available data.

Other sections of importance in the May 2003, draft include:

- Registration. Similar to earlier drafts, the registration process is a notification process whereby all producers and importers of substances produced over 1 metric ton per year have to register their chemicals within a phase in period – 3, 6, and 11 years depending on production level and whether the substance is of very high concern. New chemicals brought to market before the legislation would be considered automatically registered and new chemicals after the regulation comes into force would have to register immediately. The registration process does not include chemicals for use in biocides, cosmetics, pharmaceuticals or medical products (unless used for products outside these uses). Also, exemptions are established for research and development though some requirements are in place. Further, there are reduced requirements for polymers and for certain non-isolated intermediates (isolated intermediates are completely exempt from REACH). Registration dossiers would be sent to a central European chemicals agency for validating data but would be reviewed by authorities in the Member State where the registrant or importer is based.

  The first step in the registration process is a pre-registration requirement so that authorities can understand what chemicals will be submitted to authorities in the future and to facilitate exchange of data. A registration includes base information on the substance – its identity, information on manufacture and uses, proposed classification/labeling (though the classification requirements of the Dangerous Substances Directive would remain in effect), guidance on safe use, and the chemical safety assessment. Chemical manufacturers and importers are required to identify in their registration the uses of at least 90% of the volume manufactured or imported (either by the company itself or intended uses). The registration process includes testing requirements, tiered by production volume. From 1-10 tons there are no in-vivo tests required. However, the proposal notes the flexibility and ability to submit alternatives to required testing if deemed adequate. Registrants are required to submit additional testing as production volume increases or if new data on risks are available.

  The draft legislation encourages manufacturers and importers of the same substance to submit joint registrations with each registrant required to submit some information particular to their company's use of the chemical. The legislation requires companies registering new chemicals to consult authorities prior to testing to avoid duplicative testing. The legislation establishes a Substance Information Exchange Forum for registrants of the same substance to inquire about available tests. The draft requires such data sharing and compensation to the manufacturer who undertook a particular test. Consortia between companies for testing are encouraged.

- Evaluation. The evaluation process has changed substantially from the White Paper. In the May 7th draft, evaluation is seen as having two roles: risk screening and avoidance of duplicative testing. There are two types of evaluation envisioned: standard (designed to minimize duplicative testing for high production volume substances); and priority (a review of registrations to identify additional information needs. Standard Evaluation applies any time a proposal for testing is received with a registration and it is completed by the authority in the Member State where the registration has been received or for some substances by Member States, proportional to their population. Priority Evaluation occurs for high production/high concern chemicals as well as other randomly selected substances and focuses on examination of the registration information (whether they have been fulfilled) or whether there are information gaps that need to be fulfilled. Both types of evaluation are time limited and in the case of Priority Evaluation, Member States are required to consult other Member States before requiring testing.

- Authorization. Authorization is a use restrictions process and applies to chemicals of very high concerned, defined as: Carcinogens, Mutagens and Reproductive Toxicants of Classes 1&2; persistent and bioaccumulative toxics; very Persistent very Bioaccumulative substances (regardless of toxicity); and other high concern substances such as endocrine disruptors and sensitizers once criteria for their inclusion are established.

  Manufacturers and importers of substances of high concerned are required to request authorization for continued use of such substances at least 18 months before their sunset date (to be determined by the European Commission). Authorizations are of two types: Community (for substances used in products that cross Member State borders) and Member State (when that substance is used only in a Member State). Companies requesting authorization are required to provide information on the use of the substance and alternatives and impacts of restricting use. Authorizations must be granted if the risk to health or the environment is adequately controlled (including exempting consideration of exposure from permitted activities in the process). The authorization should also consider alternatives to the activity, feasibility of alternatives and the socioeconomic impacts of restricting the activity. Authorizations can be subjected to time limitations (so that alternatives can be developed) and conditions. There authorization process itself is time limited.

- Restrictions process. The restrictions process is viewed as a safety-net for substances that are not covered under authorization or cannot be adequately controlled through that process. Persistent Organic Pollutants as defined by the Stockholm Convention are automatically banned under the restrictions procedure. Based on an evaluation or other concern, a Member State authority makes a proposal for Community-wide restrictions to the chemicals agency arguing why such restrictions are necessary. In a time limited process, the agency's committees prepare risk and socioeconomic assessments of the substance of concern and issue a recommendation to the European Commission which makes a final decision of restrictions which can be in the form of a ban, use restriction, etc.

- Requirements for downstream users and product manufacturers. The draft legislation places greatest responsibility on manufacturers and importers of chemicals, those with greatest control over data and production decisions. There is an incentive in the legislation for downstream users to place as much responsibility in the hands of manufacturers. For example, downstream users, while covered by the chemical safety report requirements, have only minimal registration requirements (data on site) if their use is covered in a manufacturers or importers registration. Similarly for authorization, if a particular use of a chemical in included in an authorization application, the downstream user has no further requirements other than to indicate to authorities that they are using the chemical and taking adequate precautions. For chemicals in articles (products) that might be released during normal use, there are similarly very limited registration and authorization requirements unless that substance has not been registered (e.g. it is only produced in China and then placed directly into a product).

- Establishment of a new chemicals agency. The legislation establishes a new chemicals agency for the European Union funded by fees on chemicals. The agency, consisting of an administrative staff and then committees and boards with stakeholders and Member State experts would have the following duties: establishing databases on chemicals under registration and authorization, including decisions and actual test data; conducting a completeness check of registration dossiers; completing risk assessments and socioeconomic analyses for Community authorizations and restrictions; maintaining a forum for Member State authorities for information on enforcement. Despite creation of the new agency, much of the technical expertise for implementation of the legislation will remain at the Member State level.

- Information requirements. The draft allows information in registration dossiers to be kept confidential when proper justification is provided by the registrant. Member State authorities would be responsible for determining the validity of confidentiality requests. The legislation outlines types of information – toxicological information, physicochemical data, etc. – that cannot be considered confidential. All non-confidential information is considered public and available over the Internet.

The draft also includes provisions for naming Member State authorities, vague enforcement provisions, and safe guard clauses for Member States to undertake temporary measures to protect health and the environment.

8. ECONOMIC AND INNOVATION IMPACTS OF THE PROPOSED REACH PROGRAM

The careful planning and lengthy discussions on the proposed new chemicals policy have paid off for the European Commission directors. Having vetted the proposal over several years with many potential stakeholders the proponents of the new chemicals policy proposal submitted the White Paper with a fairly clear idea of how it would be received and what resistance it might engender. What is clear is that REACH will have far-reaching impacts on chemicals use in Europe and likely internationally. Given the magnitude of the REACH proposal an important area of controversy in the REACH discussions has been the economic impacts and benefits of the proposal. Given the difficulties in projecting costs – and particularly benefits – of such a proposal, debates over economic impacts, innovation, and benefits are to be expected. Some of these debates include technical ones, such as what are appropriate multipliers in cost analyses for indirect effects and how can innovation benefits of regulations be calculated. The European Commission and European governments (particularly environmental authorities) have only limited experience with analyses and have been struggling to make a forceful case for new policies.

The response from the European industrial sector to the economic impacts of REACH has been critical. The British chemicals industry was among the first to raise concerns. Recognizing the potentially broad impacts that the chemicals policy might have on British authorities and industry, the UK Department of the Environment, Transport and the Regions contracted a private consultancy, Risk and Policy Analysts, Ltd. (RPA) to conduct a regulatory impacts study, which was released in May of 2001.

Although RPA found broad differences in interpretations of the White Paper, they concluded that the new policies could impact the United Kingdom with both substantial costs and benefits. The costs resulted from increased registration of chemicals, increased testing, and the risk assessments and risk reduction efforts associated with authorization. The benefits would arise from the provision of additional information which might lead to restrictions on use and environmental release, and, therefore, on human exposure. Specifically, the RPA report found that the benefits would include reduced costs of occupational injuries that could range from 64-129 million pounds over a ten year period, reduced costs of occupational asthma and dermatitis totaling 580 million to 1.2 billion pounds over that same period, and unknown benefits arising from reduced costs associated with occupational cancer, non-occupational exposure and environmental damage.

The study found that the costs to the British industry and authorities over a twenty year period could range up to 620 million pounds, a somewhat smaller figure than anticipated because many of the costs were assumed to be “one time” costs and it was assumed that 50 percent of the chemicals notified under the new policy would be marketed under one ton per year meaning that they would not be candidates for the new registration, testing and authorization initiatives. Because the burden of implementing the policy would be born mostly by the industries rather than government authorities, it was expected that the private sector would shoulder nearly 99 percent of the costs. This might be particularly burdensome for small- and medium-sized

enterprises who were expected to pick up nearly 44 million pounds of the costs, because a large proportion of specialty chemicals are manufactured by these smaller firms.

The RPA noted that there remained specific concerns about the ability of manufacturers to meet the full testing, risk assessment and risk management requirements within the projected time frame and about the sharing of confidential business information among competing firms. Further, the RPA raised concerns about the ability of government authorities to enforce the policy, and particularly, about how the government could monitor chemical importers and "down stream" chemical users.

In February of 2002 the British Chemicals Industry Association held a workshop focused on the White Paper. Lord Sainsbury, the UK Minister for Science and Innovation, told the participants at the workshop that the White Paper should be considered a good starting point for achieving a balance between the need for public confidence in chemicals and the need to maintain the global competitiveness of the British chemical industry.

Recognizing the growing concerns over the economic impacts of the proposed chemicals policy, the European Commission has sought to generate its own numbers. The DG-Enterprise contracted with Risk and Policy Analysts, Ltd. (RPA) and Statistics Sweden, to conduct an assessment of the proposed policy on the business sector that they released in June of 2002. To inform this study RPA conducted a survey of companies manufacturing or importing chemicals in the European Union countries and received responses from 260 companies and 51 trade associations. From results of this survey, RPA was able to refine and improve the analysis conducted for the British authorities a year earlier than anticipated.

The survey permitted RPA to estimate the number of chemicals manufactured or imported in quantities of one ton or more and, therefore, will likely be registered under the proposed policy. From this number RPA was able to subtract the number of those substances that already meet the testing requirements due to other legislation and those substances that would most likely be withdrawn from the market because of "rationalizations of the market" meaning they simply would not be worth the costs of compliance. Depending on how the new policy will be implemented RPA found that the number of registered chemicals requiring testing would range from 18,700 to 34,800. A significant amount of this fluctuation is determined by whether or not the policy would include chemical intermediates (chemicals used only in the manufacture of other chemicals), which was found to substantially raise the overall costs of testing. Assuming that the new policy would require three levels of testing–full testing, "less demanding" testing, and testing already on-going–the full costs of testing were estimated at lying between 911 million and 5,099 million Euro. Costs of preparing the registration dossier were then computed and these ranged between 414 million to 975 million euros, which includes some economies achieved by firms working in consortia.

Three different scenarios were used to determine the number of chemicals that would go to authorization and this number ranged from 1,400 to 3,900. Using a cost of 50,000 Euro per chemical for preparing the socioeconomic justification for each substance that goes to authorization, RPA calculated that the total costs beyond the costs of current compliance would range from 61.1 million to 159 million euro over a ten year period. In summarizing these

various analyses, RPA concluded that the total costs for implementing the new chemicals policy across all of the European Union over a ten year period would range between 1.4 billion and 7 billion euros. This number represents only a very small percentage of total industry turnover (though a more substantial percentage of profits).

In drawing these conclusions RPA noted that many firms raised serious concerns about the impact of the policy on innovation, new chemical development, and "product rationalization". However, the report noted that there are long standing concerns over existing chemicals policies and that there is a possibility that this new policy could improve rather than worsen conditions. Again, RPA noted the substantial impacts that may fall on small- and medium-sized firms and concerns over how this new policy would be monitored and enforced by the responsible government authorities.

This concern over the effects that the proposed new chemicals policy might have on innovation in the chemicals industry has been brewing for some time. It is a subject upon which there is little academic consensus. Some studies suggest that government regulations inhibit industrial innovation while others suggest regulations have a stimulating effect. One study commissioned in 2002 by the British Royal Commission on Environmental Pollution and prepared by the Science and Technology Policy Research Center at the University of Sussex focused specifically on the chemical industry. The study concluded that the effects of chemical notification regulation varied by sub-sector of the industry, but that, in the short term, new chemical regulations tend to have a negative impact on rates of innovation. However, the study concluded that the social and economic benefits of new regulations may offset this slower rate of innovation.

A second study completed the same year by researchers at the German UFZ-Center for Environmental Research Leipzig--Halle focused directly on the potential effects that the proposed EU chemicals policy might have on chemical and product innovation. The authors compared the proposed new chemicals policy with the existing chemicals policy and concluded that there was little basis for concern. Previous studies focusing on research and development productivity and frequency of patent applications had suggested that the rate of European innovation in the chemical industry tended to lag the United States. This study found that the existing stringent regulatory procedures for introducing new chemicals in the European Union tended to discourage innovation and continue reliance on existing chemicals that were weakly regulated. Because the proposed new chemicals policy would eliminate the separate regulatory procedures for new and existing chemicals it most likely would increase rather than decrease the incentives for developing new chemicals.

Prior to releasing this report DG-Enterprise held a workshop in May of 2002 in Brussels. The European Commissioner for the Environment, Margaret Wallstrom, noted that although 88 percent of the industry costs in implementing the proposed policies would come from testing chemicals, the results of testing will greatly add to the scientific base of knowledge and be a benefit to everyone. Of particular note was the response of the representative from the European Chemical Industry (CEFIC) who worried that the existing costs might outstrip the projected costs, that the costs might overburden smaller producers, and that the costs on "downstream users" (chemical manufacturer's customers) might be substantial. Yet, he, like others from

industry who spoke at the conference, was not in opposition to the basic concepts and structure of the White Paper proposals.

As of May, 2003 there were three studies of the projected costs of implementing the proposed new EU chemicals policies. These have included the British and EU studies noted above plus the German study described in Section 3. As noted in Section 3, the general methodology of the Arthur D. Little report for the Federation of German Industries has been criticized by the German government and economists. A June, 2003 study on the impacts of REACH in France (based on the BDI methodology), conducted by the international management firm Mercer, found that economic losses caused by REACH ten years into its implementation could be between 29 and 50 billion euros or 1.7 percent to 3.6 percent of gross domestic product (GDP). The table below presents the basic findings of first three of the studies.

Projected Impacts of the New European Union Chemicals Policy		
RPA, 2001 Study Assessing Impacts on the UK	ADL, 2002 Study Assessing Impacts on Germany	RPA, 2002 Study Assessing Impacts on the EU
620 million pounds costs to UK over 20 year time period	Loss of 0.4% to 6.4 % to the German economy	1.4 to 7 billion euros cost to the EU
Disproportionate impacts on small- and medium-sized firms	Loss of 150,000 to 2.4 million jobs	Disproportionate impacts on small- and medium-sized firms
640 million to 1.3 billion pounds quantified benefits in terms of public health effects	No benefits considered	No benefits considered

It is important to note that these projections are based on the White Paper and early drafts of the REACH legislation. The May 7, 2003 version of the REACH legislation allows for reductions in testing requirements if adequate data (from in-vivo or in-vitro tests on the same chemical or other similar ones) are available, requires sharing of data, and exempts many polymers and intermediates. Further, requirements for downstream users of chemicals are significantly reduced and there is a great incentive to place as much responsibility as possible on producers. It is likely that the final October 2003 legislation will relax some of these requirements even further. Thus, it is important that economic projections consider the impacts of the actual legislation.

Based on the May 2003 draft REACH legislation, in late August 2003, Arthur D. Little produced an update of its 2002 study for the Federation of German Industries. The report found that if polymers of less than 10,000 daltons were included in the final legislation, the legislation would result in a 14.9% production loss in the manufacturing sector and a 4.7% gross value added loss

to the German economy, with a potential loss of 1,735,000 jobs. These report notes that qualitative losses, such as innovation in the chemical industry could also be expected.

It is important to note that as of March 2003 only one of the economic impact studies, the RPA study conducted for the British government, considered the projected benefits and, then, only a few public health benefits were estimated (and not the innovation or market benefits). These estimates, plus a March 2003 RPA study on occupational health impacts, suggest that were public health benefits of the proposed new EU chemicals policy to be included, the private costs of implementing the REACH program could be well justified.

The March 2003 European Commission detailed assessment of the impacts of the new chemicals policy involved a consideration of occupational health effects. This study was completed by, once again, the Risk and Policy Analysts, Ltd (RPA). The aim of this study was to identify the potential reduction in occupational health impacts that could be expected to arise from the implementation of the REACH proposal. This study considered only the direct occupational health effects on workers in both the European chemical industry and the downstream users of the chemicals and is based on pre-existing data from the Member States health and safety agencies, trade organizations and labor organizations. The study attempted to calculate the number of cancers and other common occupational diseases (health end points) that could be reduced as a result of implementing the REACH proposal and then calculating the consequent cost savings. The findings suggested that the new chemicals policy could result in some 1350 to 12,000 less skin diseases, 275 to 3,680 less respiratory diseases, 50 less eye diseases, 50 to 485 less central nervous system diseases and 2,167 to 4,333 less cases of several different forms of cancer. Given various economic assumptions, the overall projected savings in terms of (present value) health costs over a 30-year time period range from 18 billion to 27 billion euros for the lower bound health end point assumptions. In terms of future cases of occupational diseases avoided this suggests a significant economic value in implementing the proposed new chemicals policy.

In June 2003, the DG Environment published an Assessment of the Impact of the New Chemicals Policy on Environment and Health, completed by Risk and Policy Associates. The purpose of the study was to test the hypothesis that REACH can deliver environmental and public health benefits. To study this hypothesis, four chemicals were selections whose uses were or are in the process of being prohibited or restricted following risk assessments under the Existing Substances Regulation. These chemicals are nonylphenol, short chain chlorinated paraffins, tributytin, and tetrachloroethylene (or PERC). Given the difficulties of calculating costs and benefits of REACH, the report does not purport to study economic benefits of REACH but rather how it could lead to more efficient chemicals management. The report provides an in-depth analysis of regulatory activity surrounding the four chemicals as well as the impacts of not having acted to prevent exposures to them. The report finds four advantages of REACH over the current system: (1) by assessing the properties of substances and thereby making information available more quickly, it has the potential to identify a hazard before substantial damage occurs, rather than waiting for monitoring to provide evidence of harm; (2) by providing data in a systematic manner, it enables risks to be assessed rigorously, allowing effective risk management measures to be identified; (3) the availability of information on risks enables industry to take voluntary action in response to stakeholder pressure; and (4) it provides a basis for quicker

regulatory action for the most hazardous substances. Additional case studies of implementation of chemicals regulation – of particular chemicals for example – would be extremely useful in understanding impacts of REACH.

Concerned that industry impact analyses had generally been skewed against REACH and had not considered benefits, the World Wildlife Fund UK commissioned a respected environmental economists David Pearce and Phoebe Koundouri to prepare a report on the Social Cost of Chemicals. The authors noted while important information to prepare a thorough costs and benefits analysis are not available, estimates of whether the benefits of REACH will outweigh its costs can be made. They further note that data on how indirect costs of REACH have been calculated are not available. Using three different models involving Disability Adjusted Life Year and Willingness to Pay, as well as data on environmentally attributable fraction of diseases, the authors conclude that REACH will generate net benefits, considering their analysis did not include environmental impacts/benefits of the proposed legislation. Nonetheless, they calculated a wide range of benefits to cost ratio possibilities depending on the model and assumptions.

The European Union is currently conducting additional cost and benefits analyses based on the May, 2003 draft legislation. However, for the most part, the European Union has not adequately examined the impacts of its existing chemicals regulations – both negative and positive, which makes understanding the impacts of REACH very difficult. European governments have not regularly examined the post-implementation impacts of policies in terms of reducing use of substances, impacts on innovation, etc (see Section 10). Thus, it is difficult to tell how use of certain chemicals has been affected by chemicals regulations in Europe, though we have presented some limited data are presented in the various country sections (Section 3).

Since benefits of existing policies have not been examined and are in general more difficult to calculate because they occur in the future and are more diffuse, there tends to be a bias in these types of analyses towards overestimation of costs. Projections of large economic losses and dislocations from environmental policies have not materialized to this date. Many analyses of chemicals regulations have found that predicted costs of implementation are often greatly overestimated compared to actual costs. One reason for this is that innovation occurs, lowering costs. Cost estimates to date, have not thoroughly considered that products will still need to be made and that chemicals will be necessary. Downstream users will ultimately have to work with manufacturers to find alternatives to chemicals that might be dropped as a result of the authorization process. Support to firms in substitution would provide an important benefit in supporting innovation.

9. REACTIONS TO THE WHITE PAPER AND REACH PROPOSALS

The REACH proposal has arguably been one of the most contentious environmental legislative proposals ever in the European Union. This is logical due to the controls it will place on chemical production and use and the projected costs of implementation. The REACH legislation will set an important precedent in the ability of government authorities to regulate commerce and trade. Given the scope of the legislative change, the European Commission has carefully engaged stakeholders throughout its development of the White Paper and the legislative drafting. The goal is maximum integration of stakeholder concerns in the draft legislation. In this section we examine the various stakeholder positions on REACH. Each stakeholder group has repeatedly lobbied its position to the European Commission Directorates, the Council of Ministers, the European Parliament, and Member State governments. The analysis is divided by European governments, industry, labor, non-governmental organizations, and foreign governments and industry groups.

European Governmental Responses to REACH

Competent Authorities in all of the EU Member States have been able to follow and comment on the development of the REACH program through regular meetings and seminars. In some cases countries, such as the Netherlands, have hosted meetings to discuss aspects of REACH or to develop a workplan to implement the program while legislation is being drafted. In other cases authorities in the Member States, have offered technical assistance to Commission Directorates in drafting the REACH program. However, with the exception of those countries instituting their own policy discussions, most have not taken public stands for or against REACH.

Nonetheless, some countries that have not established their own chemicals policy dialogues have expressed support for implementation of REACH. At an early 2003 Franco-German summit, both France and Germany concluded in a statement that the REACH process should be translated into law as soon as possible. The Austrian Ministry of Environment determined that due to its small size, it could most effectively influence the REACH process through direct involvement in the policy's development, rather than developing its own policy. In November 2001, the Austrian Ministry of Environment hosted a conference on precaution and chemicals policy to provide input as to how the precautionary principle could be integrated into the new policy. The Finnish government has taken a position on REACH similar to that of its Nordic neighbors. Finland has been active in the development of Nordic chemicals policy, through the Baltic and Nordic Council discussions. The Spanish Ministry of Environment has expressed support for REACH as well, particularly to support efforts towards protecting the Mediterranean. The Ministry, along with Swedish Ministry of Environment hosted an October 2002 conference on Management of Toxic Substances in the Marine Environment to improve Northern-Southern European collaboration on chemicals management. On the other hand, Italy, which has many small- and medium-sized chemical companies has taken a relatively negative view on REACH due to its potential impacts on the country's industry. Other countries, such as Portugal and Greece have not issued public statements.

On the basis of the draft chemicals policy legislation, many Member States are engaging in national stakeholder discussions to formulate a national response and to influence the

Parliamentary and European Council debates. The chemicals policies of Sweden, Denmark, the United Kingdom, the Netherlands, and Germany all hinge on influencing a European-wide policy that supports their domestic agenda. Some countries—Sweden, the United Kingdom and Germany—however, have issued detailed positions on REACH. For example part of the German government strategy to establish support from industry and labor for REACH was to develop an agreement described in Section 3.

The Swedish government issued statements on REACH in November 2002. In particular, its positions address the authorization procedure, arguably the most important aspect of REACH for the Swedish government. With regards to Authorization, the government argues that:

- Authorization should apply to all substances of very high concern, including known and probable carcinogens, mutagens and reproductive toxicants, as well as POPs, PBTs and very persistent very bioaccumulative substances. The authorization process should include a review clause to facilitate its extension as properties of similar concern (such as sensitization and endocrine disruption) become better defined.
- Authorization should be time and use limited and firms that are afforded authorization should be developing alternatives.
- There is a need to develop prioritization for authorizations, starting with the substances with the most dangerous properties and use patterns, such as open professional uses and in articles, as well as substances that if released will persist for long periods of time in the environment.

In addition to comments on the authorization process, the Swedish government argues that the Commission must develop a common process for accelerated risk management so that rapid action can be taken on chemicals not included in the authorization list. Further, REACH must include a general duty/responsibility on industry to generate and provide sufficient knowledge to ensure chemical safety. There should be basic information requirements for substances and guidelines should be developed to ensure the quality of data submitted.

In December 2002, the UK Department for Environment, Food and Rural Affairs issued a Position Statement by the UK Government and Devolved Administrations, outlining the government's ideas and negotiating strategy on structure of the new REACH program including: rapid screening, prioritization and action on chemicals; minimizing animal testing; and maintaining or enhancing the competitiveness of the chemical industry (including its ability to develop new safer chemicals). The UK supports a phased approach to implementation of REACH focusing on the highest concern/use chemicals to ensure workability and not overburdening the system. It outlines a proposed decision-structure for REACH that limits testing (a focus on information), avoids duplicative data and "piggy-backing" by industry, outlines responsibilities of producers and downstream users, and sets out EU and Member State responsibilities for REACH. The position supports the notion that industry has responsibility for chemical testing and management and that the EU policy should ensure coherence with WTO, multilateral agreements and other legislation. The position states that chemicals used in products should not be included under the REACH scheme. With regards to intermediates, the government suggests a scheme for excluding non-isolated and on-site intermediates from registration. It also includes recommendations for limiting registration of polymers, and support

for an expanded authorization scheme. Once a final EU draft legislative package is produced, Defra will engage in a stakeholder dialogue to develop its official positions.

Non-Governmental Stakeholder Responses

This section presents an analysis of non-governmental stakeholder reactions and efforts to influence the REACH proposal as well as chemicals policies in the Member States. There is a great diversity of stakeholders throughout the EU and to the extent feasible differences between them are outlined. We divide stakeholders by industry, labor, environmental organizations, and animal rights organizations. We first examine industry response to REACH and then discuss industry response to Member State policies.

Industry

The chemical industry and some downstream sectors have been important actors in influencing the shape of REACH and Member State policies. However, it is difficult to discuss industry as one single entity. Even within the chemical industry there is a range of types of producers (raw chemical producers, specialty chemical producers, big and small companies) that might be impacted differently by the REACH proposals. In this section, we examine the industry responses and activities on REACH and Member State policies, examining the influence of chemical producers, downstream user sectors, and retailers.

Chemical industry

At the EU level, industry participation in the White Paper process has been dominated by the European chemical manufacturers trade association – CEFIC. Chemical industry trade groups and manufacturers in the Member States, such as the Chemical Industry Association in the UK, have, for the most part, echoed CEFIC's positions in establishing their own positions. Nonetheless, there are important differences, discussed below, in the chemical industry responses to REACH in the Member States. Some formulator industries (paints, dyes, fragrances, and individual companies, such as Procter and Gamble) have been involved in the REACH discussions, but downstream users and retailers have been, for the most part, missing in the debates at the EU level.

The chemical industry, in general, feels unduly targeted by REACH but realizes that there is a general loss of confidence in chemicals (due to lack of testing, incidents, etc.) that they need to reinstate by being proactive. The industry is attempting to be proactive through Responsible Care efforts, as well as initiatives coordinated by the International Council of Chemical Associations (ICCA). ICCA is an umbrella trade organization of chemical industry associations. ICCA has taken an active role in coordinating international testing efforts for High Production Volume chemicals and participating in OECD's chemical testing process. It is also coordinating a major chemical impacts research initiative called the Long Range Research Initiative. In 2001 ICCA developed a Global Strategy on Chemicals Management. The strategy calls for industry to actively participate in efforts to prioritize chemicals based on use and exposure patterns; establish risk reduction policies; provide information along product chains; and where appropriate undertake phaseouts of specific uses of chemicals. The strategy notes the shared

responsibility of producers, distributors, users of chemicals and industry in the safe management of chemicals and that the goal should be fair, consistent, and balanced policies that acknowledge the benefits of the industry to society.

Given the many voluntary initiatives and risk management regulations that they already implement, the chemical industry believes their efforts are sufficient to address chemical risks (i.e., process risks and worker health and safety). Rather than establish a new system, they argue that the existing system should be modified and improved. The most important question for the chemical industry is whether chemicals, particularly those of greatest concern, can be managed safely. They believe that they can under current policies. However, it is quite clear that CEFIC has conceded that major changes in chemicals management policy are coming about and that the industry must be proactive in shaping those changes to minimize the impacts.

The chemical industry has expressed modest support for the REACH proposal yet the industry would prefer a harmonized, voluntary global system. For CEFIC it is not an issue of whether a new system is coming, but whether it will be workable. It believes that the political objectives of more testing, accountability (linking new and existing substances), and risk reduction are in line with its goals. It also supports greater responsibility in testing, conducting risk assessments and in involving downstream users in sharing burdens.

The chemical industry would like to see a clear, consistent and transparent process through the REACH regulations. They want a process that screens chemicals and addresses only those identified as highest risk concern. Implementation should stress flexible, voluntary measures to the extent possible. Industry's main concerns relate to the timeline for testing, which it feels is not feasible; the burden of testing; protection of confidential information; and the authorization process. They feel that an unworkable system (based on far reaching Nordic phaseouts) with overly ambitious goals will lead to them being blamed for not acting when goals are not fulfilled. The chemical industry would like to ensure a single European system, which prohibits Member States from unilaterally introducing additional or different requirements.

Many of the chemical industry concerns about REACH have been outlined in a series of discussion papers, analyses and a website prepared by CEFIC. These include:

- <u>Testing requirements that will be costly and hinder innovation in new chemicals</u>. Industry believes that the voluntary ICCA testing initiative on High Production Volume (HPV) chemicals is already ambitious enough and to add all of the additional requirements envisioned under REACH is not feasible. They believe the costs of testing proposed by the Commission are underestimated and that the requirements would lead to excessive animal testing (though it is unclear to what extent the industry is concerned about animal testing). Industry also believes that the timelines proposed by the Commission are too short. The Commission has responded that their main concern is collection of information and that the timelines are reasonable considering that industry should have taken responsibility for collecting this information decades ago.

  Industry argues that a greater use of structure activity analysis (SAR) and more limited datasets would be acceptable to define a core set of information leading to additional tests

rather than a formulaic set of tests. They prefer the United States' new chemicals notification process under TSCA, which is less data-intensive and, they argue, more leads to greater innovation. Further, industry believes the evaluation process proposed under REACH would be too big a burden for agencies that have been unable to finalize a much smaller universe of risk assessments.

- An authorization process that is too strict. For the most part, the chemical industry rejects the concept of authorization based on inherent hazards of a substance. They prefer that decisions on chemicals be completed on a case-by-case basis, prioritizing chemicals and considering actual risk as well as the benefits of the substance. The industry has tried to interject risk-benefit considerations into the REACH process.

  Industry believes that the authorization process as proposed will be too time consuming and bureaucratic and duplicative of existing management regulations, which have worked well to restrict chemicals (e.g., the Limitations Directive). It also fears that the authorization process will create legal uncertainty for producers who will not know whether a particular chemical use will be authorized. Nonetheless, industry accepts that it will not escape an authorization process and thus believes it should be limited to known or highly suspect CRMs (carcinogens, reproductive toxicants, and mutagens), must include analysis of impacts of alternatives, examination of economic impacts of substitution (as well as feasibility of substitution) and have exemptions for research and development, well controlled uses, etc. Authorization should be based on risk rather than intrinsic properties, though industry is supportive of authorization for POPs. If authorization is based on intrinsic properties these categories should be clearly defined. One option industry has suggested for authorization is an initial scanning risk assessment to determine which uses are acceptable.

- Economic impacts of the REACH proposals. Industry believes the impact of the REACH implementation could be potentially great, though it is unclear what substances might go from market and what downstream effects might be. It feels that REACH will discourage research and development of new products. Particularly concerning are impacts to small- and medium-sized industries (SMEs) and specialty chemical manufacturers who make small batches of chemicals for short periods of time. Alternatives can take time to develop and their performance might not be as good. There is also the chance of a shift in production to Asia or elsewhere where costs of compliance are lower. It is hoped that requirements to apply the system to imports would help reduce impacts, though if a chemical is brought in to the EU in a preparation (not raw chemical) then there is no cost of registration to the raw material manufacturer.

  Industry's strategy has been to highlight the impacts and potential job loss associated with REACH, thus forcing the European Commission to undertake as extensive regulatory impact analyses as possible. It has lobbied EU trade and commerce officials about its concerns over impacts. It also has lobbied Member States, particularly Germany and the UK, to place pressure on the Commission to minimize the impacts of the policy. Finally, CEFIC has worked closely with trade associations in other countries, particularly the United States, for them to put pressure on their governments to raise

concerns about REACH.

- Protection of trade data. CEFIC argues that formation of consortia and disclosure of data on chemicals in products will sacrifice intellectual property. For some firms that produce specialty chemicals, such as lubricating oils, the issue with REACH is not so much the costs of testing than the impacts the regulation might have on their ability to protect markets. Firms argue that downstream users are not going to be willing to provide exposure information to producers for fear of discovery of protected processes. CEFIC argues that there is sensitive information on product composition, uses, and production volumes that should be shown to regulators but protected from public disclosure. Public information should be "meaningful and related to hazards." Data collected under REACH should be compiled in a central database controlled by a central entity to protect confidential data.

In September, 2001, CEFIC developed its "Thought Starter on REACH", in conjunction with several chemical industry associations, to propose a practicable, alternative decision-making procedure for implementation of the REACH proposal. While supporting the overall goals of REACH, the paper notes that the goals of their proposed decision-making procedure were to make best use of existing legislation; generate relevant and appropriate information; avoid complexity; and ensure close collaboration between industry and authorities. The Thought Starter includes the following elements:

- Registration for all non-polymer substances placed on the market (not those produced and used within a manufacturing process) over 1 ton per year. Companies should be required to provide information based on likely exposure and tonnage, starting with a core dataset (in-vitro testing). The core dataset requirements would be increased based on increasing production and type of use (consumer use, professional use, or industrial use). Registration would occur first within five years for substances on the market above 10 tons per year and within eight years for those on the market from 1-10 tons per year. Importantly, intermediates would for the most part be excluded from the process unless sold off-site. This would significantly reduce testing requirements.
- Companies could complete registration alone or through a phased approach that consists of: declaration to the central entity of substances, tonnage and uses; formation of consortia to provide data; information gathering; preliminary risk assessment; and registration.
- Evaluation should be applied only to substances marketed above 100 tons and those prioritized due to hazards and uses. If more data are required for evaluation, the central entity should be able to request further information for risk assessment and any risk reduction measures should be based on that assessment.
- Authorization should occur only after registration and should only apply to substances placed on the market. It should only apply to substances of very high concern – CMRs category 1 and 2 and POPs. Authorization processes should not apply to substances already controlled under other legislation and to those thought to pose minimal risk or exposure. Any decision on authorization for specific uses would be based on risk assessment; socioeconomic analysis; the availability and impact of alternatives; and risk reduction measures to minimize exposure to acceptable levels. Industry would be

responsible for providing this information and could continue to market the substance while awaiting an authorization decision (unless the substance is of serious concern).

CEFIC hired consultants Risk & Policy Analysts (RPA, the same firm which conducted the EU and UK cost analyses of REACH) to implement and analyze a pilot trial of the CEFIC Thought Starter (published in March, 2002). The trial involved 11 chemical companies, each of which chose a chemical for the trial. While concluding that the Thought Starter could provide a good basis for implementing REACH in a cost-effective manner (estimated costs for completing the trial were less than those projected by the EU for implementation of REACH requirements), the RPA study did identify some concerns with industry data. The report noted that firms often lacked basic production level data and that data are often dispersed throughout the firm. They found that involving co-producers in establishing consortia to share data can be complex and time consuming, and that there is no mechanism to bring non-EU producers to the table. In terms of data, RPA found that industry had gaps in basic hazard data that could not be justified and hindered the ability to complete a risk assessment. Data provision was even more difficult when substances are complex or marketed as a preparation. Data on downstream uses was also lacking, in part because downstream users were not aware of REACH and did not understand what was required of them. Often data provided were insufficient to understand exposure and how it is controlled. Because of the wide range of uses of some substances, technical data for each use as well as information on controls was complicated. The lack of downstream data made evaluation and risk assessment considerably difficult. The study concludes that there is a need for mechanisms to improve information exchange between producers and users of chemicals, which might be remedied once REACH becomes a mandatory requirement. It is important to note that despite chemical industry efforts to voluntarily compile information, the study finds that firms still lack even basic information on production and chemical hazards.

There is evidence that some chemical industry associations are beginning to work with members to form consortia to pool hazard and risk data in anticipation of the REACH requirements. One example is the European isocyanates producers association which has estimated that it will complete data for the chemicals required to produce polyurethanes by the end of 2004.

Chemical industry support for REACH and broad chemicals policy change has varied at the Member State level. The Italian chemical industry and government have expressed concern about REACH due to their concentration of small- and medium-sized producers. The French chemical industry has been relatively silent on REACH, though the French firm Rhodia chaired the board of CEFIC and integrated concerns through that mechanism.

Chemicals manufacturers' associations in the Nordic countries have been more supportive of the REACH process and national chemical management efforts. They tend to speak with one voice to explain (though not necessarily) defend policies in their countries. They understand that the policies are moving forward, public concern over chemicals is high, and that they must be proactive. The Dutch chemical industry was one of three partners involved in the Strategy on Management of Substances Process, along with environmentalists and government. The industry association has developed a Declaration of Intent to implement SOMS (outlining some concerns) but its central involvement in the development of the policy has been important to its overall support. The Dutch industry believes that it is in its best interest to cooperate and quickly

implement the policy so as to have a competitive advantage over producers in other countries. Denmark has only a very limited chemical industry so implementation of REACH is likely not a large problem.

The Swedish chemical industry, which is relatively large for that country (the country's third biggest industry), has been active in the development of the Swedish policy. The industry association has also been active in several government-sponsored projects to implement aspects of Swedish policy. While not agreeing with all of the details of REACH or Swedish policy proposals, they have been supportive of the various processes in that country and understand that market demands will push them to innovate in new chemicals to meet needs of users. They prefer market pressure for development of new chemicals or phaseouts over regulatory demands. However, they believe that the chemicals policy implementation to date in that country has not hurt the industry. In an early 2003 newspaper interview, the chair of the Swedish chemical industry association noted that the REACH program will not have adverse effects on their operations or jobs.

Concerns have been growing in the Germany industries. The powerful Association of the German Chemical Industry (VCI) has maintained a highly critical position of REACH, despite its entering into an agreement with government on REACH. The response of the German industry association Bundesverband der Deutschen Industrie (BDI) has been more far reaching. In a September, 2002 position paper the BDI offered a defense of existing chemicals regulations and a strong critique of the REACH proposal. Their economic analysis, previously discussed, has proven a useful lobbying tool to demonstrate the adverse effects of REACH on jobs and the economy.

Given the size of the chemical industry in the UK, it has been active in attempting to shape UK, as well as the EU, chemicals policy. Much of the UK chemical industry effort has been focused on working with CEFIC to encourage a workable EU chemicals policy as well as to shape the UK position, through the Stakeholder Forum and other venues. The UK Chemical Industries Association (CIA) undertook a strategy similar to the German industry in engaging the labor movement on chemicals. This resulted in a July 2002 joint position statement, of much less influence than that developed by the German industry and trade unions. It notes that the White Paper could lead to large job loss if implemented in its current form. While vaguely written, the statement notes that the EU should seek global legislation; that right to know should be an important part of the EU policy; that timelines are overly ambitious; that the policy should only apply to substances entering the supply chain; and that workers should be more effectively integrated into the White Paper discussions. A separate October 2002 statement presents a joint agreement between industry and labor on how intermediates should be covered in the EU legislation.

Downstream chemical users/manufacturers

While downstream users of chemicals have not been particularly active in the REACH debate, several trade organizations whose members extensively use chemicals have expressed concerns about REACH. However, their impact on the policy proposals to date has generally been minimal. The European Commission understands that it has missed an important opportunity by

not effectively engaging downstream users in the development of the REACH proposals. This is particularly important, because many downstream user groups, such as textile and electronics manufacturers, have presented "worst-case" scenarios of the impacts of REACH – for example that each company would have to register use of every chemical. The Commission missed the opportunity to correct this misinformation about REACH (the draft REACH legislation contained relatively small requirements for downstream users) and to engage downstream users on the potentials for REACH to improve access to information on product hazards. At the Member State level, however, downstream users have been more active, in shaping national policy and providing input on national chemical policies and REACH.

At the European level, several downstream user sectors formed an ad-hoc organization called the Downstream Users Chemicals Co-Ordination group (DUCC). DUCC consists of several trade organizations of detergent, paint, cosmetic and perfume, aerosol, adhesives, and distributor organizations working closely with CEFIC. DUCC is concerned about competitiveness of small- and medium-sized firms due to the REACH requirements. DUCC's positions on REACH closely resemble those of CEFIC regarding the scope and implementation of the authorization procedure, protection of confidential information, and public information. Due to the specialty nature of many of their products (individual formulations, etc.) the group is particularly concerned about how responsibility and costs for testing will be shared amongst producers, without sacrificing trade data or allowing importers to be free riders. Similar to the CEFIC Thought Starter, DUCC suggests that a pre-registration phase be built into REACH to allow formation of consortia involving manufacturers and downstream users from the start of the registration process to develop appropriate hazard and exposure data and risk assessments. The DUCC group also is concerned with not overusing the concept of "hazard" as over labeling products as containing hazardous substance could cause consumers to lose perspective on the scale of hazards. The group wants to ensure that decisions are based on risk, rather than hazard to address this issue. Two of the largest and most influential companies in the downstream users group – Proctor and Gamble and Unilever – have generally taken positive positions on REACH, though their policy positions have been similar to those of the DUCC group.

DUCC, along with CEFIC, was involved in the establishment of the Human and Environmental Risk Assessment (HERA) project in 1999 to increase transparency on product risks by conducting publicly-accessible risk assessments on detergents and cleaning products. Through a team approach, about 115 substances have been studied. Project partners hope that its results will influence the EU policy by integrating their experiences in the REACH time-tables for implementation as well as ensuring a focus on risk rather than hazard.

In some countries, such as Denmark, Sweden, and the UK, downstream manufacturers have been much more involved in the chemicals policy developments (see Section 3). The Danish government has worked with numerous manufacturers to develop alternatives to particular substances/products of concern. The Swedish chemicals committee held several discussions with chemical user sectors—including companies like Volvo, Electrolux, and Ericsson—and found these to be very supportive of implementation of the policies as long as high quality substitutes are available. In both of these countries, through strategies such as Observation Lists, authorities have been aggressive in obtaining voluntary commitment to substituting problematic chemicals. For example, the Swedish electronics manufacturer Ericsson has committed to

substituting lead in solder, halogenated flame retardants in circuit boards, and beryllium oxide in all of its products and has made substantial progress towards reaching those goals.

Wholesalers, retailers and non-manufacturing users of chemicals

With few exceptions, wholesalers, retailers and non-manufacturing users of chemicals have been absent from the REACH debate, though some individual companies have been more active in national chemicals policy discussions. Wholesalers, large retailers and other large purchasers of chemicals and chemical products could have an important impact on the implementation of REACH through procurement policies that minimize the use of specific chemicals. The lack of involvement of such downstream users and sellers of chemical products has seriously limited the European Unions outreach efforts.

In October, 2002 EuroCommerce, a trade organization of retail and wholesale sectors issued a statement of support for the REACH program with a variety of positions on aspects of REACH. The group notes that many of its members have already made substantial progress in restricting chemicals of concern and committing to the generational goal.

EuroCommerce members are particularly concerned about burdens under REACH. They argue that burdens of testing and demonstrating the safety of chemicals should rest squarely on manufacturers. Further, they are concerned about liability when products are not used for intended purposes. Finally, the manufacturers want to ensure that there is a consistent pan-European regulation so that restrictions or substitution requirements are mandatory in nature. As retailers are increasingly the targets of advocacy campaigns, they are concerned that consumer pressure and not regulation will lead to differing restrictions in different places. They would like to see more certainty about restrictions that would stimulate innovation and make compliance easier for retailers. They believe that information on chemical restrictions at the Member State and EU levels should be compiled in some type of centralized clearinghouse.

Many major retailers and non-manufacturing users of chemicals have developed internalized chemicals policies in absence of REACH. Often these are the result of consumer campaigns or negative press attention. They are using these policies to influence suppliers and encourage the development of safer substitutes. These efforts demonstrate the critical importance of market forces in stimulating the development and implementation of safer chemicals. For example, the Swedish retailer Ikea has long been a leader in environmentally friendly products. The company has developed binding purchasing specifications that restrict certain chemicals such as lead, cadmium, brominated fire retardants, and PVC in products sold, and is discussing more generic restrictions of chemicals of concern (such as mutagens, reproductive, toxicants, and carcinogens). The company works closely with suppliers and upstream manufacturers in adhering to its requirements. Two other examples are worth noting:

The Swedish construction firm Skanska, one of the largest in the world, began developing chemicals management policies in the mid-1990s after concerns about sick buildings and a highly publicized incident involving acrylamide leaking from a tunnel under construction. To restore its image Skanska took the Swedish Observation List and translated it for use in the construction industry. Skanska began collaborating with other Swedish construction companies

(and with NGOs and university researchers) on harmonized lists of chemicals of concern, as well as working with suppliers on replacements. The company has established three lists of chemicals of concern: The company set ambitious goals for suppliers which ultimately were forced to internalize the Skanska policy and place requirements on upstream producers. The company understands that it will still have to do on-site risk management, and as such has integrated health and safety into its chemicals management program, which now includes materials use as well. Skanska views environmental and health protection as a "brand" issue, and while the chemicals program has only been applied in Sweden to date), it will soon expand the program to Nordic countries and elsewhere.

The British retailer Marks and Spencer has also developed an aggressive chemicals policy, in response to NGO pressure. Following a campaign initiated by Friends of the Earth which benchmarked retailers, and responding to consumer pressure on genetically modified foods and pesticides, Marks and Spencer was forced to address consumer concerns. The company notes that in an age where NGOs are more respected authorities than government (given food scares), retailers must take into consideration consumer concerns (social risk) in its risk assessment and risk management processes. Further, as Marks and Spencer is a global, mid-level retailer that competes on quality, it has an opportunity to distinguish itself from the competition by being an environmentally friendly company. Having its own brands the company was in a unique position to influence upstream production. The company began with a list of 20 priority chemicals for substitution in products, including PVC plastics, and rationalized their supply chain to target the biggest suppliers so that they could then influence upstream producers. The company met with supply chain companies to identify alternatives for particular products such as brominated fire retardants. The company views substitution in practicable terms. For some substances of concern, such as bisphenol-A in tin can linings, there may not be available alternatives, so the best approach is to restrict exposure as alternatives are developed. The company also has collaborated with other large retailers—Boots Pharmacy, and B&G a large home building store—committed to integrating chemicals management into their businesses and with strong technical capacity. Finally, it has tried to influence the chemical industry to take the initiative to implement REACH.

Organized Labor

Organized labor has been only minimally involved in the REACH process and in chemicals policy discussions at the Member State levels. Concerns of trade unions differ widely between countries. The most important unions for the chemical industries—the European Chemical Energy and Mine Workers (EMCEF), as well as the German and UK chemical workers unions have expressed serious concerns about the impacts of the REACH program on jobs. This is important given that these are well-paid, skilled jobs and there is high unemployment in countries like Germany. As noted previously, both the German and UK chemical workers unions have entered into agreements with chemical industry associations (and the government in the case of Germany). Transition assistance is not as much of an issue as job loss (since unemployment is high), as a social safety net exists. However, retraining assistance is high on labor's agenda. In addition to concerns about job loss, these unions have also expressed concern about the timetable and extent of REACH, burdens on small- and medium-sized enterprises, and their lack of involvement in the social dialogue and change processes leading to REACH.

Further, EMCEF argues that current occupational health directives adequately protect workers in the chemical industry and that there is no need for REACH. This assumes that all countries in the European Union have similar workplace controls as in Germany and that workers are protected similarly in the chemical industry and in user sectors.

Neither the European Commission nor environmental NGOs have engaged labor to a great degree, integrating worker health and safety concerns into the development of the REACH policy or making arguments about potential benefits to workers. This has made it easier for industry to create the case about REACH's impacts on workers and to create alliances with organized labor.

Nonetheless, some trade unions, particularly the Comisiones Obreras in Spain, the European Trade Union Confederation, and the Danish General Workers Union, have taken a pro-active view on REACH. Comisiones Obreras sees REACH as an opportunity for innovation and clean production. Rather than waiting for change to happen and impact workers, Comisiones views its role as proactively setting an agenda that is good for workers and good for the environment. Comisiones has actively collaborated with environmental NGOs on chemicals policy issues, having been a participant in the negotiations leading to the Stockholm Convention on persistent organic pollutants.

The European Trade Union Confederation (ETUC) also views REACH as an opportunity for advancing occupational health, though have been less active participants in REACH debates. ETUC argues that REACH should be an integrated chemicals policy that addresses worker, consumer, and environmental concerns. For example it should have strong right-to-know provisions and address low volumes chemicals on the market and intermediates, as these are important worker health concerns. The REACH authorization process should be extended to chemicals that might pose high hazards to workers such as sensitizers. ETUC is also concerned that the REACH program include assistance for cleaner production and development of safer alternatives, as chemical substitution can lead to process changes that might have adverse impacts on worker health. ETUC disagrees with the EMCEF position that workers are currently protected under current legislation as implementation of legislation varies by Member State and workers in downstream user industries receive less protection. They see REACH as an opportunity to make occupational health gains outside of current legislation, particularly for workers in downstream user industries and the service sector.

At the Member State level, Danish, Swedish and Dutch Unions have been supportive and more involved in government discussions on the chemicals policies. While unions have not worked closely with environmentalists in influencing the policies, they believe that such policies are important and are willing to accept some job loss for implementation. Unions in these countries represent some 75-90 percent of the workforce and have substantial influence in decision-making at the firm level. Swedish unions have initiated a chemicals substitution initiative focused on chlorinated solvents and Danish unions have been active in pesticide use reduction programs. For several years, Danish unions were instrumental in the development of a "green jobs" initiative focused on providing jobs in sustainable industries; however this program was eliminated with the conservative changes in government in 2001.

Environmental Non-Governmental Organizations.

The European environmental movement has been a major actor in the push for the development of the REACH program. During the last five years NGOs in Europe have become more active in organizing on chemicals policy. The efficacy and involvement of the environmental organizations across Europe differs but there is increasing coordination of message and activities. In some countries, such as Denmark, there are strong links between environmental and consumer NGOs that have been critical to increasing public awareness and advancing debates on hazards of chemicals in products. For the most part, however, the consumer movement has been relatively absent in chemicals policy discussions, with the exception of European Consumer's Organization (BEUC).

While organizations have been active on toxics in Europe for decades, much of the coordination and movement towards an EU integrated policy began in the late 1990s. Groups such as Friends of the Earth and World Wildlife Fund had worked on general principles of chemicals policy which culminated in a five point agenda at a meeting of the European Environment Bureau (EEB) in December 1999. At EEB's Copenhagen conference on a future chemicals policy with government and NGO experts in October 2000 these five points were named "The Copenhagen Charter." They include:

- A full right to know, including what chemicals are present in products.
- A deadline by which all chemicals on the market must have had their safety. independently assessed. All uses of a chemical should be approved and should be demonstrated to be safe beyond a reasonable doubt.
- A phase out of persistent or bioaccumulative chemicals.
- A requirement to substitute less safe chemicals with safer alternatives.
- A commitment to stop all releases to the environment of hazardous substances by 2020.

The Charter has been signed by more than 60 environmental and consumer groups across Europe and remains a basic framework for European NGO demands on chemicals. The Copenhagen conference also established a new advocacy newsletter and organization called "chemical awareness" to share information and strategies on chemicals policy. While the chemical awareness coordinating effort has since dissipated, the European Environment Bureau (EEB) – a pan-European environmental NGO policy and coordination organization – has established a "chemicals working group" of environmental, consumer and animal rights organizations from Western and Eastern Europe. This chemicals working group has met on various occasions to analyze policy, develop messages and strategies on REACH. EEB has worked closely with other Brussels-based environmental organizations – World Wildlife Fund, Greenpeace, and Friends of the Earth – on developing reports, statements, and lobbying strategies. Nonetheless, the Brussels-based toxics movement is relatively small as is the toxic movement in most of the European countries – with the exception of some such as the UK, Sweden, the Netherlands, and Denmark. As such, one strategy has been to organize support for a strong version of REACH in Member States, particularly the UK, Germany, and some other key countries such as Spain and Eastern European countries which will accede to the European Union in 2004.

From 1999-2001, environmental NGOs placed pressure on European governments and the EU for a strong statement on chemicals policy in the White Paper. They then placed pressure on the Council and Parliament to ensure an even stronger position. Their efforts were somewhat successful, with the Parliamentary environmental committee issuing a statement about expanding REACH, which was ultimately toned down in the full parliamentary discussion. In 2001 and 2002, environmental groups participated to the extent possible (given resource constraints). They also issued several statements and reports on the chemicals policy proposals, including some joint statements with animal rights organizations (see below).

While satisfied to have achieved the White Paper on chemicals, NGOs are increasingly concerned about the speed with which the European Commission is developing draft legislation and the increasing influence of industry in that process. Several Member State governments and DG Environment are increasingly looking to NGOs to place pressure on the Commission to put a legislative proposal forward. In September, 2002 EEB hosted a conference sponsored by the Danish and German governments to address lingering concerns in the legislative process as well as to provide an impetus for the Danish government to issue a legislative proposal during its Commission presidency in fall 2002. This conference also led to increased trans-Atlantic cooperation on chemicals, critical to diffusing U.S. government and industry opposition to the REACH proposals.

Recent reports and statements by European NGOs have focused on outlining the continued flaws of the current regulatory system; criticizing the speed with which the Commission is developing its proposals; outlining key positions on the REACH program; and responding to critiques of REACH from other governments and industry. Key NGO demands on the REACH legislation include:

- Authorization of hazardous categories of chemicals based on their inherent characteristics, including: carcinogens, mutagens, reproductive toxicants, endocrine disruptors, sensitizers, POPs, very persistent and very bioaccumulative substances, and persistent bioaccumulative toxics. The NGOs see the authorization process as the implementation of a substitution requirement and want to see the list of substances included as broadly defined as possible. Exemptions should be as narrow as possible and companies should have to demonstrate that no safer alternatives exist or economic hardship if safer alternatives were to be implemented. Additionally, there should be a general duty of substitution on all firms using potentially harmful chemicals, not just those on the authorization list.
- Extending the REACH requirements to products, including imported ones. NGOs want the chemicals policy to apply broadly to chemicals, preparations, and their use in final products, which they argue is an important source of exposure. They would like to see something like a register of hazardous substances in products, which has not been taken up by the Commission (i.e., a red flag list).
- Right to know. NGOs want as much data on chemical toxicity, exposure, and use in products publicly available as well as limitations on the ability to claim Confidential Business Information. Industry should be responsible for providing this information. Testing and evaluation should be as transparent as possible and independently verified.

- Enforcement and implementation. NGOs are concerned that the REACH proposal will take too long to implement and thus are pressuring the Commission for a rapid introduction of the system. They want to see REACH applied, albeit to a lesser degree, for chemicals produced under 1 ton per year. They argue that REACH must have strong enforcement measures built in, including a no-data, no market provision to ensure that adequate data is produced.

Responsibility of industry is a key aspect of the NGO demands. They argue that industry has gotten away without testing or assessing the vast majority of chemicals for many years (about 85 percent of the projected implementation costs of REACH). Industry must, therefore, bear the costs of testing and assessing, as well as replacing harmful substances.

Recently, NGOs have been attempting to address critiques that REACH is too expensive and will stifle innovation. In doing this, they have worked closely with German NGO and government researchers examining the innovation questions. They are also attempting to identify downstream users of chemicals that might be supportive of the REACH proposal (a strategy that has been more effective at the Member State level). Responding to concerns about the dramatic projections of costs and job loss in some analyses has been critical, given concerns about labor opposition to REACH. A January 2003 report by WWF and EEB argues that cost estimates are grossly overestimated and have failed to consider the potentially positive effects on innovation and competitiveness of REACH; that the REACH proposal is flexible and provides opportunities for innovation; and that implementation of REACH will increase global competitiveness of the European chemical industry.

At the Member State level, NGOs have been active in shaping policy on chemicals – both government and industry. In some countries, however, such as in Germany and Norway, environmental organizations have been less active. NGOs have been most active in the following countries:

Denmark. NGOs in Denmark, funded for years by the Danish government, have been active players in shaping the country's proactive chemicals and product policies. The strong involvement of consumer organizations in that country has ensured that the Danish approach to chemicals includes a product component and is not only restricted to chemicals. Despite the fact that the main Danish environmental group lost its funding when the conservative government came into power in 2001, the government has maintained strong position on chemicals policy.

Sweden. NGOs in Sweden have long had a strong ally in the Swedish government. Government policy on chemicals in this country are very consistent with the NGO vision. The two main NGOs in Sweden – the Swedish Society for Conservation of Nature (SSCN) and Greenpeace – have actively participated in the various committees and processes for developing Swedish policy and have close ties with government. Given the government commitment to implement a strong chemicals policy – yet its restrictions because of the internal market – Swedish NGOs have focused on highlighting key problems and ensuring that hazardous chemicals are a public issue. For example, SSCN has initiated its Brominated Fire Retardants campaign to highlight the problems of the current chemicals policy in Europe and solutions. These groups are also working with industry to get them – retailers such as IKEA, electronics manufacturers, auto

manufacturers, and the construction firm Skanska – to move forward with implementing internal chemicals policies in absence of the binding, final REACH program.

Netherlands. Dutch NGOs have focused their efforts on participating in the development of the SOMS process, as well active campaigning on particular chemicals, facilities, and the government itself to implement policy changes. One NGO, the Netherlands Society for Nature and Environment, was one of the tripartite members of the SOMS process and has been active in pressuring Parliament to support its implementation. They have also been focusing on developing case studies of successful implementation of chemicals policies. Greenpeace has worked on demonstrating the problems of chemicals in products through sampling household dust for toxic pollutants (this was completed in several other countries).

UK. The three major environmental NGOs in the UK – Greenpeace, Friends of the Earth and World Wildlife Fund – have taken various strategies to advance UK movement on chemicals. They have participated in the Stakeholder Forum and other UK activities, but generally feel that these are more talk than action. They appreciate the greater UK government consultation with NGOs but feel that the government's approach is still too much based on voluntary action. Given this constraint, NGOs have focused their efforts on public education, market-based campaigning (for a much different reason than in Sweden) and right to know. WWF's efforts have served to highlight the issue of endocrine disruption in the UK, a central concern for UK government agencies, as well as actions to reduce it. Friends of the Earth, through its Safer Chemicals campaign has successfully convinced retailers to voluntarily develop integrated chemicals policies through a ranking system. It has also campaigned for right to know legislation to allow more active public campaigning. Greenpeace successfully engaged retailers to minimize the use of PVC and is now focusing its efforts on chemicals in products found in the house and how they can affect children. This campaign is built on very successful consumer campaigns to force retailers to stop selling products that contain genetically modified organisms.

Throughout Europe, environmental NGOs believe that there is currently a unique window of opportunity to institute large scale changes in chemicals policy, given public awareness, concerns over specific chemicals, and lost confidence in the chemical industry. Their bottom line is that they want a clear message that hazardous chemicals will be phased out (mandatory substitution). If they do not achieve this, they will believe the policy has failed.

Animal Rights Organizations

The animal rights movement – while made up of a diverse range of organizations from the radical to more mainstream – has been successful in making alternatives to animal testing a key issue in the development of the new European chemicals policy. The movement has been particularly strong in making animal rights a central issue in UK and German policy discussions. The movement has a non-negotiable position that they do not want a single animal test under the new REACH program and argue that testing to date has been less than useful or accurate.

One of the most active groups on the chemicals policy topic is the British Union for the Abolition of Vivisection (BUAV), which is working with People for the Ethical Treatment of Animals (PETA) on the "Harmful if Swallowed" campaign "to convince the EU to implement a

chemicals policy that will effectively protect the public and environment from hazardous chemicals without subjecting animals to hideous suffering in laboratories." This campaign supports the goal of getting the most harmful chemicals off the market, but believe that it can be achieved without any animal testing. They believe that with existing information, development of new testing techniques, and grouping of chemicals for testing, further animal testing is not necessary for safe use of chemicals. They feel that the guidelines in the White Paper on Chemicals are too vague to be helpful in estimating or reducing the number of additional animal tests needed.

These groups are therefore lobbying for investment in developing better alternative testing methods, and for an industry amnesty to encourage disclosure of available data. Right to know about animal tests already done and animal testing in general is key to reducing the reliance on animal tests. Further, they advocate for data sharing to minimize duplicative testing – in that companies would pre-register chemicals under REACH, disclosing all available data, and those firms wanting to use that data would pay the initial tester for its use. They also advocate for gathering of exposure information, which would allow the screening out of chemicals which do not entail "significant" human or environmental exposure.

The animal rights and environmental protection NGOs in Europe maintain a guarded respectfulness. Much of this has to do with the fact that the European environmental movement originated from the animal rights movement, particularly in the UK. For example the UK Green Party is closely aligned with animal rights organizations. Further, animal rights groups in Europe understand that governments do tend to act on data to prevent exposure. Nonetheless, the level of collaboration between animal rights and environmental groups – while greatest in Brussels – varies at the country level.

Because of the history of the environmental and animal rights movements in Europe (many environmentalists coming from the animal rights movement and vice versa) their primary goals on chemicals policy – substitution of the most harmful chemicals – are similar. To date, environmental and animal rights groups have collaborated on several occasions to develop statements on the REACH program as well as share information and strategies. They meet regularly to come to agreement on positions regarding chemicals testing and alternatives to animal testing. The two groups increasingly share information and work together, and influence each other. Through this interaction they are trying to avoid efforts by some industry groups to split them on the basis of animal testing issues.

Environmental groups have argued that the government and industry estimates of the amount of animal tests required under REACH are far too high, and join with the animal rights groups in demanding that as much existing information as possible be delivered by industry. Yet, the environmental movement still sees that obtaining basic information on chemicals as a key goal of REACH, which could include animal testing. NGOs in some countries, such as Denmark, are very supportive of the use of Quantitative Structure Activity Relations, for rapid screening and minimization of testing. The animal rights groups, however, are strongly opposed to the testing deadlines set by the environmental groups, believing that these do not allow enough time to develop and use non-animal tests. Both groups support a new regulation system, based on testing and chemicals evaluation which is fast, cheap, non-animal-based (to the extent possible),

and capable of regulating chemicals based on their intrinsic hazards and properties. To move the environmental groups more towards their position, animal rights organizations have been trying to apply subtle campaign pressure though not publicly attacking these organizations as has been the case in the United States.

Responses From Outside of Europe

There have not been widespread responses to the REACH proposal from outside Europe. Government responses have come primarily from the United States (see below), but also Australia, Canada, and Japan and other Asian countries. The Australian government has not issued a position for or against REACH but rather has requested clarification on the proposed policy to inform its opinion. However, coalitions of non-European governments and industry have commented on the REACH proposal.

In an August 2002 letter, the Chemical Dialogue of the Asia Pacific Economic Cooperation (APEC) forum expressed "deep concerns" regarding the potential impact of REACH in the APEC region. APEC is an organization designed to facilitate trade between Pacific nations ranging from Australia, to Japan, China, Russia, Singapore, the United States, Chile, and Canada. Its Chemicals Dialogue is a public/private section partnership to discuss trade and regulatory issues affecting the chemical industry and downstream users. The letter noted that the White Paper could impose a severe burden on the chemical and downstream manufacturing industries in the region. The letter requests the ability to provide input to regulatory drafts and that any regulatory impact analysis include potential trade effects on the region.

The Japan Business Council in Europe, representing downstream users of chemicals, issued a 2002 statement of general support for the REACH process outlining concerns regarding its implementation, particularly for downstream users. The Council noted that the policy needs to protect downstream users – particularly in sectors such as electronics – which innovate rapidly and need to use new chemicals that perform according to specifications. Further, the policy should encourage the formation of consortia and data cost sharing so that downstream users are not placed at a competitive disadvantage. Chemical producers, according to the Council, should be encouraged to take the fullest burden of implementing REACH. Finally, the Council Notes that since chemicals in finished articles are already covered under separate pieces of legislation (such as the Restrictions on Hazardous Substances Directive), REACH should serve as an "umbrella" legislation consistent with existing obligations. In a separate Statement, the Japan Chemical Industry Association, reiterated concerns presented by CEFIC on the potential impacts of REACH.

United States Government Response

The United States, one of the world's largest chemical producers and Europe's biggest trading partner, has taken a generally reactive response to the EU REACH initiative. While the U.S. government has not issued any "official" positions on REACH, it has been busy lobbying the European Commission and Member State governments to rethink and substantially modify their policy.

In February 2002, the U.S. government issued its "United States Nonpaper on EU Chemicals Policy". The "nonpaper" does not reference an author or agency. According to U.S. government officials from the Environmental Protection Agency and U.S. Trade Representative's Office it does not represent an "official" U.S. position but rather outlines concerns of the U.S. government on the EU White Paper. According to these officials, it was written and agreed upon by an intergovernmental workgroup, though the American Chemistry Council notes that it was the U.S. Trade Representative's Office that was a the lead agency. The Nonpaper has been personally delivered by high-level U.S. consular officials to European Union and Member State officials, making it in essence an official U.S. government position.

While stating that the U.S. government supports the general aims of the European White Paper, it outlines a series of concerns about the REACH program that could present obstacles to the global trade in chemicals. The U.S. government concerns include:

- High costs of testing and unrealistic timelines
- Effects on U.S. chemicals production
- Reduced consumer choice
- Disproportionate effects on small- and medium-sized companies and developing countries
- Overly narrow exemptions for research and development, polymers, and low-risk chemicals
- Use of the precautionary principle could lead to arbitrary decisions, unfounded in science

Of particular concern is the authorization process, which if applied to imported products would hurt U.S. manufacturers. The U.S. government argues that authorization might violate World Trade Organization rules (by being more restrictive than necessary) and would reduce consumer choice by removing useful chemicals from the market. Using figures supplied by the American Chemistry Council, the Nonpaper estimates that applying the authorization process to just four chemicals could result in $8.8 billion of downstream products being at risk of bans or severe restrictions. This could have negative job implications in the U.S.

Another U.S. government concern is that the White Paper approach represents a move by the EU away from greater coherence of chemical regulatory approaches among OECD countries. The U.S. argues that harmonized approaches, lowering unrealistic standards in the White Paper, while raising U.S. and other country standards is the most effective way to achieve improved chemical control.

While the U.S. government raised concerns in its Nonpaper about barriers to trade if REACH were to be implemented, discussions at the November 2002 Trans Atlantic Business Dialogue meeting (an organization which promotes dialogue between European and U.S. businesses and government officials) indicate that the U.S. government now does not believe that the REACH program would violate World Trade Organization Rules. The government is now focusing its critique on the lack of sufficient European consultation with U.S. officials regarding REACH. The U.S. and European Union recently entered into an agreement to better coordinate and discuss key legislative proposals. Based on this agreement the U.S. government believes that it should be able to comment and influence early drafts of the legislation. European Commission

officials argue that their first priority is to consult with their own Member States before consulting with foreign governments, such as the United States.

The U.S. Commerce Department, Trade Representative's office, and State Department (through the U.S. Mission to the European Union) have taken a lead in critiquing the European REACH system, often misrepresenting its elements and using American Chemistry Council cost estimates as if they had prepared by the government. These officials have met regularly with European officials to outline U.S. concerns regarding REACH program. They have also met on many occasions with industry to hear their concerns and formulate a reaction to the European initiative. In speeches and publications U.S. commerce and trade officials have encouraged industry to get engaged and to offer concerns and complaints on the proposed legislation. The U.S. Mission to the European Union has set up an informal roundtable on chemicals consisting of industry officials and consultants to discuss the EU policy initiatives. The U.S. Environmental Protection Agency appears to have taken a more constructive approach, critiquing and providing input to European colleagues on technical and feasibility aspects of the European proposal

However, until September 2002, U.S. government agencies had not approached or met with U.S. environmental and public health organizations to discuss their concerns on the REACH initiative. This is logical in some ways, given a lack of response by these organizations to the European REACH initiative. In October, 2002 U.S. environmental, public health and labor organizations wrote a letter to the President outlining concerns over the U.S. reaction to REACH. They argued that the U.S. government position should reflect both advocate's and industry's views on the European proposals. At this point, while the U.S. government is actively lobbying against the White Paper and its REACH proposal, it is unclear what stance the U.S. will take with regards to the May 2003 REACH legislative proposal.

U.S. Industry Response

The response of U.S. industry to the REACH proposal has been dominated by the American Chemistry Council (ACC) though specialty chemical manufacturers, consumer product manufacturers, and electronics manufacturers have also made comments. ACC analysis on the economic impacts of REACH served as the basis for the U.S. government February 2002 Non-Paper. ACC concludes that REACH will have the following impacts:

- U.S. chemical exporters are expected to pay about $400 million over the course of the 11-year program for data generation and program administration. The cost could be much greater, especially if the authorization process is unduly burdensome.
- Virtually all U.S. chemical exports—currently representing about $17 billion annually in sales—would be affected adversely by the proposed EU policy. Particularly at risk are exports of chemicals subject to EU authorization. In the year 2000, the annual value of these exports was conservatively estimated to be between $171 million and $918 million.
- If the proposed EU policy addresses chemical constituents in finished products, the impact on U.S. exports would be wide in scope. Examination of just four commercially important chemicals on the EU potential authorization list shows that $8.8 billion worth of U.S. exports are at risk.

- If the EU is successful in targeting finished products made from chemicals, the impact would be far reaching because (1) production of nearly all U.S. exports involve chemicals subject to the proposed EU policy; (2) confidential business information would be disclosed, affecting the decision to export; and (3) innovation would be adversely affected.

The ACC concludes that testing will be much more expensive than predicted by the European Commission and that a broader range of costs must be considered, including the social implications from loss of access to beneficial products. However, the analysis fails to consider the possibility of consortia to develop and share costs of data and that when a chemical is subject to authorization, this does not indicate an immediate ban. *Further, a separate ACC analysis indicates that authorization for known and probable carcinogens, mutagens and reproductive toxicants would likely only apply to about 104 chemicals (the others not being commercially used or being petroleum and coal by-products).*

In April 2002, the American Electronics Association, the Electronic Industries Alliance, the Information Technology Council, the National Electrical Manufacturers Association and the Semiconductor Industry Association issued a statement of concern on REACH. These associations of the electronics industry are particularly concerned about the application of the REACH program to chemicals in articles and how this might slow the innovation and development of new products in this industry that has short product lifecycles and rapid innovation. These organizations argue that the proposed system places too much scrutiny on too many chemicals; that the burdens on downstream users is unclear and that many concerns can be addressed through existing policies such as the Restrictions on Hazardous Substances Directive.

U.S. industrial organizations have engaged in targeted lobbying in European to soften the Reach proposal. In November 2002, several trade organizations representing the chemical, agriculture, nutrition, and cosmetic industries issued a letter to U.S. Trade Representative Robert Zoellick, arguing that the U.S. government respond to "veiled barriers to trade" being promoted in the name of protecting health in Europe. They suggest that all regulation on health and environment be subject to the following criteria to avoid trade barriers: justification based on sound-science; proportionality of costs and burdens; reasonable burdens of proof; transparency and consistency; and more trade restrictive than necessary. These organizations have worked with their European counterparts through the Trans-Atlantic Business Dialog to influence the REACH process, including arguing for greater analysis of the impacts on small- and medium-sized companies and downstream users, as well as prioritisation of the new system on chemical uses posing the greatest risks.

10. Lessons Learned from the European Chemicals Policy Process

This report has examined the development of a major policy shift in chemicals management regulation in Europe. In examining the evolution of the REACH proposal there are many important lessons on the strengths and limitations of the European and Member State approaches that warrant further analysis. Many of the strengths and limitations have to do with the structure of the European Union. For example, technical support, centralized data collection and enforcement, and post-implementation analysis would typically be tasks conducted at the Member State level due to the lack of expertise and resources at the European Union level. However, if the goal of the European Union is a new centralized approach to chemicals policy, it will need to ensure that adequate resources are available to central authorities to achieve that goal. It is hoped that this analysis can inform global debates on the most effective approaches to chemicals policy, particularly in the United States. These are likely to be politically and culturally dependent.

We present a series of lessons from the Lowell Center's research on European chemicals policies below. Many other key points and lessons are integrated into the text of this report and are highlighted when possible.

A. *A major change in chemicals regulation is moving forward at the European level.*

There is little doubt now that the European Union will finalize draft legislation to implement the REACH program in 2003 and that it will eventually be approved by the European Council of Ministers and Parliament (though perhaps with some modifications from the European Commission's proposals). The European Commission is proposing a large-scale change in chemicals regulation that requires basic information on all chemicals in commerce, places responsibility on industry for assessment and safety of chemicals, and restricts those chemicals of highest concern. Experience indicates that once a White Paper and legislative proposal are developed by the Commission, legislation is very likely to be passed. This provides an important signal to the regulated community to begin implementing changes that will be required in some years.

The European Union has been able to achieve this policy shift through a concerted, carefully planned, and long-term process of engaging stakeholders in discussing the problems of chemicals management and solutions. A series of policy failures and public understanding of the risks of everyday chemicals has created the right atmosphere for change. This transparent process and public debate has led to a situation where even the chemical industry must acknowledge the need for fundamental change in policy, and thus can only argue about the details of the approach.

The European Commission, with support from Member States and advocacy organizations has been able to create the conditions that support a broad legislative change and ensure its ultimate passage and implementation. While the proposed policy may not be as strong as some stakeholders, such as environmentalists, would want, the actual process of developing the White Paper and publishing the draft legislation provide a strong impetus for advancing implementation

of voluntary and regulatory chemicals management policies in EU Member States, the EU itself and internationally. The process establishes a new "culture" in chemicals management.

This new understanding and culture in chemicals management may be the greatest success of the REACH proposal. Discussions leading to REACH have been able to highlight the fact that most chemicals in commerce lack basic test data, that they are used without limitation in processes and products and that the burden rests on governments and the public to collect data and demonstrate damage before action occurs. The REACH proposal changes this existing paradigm by stating that all chemicals should be monitored and managed, that industry should have the duty for managing chemicals, and that the burden of proof should be shifted for chemicals of concern – rather than unrestricted use of problem chemicals, industry should have to apply for permission to use them, much like the pharmaceutical industry must be granted permission before marketing drugs.

B. *The REACH proposal represents a far-reaching change in chemicals regulation that will require attention to many complex implementation details.*

The REACH proposal represents the most detailed chemicals regulation in the past thirty years and will affect thousands of chemicals and producers. Given its size and complexities it is thus logical that the draft legislation has taken several years to draft. The European Commission has further engaged stakeholders in the development of the proposed REACH legislation, allowing informed debate on the nuances and complex details that accompany a major legislative proposal. The European Commission and stakeholders clearly want a system that does not adversely impact industry; that achieves results in terms of improved information on substances and reductions in priority substances; that does not overload regulators; and that does not repeat problems of previous chemicals regulations.

Through working group and Member State authorities discussions, as well as stakeholder reports, it has been possible to understand the complex details of implementing a major policy shift. Several key areas of debate during the REACH drafting process include: the extent to which downstream users of chemicals, product manufacturers, and importers will be included under REACH; the scope of the registration and authorization processes in terms of requirements, chemicals covered, and exemptions; ensuring improved information flows while protecting trade secrets; and the distribution of responsibilities between governments and industry. The centralization of a decentralized chemicals management system in Europe as well as enforcement of the programs have presented an important challenge.

Leaving sufficient flexibility in the REACH process (for example to allow data on surrogate chemicals or other alternatives to animal testing) as well as having a phased-in approach to its implementation are critical to helping ensure that problems and difficulties are quickly identified and fixed and to "learn by doing", while allowing the European Commission to measure the impacts of its implementation.

C. *Existing EU legislation and policy has achieved some successes in chemicals management.*

Current European chemicals legislation has been successful in some areas. New chemicals regulations have ensured basic testing for all new chemicals in commerce. The Dangerous Substances Directive has ensured labeling and classification of many harmful chemicals. The Limitations Directive has achieved restrictions on numerous chemicals, particularly carcinogens, mutagens, and reproductive toxicants in consumer available preparations. Other regulations, such as the Restrictions on Hazardous Substances Directive will restrict particular chemicals of concern.

Importantly, several pieces of occupational and environmental legislation have embedded the concept of substitution – that chemicals of high concern due to their inherent properties, risks, or exposures – should be substituted where feasible – in European legal policy regarding chemicals. For example, the European Commission has established that several classes of chemicals – carcinogens, mutagens, reproductive toxicants, endocrine disruptors, POPs, persistent and bioaccumulative toxics, and very persistent and very bioaccumulative substances – are of priority concern for regulatory attention based on their hazards alone.

Nonetheless, current legislation has been implemented generally though directives, which require Member State implementation. This means that enforcement likely varies from country to country. Further, the lack of centralized data on impacts of chemicals policies limits the ability to measure successes (see below).

Several Member States have gone far beyond the European Union in instituting chemicals policies. Sweden and Denmark have achieved important successes in integrating chemicals management into government and industry decision-making processes. Other countries, such as the Netherlands and the United Kingdom have been able to engage stakeholders in developing and implementing new approaches to chemicals management. Germany has commissioned research to support substitution in industry of problem substances. Several Member States have undertaken either voluntary or mandatory requirements to restrict chemicals of concern.

D. *The REACH program is likely to respond to problems of the current system, encourage internalization of chemicals management in firms, and to have positive environmental and economic impacts.*

It is likely that REACH will address the limits of the current chemicals management policies. For example, information on existing chemicals will become available and responsibility for the slow risk assessment process will, for the most part, be passed to industry with timelines for implementation. Evaluation will also be subject to timelines ensuring that risk assessments and management on chemicals of concern does not take years to complete. REACH also takes a sweeping approach to chemicals of concern, by shifting the burden onto industry to seek authorization for high concern chemicals, rather than assuming their safety until government takes action. As long as there are systems in place to ensure compliance with deadlines, progress towards implementation of REACH should occur.

The registration requirements of REACH have the potential to encourage improved information

sharing along supply chains. As chemical manufacturers and importers have responsibility to assess risks, there is an incentive for them to more effectively communicate with downstream users to obtain critical use data and for downstream users to ensure that they obtain hazard data from manufacturers. Improved data on materials is critical to ensuring improved materials management.

The requirements for testing and authorization also have the potential to stimulate innovation. Some firms will not want to undergo the costs associated with registration for chemicals that either might have characteristics that could lead to authorization or that are low margin or use. Equalizing the requirements for new and existing chemicals will provide an opportunity for some new chemicals – which in many cases could be safer replacements to older substances – to gain market share and growth. The authorization process can also stimulate innovation by forcing firms to identify alternatives to chemicals for which authorization would be necessary. Further, the stigma associated with a chemical being on the authorization list may be sufficient for downstream users and retailers to demand that manufacturers substitute them. Uncertainty as to whether a particular chemical subject to authorization will actually be authorized (or if a time limited authorization is revoked later on) provides another incentive for users of chemicals to find alternatives. Widely publishing a list of chemicals of concern subject to authorization could support this change in procurement among downstream users.

An important aspect of REACH is that it establishes industry responsibility for chemicals management – a general "duty of care." REACH creates a framework to enable and encourage industry to take responsibility before authorities require take regulatory action to restrict specific chemicals. The process of testing, risk assessment, and authorization is likely to internalize improved chemicals management consciousness in firms. The fact that European Commission policy proposals tend to ultimately result in legislation provides an additional incentive for industry to move forward now to voluntarily implement REACH type policies.

It is impossible to know with any certainty what the economic and environmental impacts of the REACH system will be. While several competing analyses have examined the economic impacts of REACH and one under development by DG Environment examines benefits of the program, the results will not be known until the program is implemented. What can be said is that the worst case impacts that have been suggested by some analysts will most likely not take place for several reasons: First, REACH operates in a realistic political system whereby the policy is not going to be implemented if it would force large sectors of industry out of business or result in the loss of hundreds of thousands of jobs; the European Commission will lose much legitimacy if the program fails or results in major impacts and thus is intent on developing a workable system and ensuring that problems can be remedied; and experience demonstrates that worst case scenarios almost never come to fruition and that companies often innovate to comply with new regulations. That said, it is quite possible that some individual firms or sectors may be adversely affected economically by REACH and thus may need support from government to address these impacts.

Given the high profile nature of the REACH legislation, it will be important for the European Commission to closely monitor economic and environmental impacts of the program once implemented.

E. *REACH will have large impacts on global trade in chemicals and force an upward international harmonization of standards.*

Given the implications of REACH for international trade of chemicals, the EU has taken great strides to integrate its approach to chemicals management in international policies and to ensure that their proposed legislation will survive a World Trade Organization Challenge. Harmonizing international chemicals standards upwards will help ensure the stability of the European legislation in the face of trade challenges as well as to protect competitiveness of European companies globally.

REACH will have clear impacts on companies in the United States and elsewhere wanting to sell products in Europe. This is particularly true for chemical producers who will have to comply with REACH rules for registration and authorization. However, U.S. companies have been complying for some 20 years with European requirements for testing of new chemicals, which are similar or even in some cases more stringent than what would be required under REACH. Downstream users of chemicals and product manufacturers will have less stringent requirements at the registration stage but would potentially have greater regulatory hurdles at the authorization phase. There is some evidence that companies in some downstream user sectors, such as automotive parts and electronics, are already beginning to implement REACH, particularly though lists of chemicals for substitution.

REACH, combined with recent chemical incidents in the U.S., for example on brominated fire retardants and perfluorooctanylsulfonates, will inevitably force a debate on chemicals management in the United States. It will be up to the U.S. Environmental Protection Agency, state governments, and other stakeholders to ensure that this debate occurs. Nonetheless, the U.S. is at least several years behind European countries in public discussions on chemicals policy. There is a need for that discussion to occur before major policy proposals can be initiated.

F. *Chemicals policies being currently developed and implemented at the Member State level in Europe are more integrated, pragmatic and diversified than those proposed under the new European chemicals policy. However, they will ultimately be impacted by the EU decisions.*

Much of the international discussion about REACH has occurred in absence of a discussion about the rich policy initiatives that have moved forward in the Member States. As previously discussed, these policies, many of which are voluntary, incorporate a variety of regulatory and non-regulatory tools including: gathering of information on chemical risks, development of lists of chemicals of concern, procurement, taxes, research, technical assistance, and demonstration projects, information and labeling, emissions permitting requirements, and mandatory phaseouts. The Netherlands has, for example, has focused on pragmatism and consensus in its chemicals policy – trying to fill in information gaps with any information available and encouraging industry to rapidly assess and act on chemical risks. The Dutch have used sectoral "covenants" as one approach to encourage change while providing sufficient flexibility to industry. Several countries also have integrated chemicals policies into product policies, achieving a more holistic approach to chemicals use. This results in a more holistic approach that can take advantage of

several places along the lifecycles of chemicals to reduce impacts. It also can lead to a greater internalization of chemicals management consciousness in firms and government agencies as a wider range of actors are involved in implementing policy.

Nonetheless, the ability of countries to implement their policies will be directly affected by the REACH proposal. While Member States will be able to continue voluntary policies – such as lists of chemicals of concern and procurement and those that do not affect the internal market, such as emissions restrictions, and mandatory restrictions and requirements that may conflict with REACH requirements will be more difficult to implement.

Potential limitations with the EU REACH proposal and chemicals policy efforts to date

Despite the strengths of the REACH proposal, outlined above, our analysis has identified several gaps or limitations in the European approach. The REACH proposal represents an important attempt to remedy the limitations of current chemicals policy. However, it could be substantially strengthened, becoming a more holistic and integrated approach, by addressing some of the issues discussed below.

1. *Limited data on measurement of economic or environmental impacts of existing policies.*

It is virtually impossible to understand the impacts of policies or improve their implementation without data on costs and effects of reductions in chemical use or emissions. Yet, the European Commission and Member States rarely conduct retrospective impact analyses of policies. In some cases Member States developing risk management plans under the Existing Substances Regulation develop impact assessments on measures already taken, but only few such plans have been developed.

For example, while there are almost 900 chemicals on the list of restricted substances under the Limitations Directive, there has been no analysis to understand whether those substances are still in processes and products and to what extent different countries have been successful in implementing the restrictions. The capacity of different Member States to analyze impacts of policies is varied.

While Sweden notes that it has phased out numerous substances, there is little data to understand whether they have actually been removed from commerce and the costs and impacts of that policy. It is true that if a chemical restriction had severe adverse economic impacts, that information would likely be readily available; however, information on positive impacts would need to be collected. It also is clear that information linking reductions in chemical use with improvements in health would be nearly impossible to collect due to the limits of epidemiology and complex determinants of environmentally-related disease.

There have been several projections of the impacts of REACH, which mainly focus on costs of implementations and not benefits (though the European Commission is currently finishing one such analysis), but it is not in the culture of European governments to understand what has happened after policies have been implemented. There are two reasons for this: first, it is expected that environmental regulations will be good for health and the environment and that

health is a priority; and second, regulators would rather spend scarce resources tackling new problems instead of looking back of decisions previously made. An important result is that at the European level authorities do not have the resources or power to collect this type of information. The application of legislation and data collection to date have been predominately Member State issue.

Some Member States such as the UK, Germany, Sweden, and Denmark have collected limited post-implementation impact data on chemicals policies. The UK collects such data at times to support regulatory impact assessments of new policies. The Norwegian government's recent analysis of impacts of a tax on the use of perchlorloethylene and trichloroethylene represents the type of analysis that provides support to understand the efficacy of different approaches to chemicals policy. The Norwegian statistics office noted a more than eighty percent drop in use of these two solvents as a result of the tax. The Nordic Product registers provide an interesting data source for understanding reductions in chemical use in products. The various registers, which keep track of chemicals (type and quantities) used in products have been compiled into a database called the SPIN database, though no publicly available studies of changes in chemical use have been conducted using the data.

The lack of post-implementation data collection represents a critical gap in the European approach to chemicals management, and one that makes regulators and others in other countries, such as the United States highly skeptical of the impacts of European policies. The lack of such data inhibits the ability to understand the efficacy of various policy tools, impacts of enforcement, and the overall impacts of policy on chemicals management culture and the economy.

Centralization of registration and authorization data under REACH will provide additional data to understand the numbers of chemicals in commerce, the level of data available and the particular uses that have been authorized. It will be important to develop databases that allow useful analysis. Nonetheless, additional structures for examining impacts will be needed. At this point, REACH does not include sufficient data requirements or attention to this problem.

2. *Limited linkages to technical support and research and development policies.*

The White Paper on Chemicals and other analyses assume that the registration and authorization procedures under REACH will lead to innovation in safer chemicals and processes. While in many cases this may be true, the potential innovation impacts of REACH may be limited by relying on only a regulatory approach.

Analysts of technology change note that innovation requires a series of conditions to be successful, which can be termed "willingness and capacity" or "motivation and facilitation". The REACH legislation itself institutes willingness by requiring data collection and action on particular chemicals and by instituting a culture of sustainable chemicals management. However, capacity or facilitation oftentimes are as important or more important factors for stimulating innovation as is regulation. Industry is not always that innovative on its own, particularly small- and medium-sized companies. Thus, support for innovation through technical

assistance, information, and research support on process design, chemical synthesis, and green chemistry should play an important role in implementation of a new chemicals strategy.

But such support is missing from the REACH proposal. While the European Commission has established research support grants to small- and medium-sized companies as a key part of its research strategy (innovation in SMEs is an important part of DG Research's program) and other research support opportunities do exist, there is no integration of these efforts with the regulatory framework being established under REACH. Similar to the problem with post-implementation economic and environmental analyses, much of this type of support would be provided at the Member State level, and it is true that some countries such as the UK, Germany, the Netherlands, Denmark, Sweden, and Norway have been providing support for demonstration projects, research on new technologies, and substitution methods.

However, if REACH is to institute a European-wide approach to chemicals management, it will be necessary to more effectively centralize and coordinate innovation efforts, so that industry in countries with less resources to support industry research and development are not left behind. One option would be to take a percentage of the fee on chemicals proposed under the REACH policy to fund a central agency that will provide voluntary technical assistance on chemicals so that industry then obtains something in return for the fees they pay on chemicals.

The March 2003 European Commission Communication on Developing an Action Plan for Environmental Technology, could provide an important impetus for support to more environmentally friendly chemicals and processes. The Communication builds on the European Union's Lisbon Strategy which states that the Union should invest at least 3% of GDP on new technology research and development. The Communication argues that this investment should be directed towards more environmentally-friendly technologies and it outlines an approach to addressing barriers to their development and marketing. It will be important to effectively integrate this action plan with the REACH process to achieve greater benefits from the new chemicals strategy.

3. *Limited integration of REACH with other policy tools.*

The current EU policy focuses on a single tool for its chemicals management strategy – Registration, Evaluation and Authorization, to the exclusion of the more integrated multi-tool approach of some Member States. Testing of chemicals and authorization alone may not achieve the ambitious goals of the new chemicals policy, though they are a critical part of an overall approach. For example, the list of chemicals subject to authorization could be used as an "observation list" much like the Swedish, Danish, and Norwegian lists, which guide procurement decisions, voluntary initiatives with industry, and enforcement/permitting actions.

It also is true that certain aspects of existing policies, such as designation as a dangerous substance under the Dangerous Substances Directive, can have numerous "downstream" implications for other policies. The new policy will maintain those implications. However, REACH could be substantially strengthened if integrated with product policies – such as the Waste from Electronic and Electrical Products, and other directives, green chemistry and

sustainable design initiatives, demonstration projects, labeling efforts, multi-media permitting, etc.

For example, following the publication of the White Paper on Chemicals, the European Council of Ministers called on the European Commission to incorporate consideration of Integrated Product Policy into the REACH proposal. In February 2001, the European Commission issued a Green Paper on Integrated Product Policy. The Paper proposed a strategy to strengthen and refocus product-related environmental policies to promote the development of markets for greener products. Integrated Product Policy is defined as "an approach which seeks to reduce the lifecycle environmental impacts of products from the mining of raw materials to production, distribution, use, and waste management." In essence it integrates concerns about toxicity of materials with those about materials intensity (conservation) into a package of tools and instruments (such as ecolabeling, takeback, etc.) aimed at stimulating more sustainable design (for durability, longevity, reduced material use/toxicity, etc.). Despite the calls from the Council for REACH to include Integrated Product Policy concepts, and efforts in some Member States, such as Denmark, to integrate chemicals and product policy, there is no particular product policy component of the REACH proposal.

In addition to the lack of a product policy orientation in REACH, there is no mention of cleaner production. Cleaner production efforts – process and product redesign to reduce risks at source – could lead to substantial reductions or even elimination of particular chemicals or groups of chemicals of concern (both acutely and chronically toxic), providing synergistic benefits to the REACH effort. A focus on cleaner production is particularly important as a way to engage downstream user sectors in the REACH process. For downstream users, chemicals provide a "service" (for example chlorinated solvents provide cleaning or degreasing) that may be provided using a less toxic material. In Massachusetts, through the Toxics Use Reduction Program, manufacturers have reduced toxic chemical use by some 40% over a 10 year period through cleaner production – including substitution – efforts, saving these companies some $14 million, not including environmental and health and safety benefits. Unfortunately, the Commission has focused its stakeholder outreach on chemical manufacturers and not enough on downstream users and retailers of chemicals who have much more to gain from REACH.

A truly integrated European chemicals policy would consist of voluntary and mandatory tools, technical support and research structures on chemical risks and alternatives, and a consideration of lifecycles of substances and their use in products. It would also integrate protection of consumer and environmental health with occupational health. To date, REACH has been limited in its addressing occupational health, though the Commission notes that a substantial portion of the benefits from REACH will come from improved occupational health. Yet, the Commission has failed to effectively engage trade unions and occupational health professionals in the REACH debate and may even alienate workers by limiting treatment of intermediates.

Given the structure of the European Union, an integrated chemicals policy approach at the EU level might be difficult. As such, REACH could stimulate the development of Member State integrated chemicals programs such as those that have been analyzed in this report.

4. *Limited Linkages of REACH with product and process design concerns.*

The White Paper on Chemicals and legislative proposals discuss REACH's impacts on substitution and development of safer chemicals. We have noted that the proposal does not go far enough in providing incentives and support for the development of safer chemicals and processes. The proposal also fails to consider the implications of substitution or chemical reduction on process and product design. A chemical substitution can often result in substantial changes in work organization and worker, community and environmental exposures; it is a process change.

Support for cleaner production in the REACH process, can ensure that manufacturers, downstream users, and retailers consider the potential trade-off risks involved in chemical substitution and to consider other options for reduction in hazardous chemicals use (e.g., process efficiency). These may not be only chemical risks but also physical and psychosocial risks associated with changes in work patterns. A cleaner production focus may also help reduce exposures to other chemicals that may not be of high concern under REACH but may be of concern due to their potential for safety or accident risks.

A second concern is one of technical feasibility. While registration and authorization may result in substitution, the alternatives may not provide the same level of product quality or characteristics. For example, in one case, a pharmacy company wanting to substitute nonylphenols in its products, found that it would need many other chemicals to provide the "service" that nonylphenol provides across various types of products. A great concern for companies is product quality, and if product quality will be reduced as a result of substitution, managers will be hesitant to move forward. A cleaner production and product design focus would help integrate such decisions into the substitution process. While this concern should not stop the substitution process, it is an important consideration. Technical support to firms in substitution could play an important role in ensuring safer and technically feasible alternatives.

While a goal of substitution is to move towards safer chemicals, it is important that this occur without trading off risks between the environment, consumers, and workers. This can be achieved through a greater focus on cleaner production and product design as well as the development of concrete processes and technical support for substitution, particularly for small- and medium-sized firms.

It would be useful for the European Union to investigate and develop a guidance document for substitution efforts to support substitution planning and minimize potential negative impacts of REACH. Some governments, such as the UK and Germany have already engaged in such efforts. Further, the Commission could strengthen substitution capacity at the firm level by providing software to assist firms in evaluating and comparing alternative process conditions and chemicals. Such software has been developed by the U.S. Environmental Protection Agency and provides a tool for "internalizing" smarter substitution decisions at the firm level.

5. *Improving rapid assessment and action on chemicals*,

One potential pitfall of REACH is a focus on data collection and detailed assessment leading to

the types of delays experienced in the current system. One concern of industry is the vast amount of data companies will have to compile on chemical toxicity and uses. The Commission has responded to these concerns with substantial revisions to earlier REACH proposals allowing the use of surrogate data and requiring data sharing. This shifts the goal of the registration process from simply testing to gaining sufficient information to make informed decisions. To allay an additional concern that industry will just be providing data that will never be used, the Commission needs to ensure that data are made publicly available and that sufficient databases are developed so that information can be collected and applied to make more rapid decision-making possible in the future.

While REACH includes deadlines for evaluations and authorization and limitations decisions, it will be critical to ensure that such deadlines are kept. REACH could be substantially strengthened by learning from the U.S. system for new chemicals review under the Toxic Substances Control Act (TSCA). Under TSCA, EPA undertakes a detailed, multi-disciplinary review of new chemical substances using actual test data provided by manufacturers, data from structure activity relationships, and data on some 30,000 chemicals previously reviewed. This review examines toxicity, fate, exposures, potential production, and, in some cases, pollution prevention opportunities. The rapid assessments undertaken by EPA build on accumulated experience and understanding of chemical toxicity and exposures and expertise of staff.

Such rapid assessments would allow the Commission to more effectively use data collected, prioritize chemicals or classes of chemicals for risk management, and to act quickly on accumulated knowledge. However, such rapid assessments rely on sufficient expertise being available. It is unclear at this point whether the central agency will have this level of expertise.

6. *Limited centralization of a currently decentralized system.*

REACH will centralize in some ways what has been a decentralized chemicals management system in Europe. However, while creating a new centralized chemicals agency, REACH as proposed maintains much of the decentralization of the current system. This may work against the integrated approach that the Commission hopes to implement through REACH. It is true that Member State authorities have greater access to firms and better communication with managers increasing the potential influence of REACH on firm-level decision-making. This ability for Member States to work with their firms and consumers to reduce chemical risks and use of problem substances through a variety of tools should be maintained. However, expertise, as well as enforcement, will be substantially different between Member States. REACH attempts to establish a strengthened and coordinated enforcement system, but it is unclear how it will fix weaknesses of the past.

REACH could be substantially strengthened by increasing the centralization of expertise in the new chemicals agency. A more centralized risk assessment review process would ensure a single high standard for chemical analysis and risk management review, limiting long term debates over the nuances of each assessment by Member States (though Member States would still maintain ultimate decision authority as is the case in the European Union). It will also ensure that all Member States have access to the same high level of technical expertise to implement chemicals policy efforts and take advantage of the scientific and technical strengths

of the entire European Union. Such centralization could be combined with centralization of technical support on alternatives substances and processes.

One weakness in the REACH proposal is limited attention to enforcement. For example, the proposal does not indicate how a Duty of Care would be enforced by authorities. Further, there are no provisions to ensure that deadlines are maintained, particularly by authorities. One critique of the existing system is the slow nature of risk assessment and risk management and while there are timelines set in the REACH proposal for evaluation, restrictions, and authorization, there are no penalties should the deadlines not be met. One option would be to include "hammer provisions" that enforce some action if deadlines are not met. Further, since enforcement capabilities differ by country, a more centralized enforcement process would also help ensure a level playing field in the European Union for businesses and equal levels of protection for consumers throughout Europe.

7. *Limitations in information development.*

Information is critical for companies, authorities and the public to understand and act on risks. The REACH proposal significantly expands data on chemical toxicity, possible exposures, and uses throughout supply chains. Much of this information would be provided to the public, though concerns have been raised by NGOs and some others about limitations in right to know and overprotection of confidential information in the proposals. However, the REACH information requirements provide little information on chemicals use and emissions or material flows. As noted above, the registration requirements will likely enhance supply chain information flows but it is unclear whether they will improve materials management as information on toxicity and exposure will not necessarily lead to development of information on materials use. To more effectively harness the forces of information for stimulating safer and cleaner substitutes, some modifications to REACH would be useful.

REACH does not include requirements for firms to understand their materials use or flows. Experience with toxics use reduction in Massachusetts has found that many companies are extremely inefficient in chemicals management, with information on chemicals use being dispersed throughout the firm. When firms are required to conduct a materials accounting (how the chemical comes into the firm, is transformed, and leaves the firm), many recognize this inefficiency in materials management and institute programs to improve efficiency and reduce risks. Materials accounting (combined with facility planning) has thus been of critical importance for stimulating toxics use reduction in Massachusetts.

Similarly, the Toxic Release Inventory requirements of the 1986 Emergency Planning and Community Right to Know Act in the U.S. have led many business leaders to institute production and product changes for pollution prevention.

Including materials accounting requirements or at least strongly encouraging and supporting firms to do so, would greatly increase the efficacy of REACH, particularly for downstream users, by stimulating improved materials management in addition to data on hazards of chemicals in products.

Another area where the proposal could be strengthened is in information on alternative materials, substances, and processes. Knowledge of these alternatives to hazardous substances is critical for stimulating their adoption by firms. Massachusetts experience has found that firms are much more willing to substitute a problem chemical and more quickly when presented with information about feasible alternatives.

Finally, the proposal's confidential business information provisions provide protection for information that is currently available in the trade press or publications such as the Chemical Economics Handbook. It is important that risk information as well as any information relevant to exposure – such as production levels, emissions, etc. not be considered confidential. In cases where there are legitimate confidentiality questions, the burden should rest on those requesting such protection industry to provide evidence supporting such claims. Indeed much information deemed proprietary is often well known within the industry itself and some industries, such as metal platers, have a long history of sharing information.

Provision of information should be an active requirement of firms, particularly to workers and community members who request such information. The use of an Internet database is important – for information on risk and regulatory actions.

11. CONCLUSION

Our analysis has shown that the European Union is moving forward with an ambitious new chemicals policy – Registration, Evaluation and Authorization of Chemicals (REACH) to correct many of the limitations of existing chemicals regulation that have surfaced over the past twenty years. The development of this new European framework has been the result of extensive debate and stakeholder consultation. This slow, thoughtful process has strengthened the momentum for reform and public awareness about the need for a new approach.

The REACH proposal eliminates the distinction between new and existing chemicals, requiring basic information on all chemicals in commerce produced above one ton per year. For chemicals of very high concern on the basis of their hazardous properties – persistence, carcinogenicity, etc. – the proposal requires that firms apply for authorization, much like for drugs – to continue using those substances. The goal of the REACH proposal is to stimulate substitution of problem chemicals and development of safer ones through information requirements, facilitation of supply chain communication and restrictions.

The REACH proposal has been heavily influenced by European Member States and several international initiatives, particularly those emanating from the northern European countries. While influenced by policies from countries such as Sweden, Denmark and the Netherlands, the REACH proposal does not have the type of integrated approach to chemicals management – using multiple regulatory and voluntary tools, providing support to industry, etc. – found in these countries and as such is limited in some ways. The proposal could be substantially strengthened through more effective integration with other policy initiatives, such as those on Integrated Pollution Prevention and Control, Integrated Product Policy, and environmental technology. The European Union could take numerous steps to enhance the positive innovation impacts of REACH by providing technical and research support to firms in substitution as well as in assessing chemical risks. To the extent possible the Commission should use whatever tools it has at its disposal to internalize more sustainable chemical decisions at the firm level.

It is likely that REACH will have substantial impacts in reducing exposure to hazardous chemicals – through the authorization and information requirements as well as market forces. The registration and authorization requirements also will have an important impact on the chemical industry and downstream sectors in Europe and beyond.

The impacts in terms of costs to industry and potential for stimulating innovation are unclear at this point. What is clear is that there is a lot of misunderstanding about the requirements of REACH, particularly on downstream users and producers of products, generally overstating the requirements for these sectors. There is an incentive for users of chemicals to put as much responsibility on producers to develop information and to develop safer alternatives to chemicals of high concern. For most chemicals, REACH will consist of a notification procedure, much like that which is already conducted for new chemicals. There is a requirement to reduce testing responsibilities on individual firms by sharing data and using surrogate information to assess chemical risks when possible. The goal is sufficient information to ensure an understanding of chemical risks and institute appropriate safety measures.

In the short term, it is important that the European Commission move forward to test aspects of REACH in particular sectors – to understand how it would work in practice and to make necessary changes to ensure its workability. This could be done on a voluntary basis. For example, the Commission has been working with stakeholders on the development of a strategy for very Persistent/very Bioaccumulative chemicals and Persistent Bioaccumulative Toxics that would utilize market and regulatory forces to stimulate substitution of these chemicals. Since the proposal has engendered so much debate, the European Commission must ensure that the REACH system provides results. Flexibility to make mid-course corrections and strong enforcement will be crucial to ensuring the success of the system. Because it is highly likely that REACH, like previous European Commission legislative proposals, will get passed, there is a strong incentive for companies and governments to begin preparing for the changes to come.

While the European Commission will likely finalize its legislative draft by fall, 2003, given delays to date, it is unlikely that even a first reading in the European Parliament will occur before summer 2004, when 10 new states from Central and Eastern Europe join the European Union. While some of these states may be receptive to the REACH proposal, others may find it very costly to economic development. While the influence of these new nations is likely to be small in the Union (only a small number of Parliament seats will be given to the new nations), their influence could change the draft to provide relief to firms from the region or to reduce requirements for all firms.

The influence of REACH on the development of integrated chemicals policy in the United States is unclear at this point. For manufacturers in the United States, REACH will likely provide a market and regulatory impetus for chemical substitution and internalization of chemicals policy considerations at the firm level. At any rate, given the unique nature of the U.S. regulatory system, some of the policy tools that have been in the Member States of the European Union might be more effective in the U.S. context. Policy makers at the state and federal levels in the United States should take advantage of the REACH proposal to stimulate a similar debate in the U.S. on the strengths and limitations of current chemicals regulations in order to identify politically and culturally appropriate solutions.

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13. EXPERTS INTERVIEWED

The following list includes the majority of individuals interviewed for this project. Some perspectives were obtained through short discussions with stakeholders at various conferences and meetings in the U.S. and Europe and are thus not included. In total more than 50 people were interviewed for this report.

European Union

Axel Singhofen – European Parliament
Robert Donkers, Catherine Day – European Commission, Directorate General Environment
Stefan Scheuer – European Environment Bureau
Reinhardt Schulte Braucks, Andrew Fassey, Nick Burge, Egbert Holthuis, European Commission Directorate General Enterprise
Nicolas de Sadeleer – University of St. Louis
John David Matthews – Rhodia
Uta Jensen-Korte, Bertil Heerink – CEFIC (European Chemical Manufacturers Association)
Jorgo Iwasaki-Riss – Greenpeace
Reinhard Reibsch – European Mine, Chemical and Energy Workers Union
Emily McIvor - British Union for the Abolition of Vivisection
Michael Warhurst, World Wildlife Fund

Netherlands

Marc Koehne – Stichting Naturur en Milieu
Frank Patterson - Greenpeace
Dick Jung, Jan van der Kolk, and Arnold van der Wielen – Ministry of Environment
Jabjela Feenstra, Saeda Moorman – Dutch Parliament
Wybe Douma – Asser Institute
Ad Vijlbrief – Ministry of Social Affairs and Employment
Dirk van Well – Dutch Chemical Industry Association

Denmark

Finn Bro-Rasmussen – Technical University of Denmark
Jacob Jessen – Danish Chemical Processing Industry
Christian Ege – Danish Ecological Council
Allan Andersen - Danish Society for the Conservation of Nature
Lisbet Seedorf – Danish Environmental Protection Agency
Jorn Jespersen, Janus Hilgaard – Danish Parliament
Jesper Lund Larsen – Danish General Workers Union

Sweden

Eva Sandberg, Viktoria Ljung, Monica Törnlund – Swedish Ministry of Environment
Anita Ringstrom – Swedish Chemical Manufacturers Association

Jan Hammar, Ingela Andersson, Nils Gunnar Lindquist – Swedish Chemicals Inspectorate
Gunnar Lind – Greenpeace
Sven Nyberg – Swedish General Workers Union
Mikael Karlsson – Swedish Society for Conservation of Nature.
Johan Gerklev – Skanska
Annelise Larsen - Ikea

United Kingdom

Colin Church – Department of Food
Mark Strutt - Greenpeace
Mike Barry – Marks and Spencer
Bob Warner – UK Health and Safety Executive
Patrick Walsh - Department of Trade & Industry

Germany

Uwe Lahl, Ralf Wessels – German Ministry of Environment
Jan Ahlers – German Environmental Protection Agency
Andreas Ahrens – Okopol
Nils Wagenknecht - FEU - Forschungsstelle für Europäisches Umweltrecht
Ralf Nordbeck

Austria

Thomas Jakl, Michael Wittmann – Ministry of Environment

Spain

Estefania Blount – Comisiones Obreras

Norway

Henrik Hallgrim Eriksen – Ministry of Environment

International

David Santillo – Greenpeace
Gunnar Bengtsson – Swedish Chemicals Inspectorate
Bo Wahlstrom – UNEP Chemicals
Cato ten Hallers Tjabes - Royal Netherlands Institute for Sea Research

14. About the Authors

Dr. Kenneth Geiser, Lowell Center Co-Director, is one of the country's foremost policy experts in the fields of toxics use reduction, pollution prevention, and clean production. He is a policy scientist who has worked closely with government agencies and non-profit organizations for many years on preventive solutions to environmental hazards. He is a Professor in the Department of Work Environment and founded and directed the internationally recognized Toxics Use Reduction Institute. He served on the core advisory council of the United Nations Cleaner Production Programme and serves on the Environmental Protection Agency's Toxics Data Reporting Committee of the National Advisory Council for Environmental Policy, and served on the Agency's Common Sense Initiative for Regulatory Reinvention. He is the author of the recent book *Materials Matter* advocating a sustainable materials policy. He holds graduate and doctoral degrees from the Massachusetts Institute of Technology.

Dr. Joel Tickner is Research Assistant Professor in the Department of Work Environment at the University of Massachusetts Lowell where he is a Principal Investigator in the Lowell Center for Sustainable Production. His training is in toxics chemicals policy, epidemiology, risk assessment, and clean production. He has served as an advisor and researcher for several non-profit environmental groups, trade unions, and government agencies both in the U.S. and abroad during the past ten years on prevention, chemicals safety, and chemicals policy issues. He is currently a consultant to the World Health Organization in its preparation of the 2004 European summit on environmental health to be held in Budapest, Hungary. He was co-coordinator of the Wingspread Conference on the Precautionary Principle and co-editor of the book *Protecting Public Health and the Environment: Implementing the Precautionary Principle*. He is also editor of the new book *Precaution, Environmental Science and Preventive Public Policy*. He holds a Masters of Science degree in Environmental Studies from the University of Montana and a Doctor of Science Degree in Pollution Prevention and Cleaner Production from the University of Massachusetts Lowell and for three years was an Environmental Protection Agency STAR Fellow.