

# European Over-REACH? Efforts to Revise European Union Chemical Legislation and Regulation

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## Introduction

The European Union (EU) has significantly expanded its political and legal authority on environmental policy since the European Single Act of 1987. During the same time, fundamental changes in institutional relations and procedures for environmental policy making have lead to an accelerated development of EU environmental law: environmental legislation currently covers over 500 items compared with 200 items in 1987 (Jordan 2005: 6). European authorities have assumed a general responsibility for protecting the natural environment and the health of all citizens, and environmental policy development has progressed steadily even as other issues of integration have been marred by political controversy – a noteworthy change from the Treaty of Rome, adopted in 1957, which contained no direct mention of environmental issues or environmental responsibility for the European Economic Community.

Recently, much European politics on environmental and human health protection has focused on chemical management through the development of a new REACH – Registration, Evaluation and Authorization of Chemicals – program. Early discussions on REACH were held in the late 1990s, and the European Commission first presented the general principles for a new REACH program in a White Paper published in 2001 (European Commission 2001). In the fall of 2003, the Commission released a revised REACH proposal. Since then, REACH has been subject to the co-decision procedure involving the Council of Ministers, the European Parliament and the European Commission. A final REACH regulation, which would be one of the largest pieces of EU environmental legislation ever to be passed, is likely to be adopted in 2007.

Chemicals are of considerable importance to modern societies, which could not function in their current form without them. The chemical industry consists of companies that produce chemicals from raw materials (mainly fossil fuels) and firms that alter or blend substances. Europe is the world's largest chemicals-producing region with one-third of global production. The chemical industry is Europe's third largest manufacturing industry

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and employs 1.7 million people (European Commission 2001). Yet, hazardous chemicals pose severe environmental and human health risks and policy makers are faced with the challenge of regulating hazardous chemicals in a socially acceptable way, often in the face of scientific uncertainty (Brickman, Jasanoff and Ilgen 1985).

Chemicals have been subject to Community legislation since the late 1960s, but recently EU chemical legislation and regulation have come under heavy criticism (European Commission 1998, 2001). Critics argue that EU chemicals legislation is too complex and suffers from significant implementation deficits, that the protection of human health and the environment is inadequate, that the influence of precaution on chemical regulation remains limited, and that existing legislation acts as a disincentive for innovation and substitution on the market (these critiques are discussed further below). In response, European policy makers, member states, industry organizations, and environmental and consumer NGOs are engaged in the development of the new REACH program.

A critical shortcoming in existing EU chemical management is the lack of basic information on chemicals (this is the case also for other regions besides Europe). For most chemicals on the European market there are very little public data on their toxicity, emissions, environmental dispersion and ecosystems and human health effects, which makes it difficult to conduct comprehensive risk assessments (EEA and UNEP 1999; European Commission 2001). As a response to this situation, REACH would increase the responsibility of manufacturers and sellers on data generation and sharing, generate more risk assessment data about chemicals in commercial use, and accelerate EU risk assessments and regulation of prioritized chemicals. REACH sets out a three-stage approach of registration, evaluation and authorization to achieve these goals:

Registration: The producer or user of a chemical have to compile a dossier containing data on the properties of that substance, production/use quantity and use areas, and a provisional risk assessment based on intended uses. Evaluation: Based on data submitted by industry, member states, under the guidance of a new European Chemicals Bureau, would evaluate those chemicals used in the greatest quantities or substances of particular concern to assess the need for risk reduction measures. Authorization: For chemicals of great concern industry would have to seek specific permission before they could be marketed. Companies that want to continue selling a chemical subject to authorization would have to demonstrate that it can be used safely or that the chemical is necessary for a particular use and that there is no viable alternative.

The development of REACH, however, has been a highly contentious political process that has raised critical issues about the balancing of environmental and economic goals within the EU. In addition, REACH is part of an important change in European politics. The dominating conflict in the 1980s and 1990s on environmental policy making tended to be between different levels of governance. In contrast, recent environmental policy debates and controversies are played out among different issue specific interests across European institutions, governments and advocacy groups, rather than between institutions at different governance levels (Jordan 2005: 12). This development and its implication for EU environmental policy making should be given more scholarly attention.

This paper examines efforts to revise EU chemical legislation and management through the development of the REACH regulation. REACH is still subject to the co-decision procedure. Rather than focusing on the many specific details of the new REACH program, this paper analyzes those factors that lead to the initiation of the REACH process as well as those factors that have shaped the politics of REACH. The paper begins with a discussion of the relevance of broader EU political strategies and goals for the development of the REACH program, including the Sustainable Development Strategy, the commitment to the precautionary principle and the polluter pays principle, and the Sixth Environmental Action Programme.

Next follows an examination of four factors driving the revising of EU chemical legislation and regulation through REACH: i) the effort to develop more effective environmental and human health protection; ii) European institutional reform strengthening the role of the European Commission, the Council of Ministers and the European Parliament; iii) the influence of environmental leader states and NGOs; and iv) the attempt to streamline present chemicals policy and address existing management problems. This is continued by a more detailed study of the development of the REACH program and examines how political negotiations and controversy on REACH are played out among different issue specific interests across institutions and stakeholder groups.

The study divided the REACH process into three closely interrelated phases: First, early discussions leading up to the publication of the White Paper on REACH by the Commission, 1998-2001. Second, the Commission's re-drafting resulting in a revised REACH proposal by the Commission, 2001-2003. Third, the initiation of the co-decision procedure with negotiations among the Council, the Parliament and the Commission leading to a final REACH program, 2003 to present. Next, the paper connects to the burgeoning literature on transatlantic environmental relations and discusses central transatlantic dimensions of REACH and an expansion of EU chemicals assessment and regulation. The paper ends with a few concluding remarks.

**Sustainable Development, Environmental Policy and Chemical Management**  
The European Single Act established a formal legal authority for Community environmental legislation and policy making. Environmental policy decisions were taken prior to this, of course, but these decisions were based on provisions pertaining to the operation of the internal market rather than environmental protection (Hildebrand 1993).<sup>2</sup> More recently, the EU has adopted a series of broader strategies, principles and environmental policy goals that guide its chemicals management and the development of the REACH program. These include its Sustainable Development Strategy, a legal commitment to the precautionary principle and the polluter pays principle, and environmental action programs.

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<sup>2</sup> The early decisions were taken mainly on the basis of Articles 100 and 235 of the Treaty of Rome.

The European Council in Gothenburg in June 2001 adopted a Community wide Sustainable Development Strategy with direct relevance for its chemicals management. This Strategy identifies sustainable development as a key principle that should govern all the Union's policies and activities. Since then, the European Commission has worked to integrate sustainable development concerns into EU policy. The Strategy focuses on five priority areas: climate change, public health, poverty and social exclusion, ageing society, management of natural resources, and mobility and transport (European Commission 2002). Under the area of public health, the strategy specifically identifies hazardous chemicals as a serious threat to human health and a significant sustainable development challenge.

As a long-term objective to improve the management of hazardous chemicals, the Strategy set the goal to "by 2020, ensure that chemicals are only produced and used in ways that do not pose significant threats to human health and the environment" (European Commission 2002: 35). In a slightly weaker wording, the world's countries at the World Summit on Sustainable Development (WSSD) in Johannesburg in 2002 based on a European proposal moreover agreed that by 2020 chemicals should be "used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment" (United Nations 2002: paragraph 23). The development of REACH with its focus on data gathering and risk assessment thus is linked to the Sustainable Development Strategy and the 2020 goals agreed to within the EU and at the WSSD.

Connected to its Sustainable Development Strategy and efforts to improve chemicals management through REACH, the European Union is also striving to implement more precautionary-based environmental policy and assessment and regulation of chemical hazards (European Commission 2001, 2003). A commonly cited definition of the precautionary principle from the Rio Declaration on Environment and Development states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (UNCED 1992: principle 15). The first legally binding Community formulation of the precautionary principle came with the Treaty of the European Union (the Maastricht Treaty) in 1992 where it is stated that all EU environmental policy should be based on the precautionary principle.

Integration of precaution in EU environmental policy, including chemical management, however, has been slow (Eckley and Selin 2004). In response, the European Commission in 2000 issued a Communication attempting to promote a common understanding of the precautionary principle and establish broader guidelines for its application (European Commission 2000). In its Communication, the Commission recognizes that the Maastricht Treaty only proscribes the precautionary principle to environmental issues, but argues that its scope in practice is much wider. In fact, the Commission states that the precautionary principle should be taken into consideration across environmental, human, animal and plant health issues. This interpretation has been supported by recent rulings by the European Court of Justice expanding the scope of the principle to include human health (Petry, Knowles and Meads 2005).

European environmental policy and standards are forwarded through the adoption of a combination of broader action programs and issue specific directives and regulations.<sup>3</sup> The EU's long-term environmental action programs outline basic policy objectives and principles that should guide Community environmental policy making and identify priority areas and measures for action. The Council of the European Communities, in approving the Fourth Environmental Action Programme (operating 1987 to 1992), stated that the evaluation of the risks to the environment and human health posed by chemicals should be a priority area (Hildebrand 1993). More recently, the Sixth Environmental Action Programme was adopted in 2002 and will run for a ten-year period until 2012.

The current Programme provides the environmental component of the EU's Sustainable Development Strategy and seeks to promote the integration of environmental concerns in all EU policies and activities. The Programme sets out a thematic approach and focuses on four priority areas: climate change; nature and biodiversity; environment and health and quality of life; and natural resources and waste. Under environment and health and quality of life, the Programme re-confirms the 2020 goal for the safe production and use of chemicals and sets priorities for chemical management. Priorities include reducing negative impacts, generating more risk assessment data, accelerating risk management, and the substitution of hazardous chemicals with safer chemicals or alternative technologies – all central aspects of the REACH proposal.

The Programme also states that EU environmental policy should be based on the precautionary principle and the polluter pays principle (Article 2). Toward the fulfilment of the set priorities for chemical management, the Programme calls for a “greater focus on prevention and the implementation of the precautionary principle.” (Preamble, Principle 5). In addition, it places the responsibility the main responsibility for generating data on potential negative impacts from the use of chemicals on producers, importers and downstream users (Article 7). Both of these ideas are embedded in REACH, which focuses attention on substances of high concern based on their inherent characteristics and those substances that are produced and used in high quantities, placing much of the responsibility for generating data on the private sector.

The first Community directive on hazardous chemicals, from 1967, was among the earliest pieces of Community environmental legislation to be passed, six years before the First Environmental Action Programme was adopted in 1973. This directive, like early Community environmental legislation in general, however, primarily intended to harmonize regulations and standards across member states for the purpose of facilitating the development of the common market. Directives in the 1970s developed Community chemicals legislation on direct user and consumer protection from chemicals. From the late 1980s until present, Community chemicals assessment and legislation has been

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<sup>3</sup> A directive is binding with regard to the results it sets out to be achieved but gives flexibility to national authorities to choose the specific forms and methods they use for its implementation. A regulation sets out more specific rules and requirements for implementation that must be followed identically by all member states.

expanded based on a broader concern of the effects of hazardous chemicals on human health and the environment (McCormick 2001).

Community chemicals legislation has come to evolve around four main sets of legal instruments in the form of three directives and one regulation (European Commission 1998; Montfort 2002; Schöring and Lund 2004). These four sets of instruments cover: classification, packaging and labeling of dangerous substances; existing substances; classification of dangerous preparations; and restriction of marketing and use. All of these instruments have been amended and specified since they were originally adopted, in some cases significantly. The different instruments are administered by the European Commission’s Directorates-General (DGs) for the Environment and Enterprise.

Table 1. The four main EU chemical instruments before REACH.

<p>▪ <i>Directive on the Classification, Packaging and Labeling of Dangerous Substances (1967)</i></p>	<p>Introduced labeling and packaging requirements for “dangerous” chemicals. The sixth amendment, passed in 1979, introduced environmental concerns and made a regulatory distinction between ‘new’ and ‘existing’ chemicals. It introduced a pre-market notification procedure for ‘new’ chemicals that entered the common market after 1979, which included testing requirements by the applicant depending on the substance’s marketing volume (all new chemicals sold in over 10 kilograms annually had to be registered).<sup>4</sup></p>
<p>▪ <i>Regulation on Existing Substances (1993)</i></p>	<p>Placed also ‘existing’ chemicals under Community regulatory control, although they did not become subject to the same regulations as new chemicals; manufacturers and importers only needed to provide competent authorities with basic data depending on the volumes in which they were produced or imported. Introduced uniform principles for risk assessment and increased testing and labeling requirements for existing substances, as well as determined that notification of a new chemical in one member state equated to notification throughout the Community.</p>
<p>▪ <i>Directive on the Classification of Dangerous Preparations (1988)</i></p>	<p>Updated in 1999, it sets out harmonized classification, packaging and labelling requirements for preparations, similar to those applying to dangerous substances. A preparation is defined as a mixture or solution of two or more substances. The directive makes no distinction between ‘new’ and ‘existing’ preparations, and those ‘new’ substances that are included in mixtures or solutions are subject to notification requirements.<sup>5</sup></p>
<p>▪ <i>Directive on the Restriction of Marketing and Use (1976)</i></p>	<p>Regulates the sale of hazardous chemicals. Under “ban with exemptions,” the marketing and use of a substance or preparation is only allowed for specifically approved uses. Under “controlled use,” which is the most common type of restriction, the marketing and use of a substance or preparation is allowed except in cases where there are specifically identified prohibitions. A 1994 amendment prohibits public sale of all substances and preparations that are carcinogens, mutagens, or reproductive toxicants.<sup>6</sup></p>

<sup>4</sup> There have been approximately 2,700 notifications of new substances since 1981, with notifications of over 300 new substances each year since 1996. Out of these 2,700 substances, approximately 70 percent have been classified as dangerous.

<sup>5</sup> Most chemicals on the European market are preparations: it is estimated that somewhere between 90 and 95 percent of all chemicals that are sold are preparations.

<sup>6</sup> To date, the Directive on the restriction of marketing and use covers approximately 900 chemicals, including 850 that are carcinogenic, mutagenic or reproductive toxicants.

Through these four sets of directives and regulation, the EU has gradually expanded its authority on chemicals management as regulatory competence has been transferred from member states to the European level. In addition to these four main sets of chemical legislation there are a multitude of other directives and regulations that cover chemicals (Montfort 2002; Royal Commission on Environmental Pollution 2003). For example, EU water directives contain a long list of regulated chemicals pertaining to water quality. Similarly, air pollution directives set emission standards on chemical by-products such as dioxins and furans. There are also directives on consumer and worker protection, as well as directives on waste management and disposal that address chemicals.

## European Chemical Management and REACH

The expansion of EU chemicals management and the development of REACH are driven by four overlapping factors. Some of these factors are important also in other environmental areas while others are more specifically related to chemical issues. *First*, the development of REACH is part of a larger European effort to create more effective environmental and human health protection standards. *Second*, European institutional reform has strengthened the role of the Commission, the Council and the Parliament facilitating the adoption of more stringent EU environmental policy. *Third*, the intensified focus on chemical management by ‘leader states’ and NGOs engaged in coalition building has increased pressure on European policy makers to strengthen existing policy. *Fourth*, European policy makers intend for REACH to streamline EU chemicals policy and to rectify problems with current management.

### *Improve environmental and human health protection*

Expanding EU policy making and risk management on chemicals is part of a larger European effort to develop more rigorous environmental and human health protection standards. Vogel (2004) argues that these broader efforts are related to highly publicized failures of past European risk management policy. Over the past decade, there has been much European political and public debate on the ability of European and national regulatory agencies to protect citizens from a host of risks, ranging from dioxin levels in food and feed, BSE (bovine spongiform encephalopathy – mad cow disease) to fears of the growing use of genetically modified crops. This debate has raised critical questions regarding the effectiveness of EU regulations for much public health protection.

The Eurobarometer from 2005 and 2003 on the environment and issues of concern and trust show that European citizens demonstrate high levels of uneasiness about chemical risks as well as lack trust in public authorities. In 2005, chemical safety was listed fifth on a list of 15 environmental issues that Europeans were most worried about. At the same time, the public deeply distrusted both the EU and national governments on environmental issues. In 2005, 12% said they trusted the EU most while 11% trusted national governments the most. In 2003, 13% trusted the EU the most and 12% most

trusted national governments. In both polls, environmental protection organizations and scientists scored the highest on trust.<sup>7</sup>

As a result of a wide spread perception of failures to adequately protect human health and the environment across a range of issues, pressures have increased on European policy makers from the general public, advocacy groups and member states to develop more precautionary policy and improve means of regulation and protection. These pressures for more pro-active and risk adverse policy have also affected European debates on the management of chemical hazards. On European chemicals management, criticism has focused on national regulatory differences, the slow pace of risk assessment of chemicals currently on the market, and shortcomings in the implementation of the precautionary principle in European chemical assessment and regulation (see also below) (Eckley and Selin 2004).

#### *Institutional developments*

EU environmental policy is negotiated among (and within) the Commission, the Council of Ministers and the European Parliament. As the competence of EU institutions on environmental policy has been expanded through constitutional developments, there has been a transferal of regulatory authority from member states to the main EU level.<sup>8</sup> The Commission, because of its growing role in setting agendas, developing policy proposals and supervising implementation, has been instrumental in strengthening of European institutional authority on environmental policy making and risk management. This expansion of the competence of the Commission on environmental issues has allowed DG Environment in particular to assume a more proactive role.<sup>9</sup>

DG Environment, under the leadership of Commissioners from two forerunners on European chemicals management, Ritt Bjerregaard (Denmark, 1995-1999) and Margot Wallström (Sweden, 1999-2004), focused much attention on issues of chemicals security and has been a strong supporter of REACH. It was largely DG environment together with the environmental ministers from a small group of northern European states (including Denmark, Finland, Germany, the Netherlands, Sweden and the United Kingdom) that initiated the early discussions about the need for a revised Community chemicals management scheme. Later in the process during the development of the revised 2003 White Paper, there were difficult negotiations within the Commission, primarily between DG Environment and DG Enterprise. Yet, DG Environment remained influential.

Changes to voting rules have also accelerated environmental policy making. Between the Single European Act of 1987 and the Maastricht Treaty of 1993 environmental decisions were taken by a combination of unanimity and majority voting in the Council with Parliament having a consultative function. Through the Maastricht Treaty and the

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<sup>7</sup> On trust, environmental protection organizations scored 42% in 2005 and 48% in 2003. Scientists scored 32% in 2005 and 35% in 2003.

<sup>8</sup> These treaties include the 1987 Single European Act, the 1993 Maastricht Treaty, and the 1997 Amsterdam Treaty.

<sup>9</sup> The Service for the Environment and Consumer Protection was established in 1973 and became Directorate General XI within the Commission in 1982.

Amsterdam Treaty of 1997 the new co-decision procedure established full equality between the Council and the Parliament on all environmental issues. The growing role of the Parliament is seen as having strengthened standards for environmental and human health protection (Burns 2005). The Parliament in general has helped generate support for REACH and many parliamentarians pressed for a stringent REACH in the Parliament's review of the Commission's White Paper and during the co-decision procedure.

*Interests of environmental 'leader states' and the roles of NGOs*

Related to issues of European institutional developments, the REACH process largely began as a joint initiative by a growing number of northern member states and DG Environment in the late 1990s, sharing an interest in strengthening EU chemicals legislation and harmonizing chemical assessment and regulation. This initiative is consistent with the set of literature that draws attention to the role of environmental leader states in European environmental policy making. For example, Liefferink and Andersen (1997, 1998) argue that much EU environmental policy is pioneered by "leader states" acting to upload their higher domestic standards. Similarly, Börzel (2002) discusses the activity of "pace-setting" where member states actively seek to shape European policy according to domestic preferences.

Liefferink and Andersen (1998) argue that much Community environmental legislation before 1995 was pioneered by Denmark, Germany, and the Netherlands. With the enlargement in 1995 when Austria, Finland, and Sweden joined the EU, the influence of "green" member states increased in all EU institutions. In the Commission, DG Environment has often worked closely with leader states on policy development. Leader states, moreover, frequently strategically place experts in the Commission to work on issues that are prioritized domestically. In the Council, the shift to majority voting and a larger number of leader states created an opportunity for the passing of more progressive environmental law. The growing role of the Parliament and the arrival of parliamentarians from leader states had a similar effect.

Chemicals management is one central issue area where a growing influence of the green member states is visible (Eckley and Selin 2004). Several northern member states including Denmark, Sweden, the Netherlands, Germany and the United Kingdom were among the early supporters of revisions to EU chemicals policy and regulation. They took these actions in part hoping to export their often stricter standards and policies to the European level. Thus, we are now witnessing a race to the top, rather than a race to the bottom, as chemical legislation and regulation are strengthened across Europe. That is, European leader states/pace-setters are actively involved in coalition building with each other and other like-minded stakeholders in a process of "trading-up" chemical standards across member states (Vogel 1995).

In addition, there has been a dramatic increase in the number of NGOs in Brussels over the past decades. Alongside the environmental leader states, environmental NGOs are involved in environmental policy making lobbying all three major EU institutions. Environmental NGOs at the European level often act through umbrella organizations such as the European Environmental Bureau, which is a federation of over 140 national

organizations headquartered in Brussels. Many environmental NGOs are also financially supported by the Commission and/or member states. Often, industry organizations such as the European Chemical Industry Council (CEFIC) act as a counterweight to the environmental NGO community in Brussels.

There has been a strong presence of both environmental NGOs and industry organizations on REACH since the early 2000s. It was a stated goal of the Commission to include a multitude of stakeholders in its development of the REACH proposal and the Commission's internet consultation on REACH in the summer of 2003 was one of the largest consultations processes ever organized by the Commission. Environmental NGOs and industry organizations have also lobbied aggressively in the Parliament as they have attempted to influence positions of parliamentary groups and votes in committees and the plenary. Similarly, environmental NGOs and industry organizations have been in close contact with national governments and ministers to influence their positions in the Council.

#### *Streamline chemical policy and address regulatory problems*

The factors and developments discussed above form a critical backdrop to the development of the REACH program and the politics surrounding REACH. More directly related to EU chemical legislation and management, however, efforts to revise EU chemical policy and regulation are based on critiques from politicians, policy makers, environmental advocacy groups, and analysts of the existing system for suffering from at least four related weaknesses.

First, a general criticism of EU chemical legislation is that it is too complex and suffers from critical implementation deficits (European Commission 2001; Nordbeck and Faust 2003). While existing legislation is built around four main legal instruments, over 100 directives and regulations cover chemicals. Few, if any, in public and private sectors have a full overview of all these (Royal Commission on Environmental Pollution 2003). Most legislation moreover is in the form of directives and national authorities have chosen diverse forms and methods for their implementation, which has created significant national differences. In addition, the notification of a new chemical to the competent authority in one member state equates to notification throughout the EU and it is difficult to get an EU-wide overview of notification.

A second criticism of EU chemical management is that the protection of human health and the environment remains inadequate. This is related to the regulatory distinction between 'existing' and 'new' substances and the fact that EU risk assessment and regulation of 'existing' substances have been slow (Nordbeck and Faust 2003; Geiser and Tickner 2003). The sixth amendment to the Directive on the Classification, Packaging and Labeling of Dangerous Substances, adopted in 1979, introduced a regulatory distinction between 'new' and 'existing' chemicals. While this amendment introduced a notification procedure for 'new' chemicals, it left all 'existing' chemicals unregulated. The Regulation on Existing Substances, from 1993, placed also 'existing' chemicals under Community control, but requirements remained lower than for 'new' chemicals.

The European Inventory of Existing Commercial Chemical Substances (EINECS) lists approximately 100,000 substances that were reported to be on the common market before September 18, 1981. For most of these 'existing' chemicals, which make up over 95 percent of all commercial chemicals, there are only scant public data on emissions, environmental dispersion, and ecosystems and human health effects. There are little or no toxicity data for 75,000 substances and only limited toxicity data for the other 25,000 substances (EEA and UNEP 1999). Many of these are still in extensive use. Since 1994, the Commission has issued four high priority lists covering in total 140 'existing' substances. By 1997, risk assessments were completed for only 10. Risk assessments were completed for 400 'new' chemicals during the same time (EEA and UNEP 1999).

A third, related problem is that the separation between 'existing' and 'new' substances in effect acts as a disincentive for innovation and substitution on the market (European Commission 2001; Geiser and Tickner 2003). For every new substance that the chemical industry wants to introduce into the market, they need to do risk assessment not necessary for existing substances. This requires both time and resources. As such, existing legislation in effect puts a barrier on substitution of an old chemical, for which there may be little or no risk assessment data, for a new chemical that has been developed with more recent technology and for which there is a better understanding about its inherent properties and environmental behavior (Nordbeck and Faust 2003).

Fourth, and related to issues of risk assessment, critics argue that the influence of precaution on EU chemical regulation remains limited. Eckley and Selin (2004) identify two reasons for this. First, the burden of proof is largely on regulators to prove that a chemical is not safe, rather than the producer and/or seller having to conduct testing and produce data demonstrating that a substance will not cause adverse environmental and human health effects. Second, there has been a tendency to spend much time producing scientifically detailed risk assessments that are not always regarded useful by policy makers, which has slowed down regulatory processes and left little room for precautionary decision-making. Moreover, member states have differed in their interpretation and application of the precautionary principle.

REACH is intended to address all these criticisms. To improve assessment and regulatory harmonization across member states REACH will be created in the form of a regulation, replacing broader directives. A core objective of REACH is to abolish the regulatory distinction between 'existing' and 'new' substances and accelerate the assessment and regulation of those 'existing' substances that are deemed to require tighter controls for effective protection of human health and the environment. In doing this, the EU seeks to find ways to better operationalize precaution in assessment and regulation, including shifting the burden of proof to manufactures and sellers. Finally, REACH contains requirements for substitution thereby hoping to promote the development of new, less harmful substances.

## Developing the REACH Program

REACH is related to the implementation of EU's Sustainable Development Strategy and intended to help the European Union to achieve the 2020 goals of safer production and use of chemicals. In addition, REACH seeks to make EU chemicals management more coherent, to increase the availability of risk information, to strengthen the management of particularly hazardous chemicals, and to expand industry responsibility while still maintaining the competitiveness of the European chemicals industry. The European Commission, the European Parliament, member states, industry organizations, environmental advocacy groups and consumer groups are all engaged in the creation of REACH (European Commission 2001, 2003; Schörling and Lund 2004). However, stakeholders displayed different interests with respect to the REACH program.

During the REACH process, coalitions of like-minded across institutions, member states and interest organizations have been formed. These were not formalized to any higher degree; rather, stakeholders coalesced around particular positions with respect to their preferred scope and stringency of REACH sometimes pitting environmental and economic interests against each other. One set of actors has been supportive of REACH. These include the environmental ministers of northern member states, including Denmark, Sweden, Netherlands, Germany and the United Kingdom. In particular in the case of Germany, however, there have been tough negotiations within the national government where the environment minister has been facing strong opposition from industry and economics ministers.

The leader states have generally found a strong ally in DG Environment, especially under the leadership of Margot Wallström. Similarly, Green Parliamentarians have been at the forefront of promoting REACH, sometimes together with other Parliamentarians often from the leader states. Environmental and public health NGOs joined the pro-REACH coalition in the early 2000s. Their activities were coordinated both through the umbrella organization the European Environmental Bureau as well as individual organizations such as the WWF and Greenpeace. More recently, the International Chemical Secretariat – founded in 2002 in Sweden and supported by the Swedish Environment Ministry and the Swedish Chemicals Inspectorate and receiving public funds – has been a strong lobbyist for REACH.<sup>10</sup>

Another set of stakeholders has been much more critical of many of the proposals under REACH. No member state has outright opposed REACH, but industry ministers and political leaders of countries with major chemical industries, including Germany, France and the United Kingdom, have questioned some of the more radical proposals that have been opposed by chemical companies and its industry associations like CEFIC. Similarly, CEFIC and most European chemicals companies have not been in total opposition to REACH, but they have been critical of many aspects of REACH. DG Enterprise and some committees in the Parliament, including the Committee on Industry, Research and

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<sup>10</sup> The International Chemical Secretariat is loosely modelled after the Swedish NGO Secretariat on Acid Rain, which has also received public funds and been a strong and influential lobby organization on European air pollution issues for over two decades.

Energy and the Committee on Internal Market and Consumer Protection, have often shared these concerns.

The enlargement of the EU in 2004 has had little direct impact on the REACH negotiations, for a few reasons. First, the ten countries did not become members until much of the general framework of REACH already had been established. Second, harmonization of domestic environmental legislation and management with EU environmental policy and standards was a requirement for accession and all the new members knew that they would have to accept a new REACH program when they joined. Third, the new members and their representatives in the Parliament have not acted as a bloc, but rather joined existing coalitions. Thus, some of the new members, like Hungary, have been generally supportive of REACH while others, like Poland and Slovenia, have allied themselves more with the skeptics.

The development of REACH has progressed through a series of phases formally similar to the development of much EU environmental legislation since the mid 1990s: Early discussions among the Commission, member states and other stakeholders ending with the publication of a White Paper by the Commission, 1998-2001; Commission's re-drafting of its proposal outlined in the White Paper resulting in a revised proposal by the Commission, 2001-2003; and the co-decision procedure involving political negotiations in the Council and the Parliament ending with the adoption of a new REACH program, 2003-2007.

Table 2. Key events in the early development of the REACH program.

• April 1998	EU environment ministers express concern about shortcomings in Community chemicals assessment and management
• June 1999	Council of Ministers request the Commission to propose changes to existing Community chemicals policy
• June 1999 – February 2001	Commission development of White Paper based on request from Council of Ministers (Environment)
• February 2001	Publication of the Commission's White Paper on the future of Community chemicals policy
• June 2001	Council of environment ministers conclusion on the White Paper
• September 2001 - May 2003	DG Environment and DG Enterprise drafting and publicly releasing the first draft of the REACH proposal
• November 2001	Parliament opinion on the White Paper
• May – June 2003	Public internet consultation on Commission REACH proposal
• July – October 2003	DG Environment and DG Enterprise re-drafting of REACH proposal
• October 2003	Adoption of Commission Proposal for Regulation COM(2003)644 and beginning of co-decision procedure

#### Early Discussions, 1998-2001

By the mid-1990s, there was a growing dissatisfaction with the effectiveness of Community chemicals legislation and management among several, mainly northern European member states, as well as in the Commission. In 1995, Austria, Finland and Sweden had joined the EU, increasing the number and influence of the “green” member

states, impacting EU environmental decision making (Lieverink and Andersen 1998; Wettestad 2002; Selin and VanDeveer 2003). At that time, DG Environment was led by Ritt Bjerregaard, who was supportive of efforts to revise and, if necessary, expand Community chemical legislation and management.

At a meeting of environmental ministers in Chester, UK, in April 1998, several ministers raised concerns about existing EU chemicals policy and assessment. In November 1998, the Commission issued a report on the implementation of chemical regulations, prompting the European Council to call for a more coherent and integrated EU chemicals policy. Partly based on a stakeholder meeting on chemicals policy in February 1999, the environmental ministers at an informal meeting, in May 1999, issued a statement on problems with Community chemicals policy. One month later, the Council of Ministers requested that the European Commission develop a strategy for a more effective Community management of chemicals (European Commission 2001; Nordbeck and Faust 2003; Geiser and Tickner 2003).

In a two-year process, which was dominated by DG Environment, the Commission began drafting a comprehensive set of new principles and ideas for a revised Community chemicals assessment and regulatory system. The appointment of Margot Wallström (Sweden) as the new Commissioner for DG Environment, in September 1999, maintained the dominance of DG Environment. In February 2001, the Commission presented its proposal for a revised Community chemicals management system in its *White Paper on a Strategy for a Future Chemicals Policy*. A cornerstone of the Commission's proposal was the creation of a new Registration, Evaluation and Authorization system for risk assessment and risk management, which would impact over 40 pieces of existing Community legislation.

Registration: The producer or user of all existing and new chemicals produced or used over a certain volume would have to compile a dossier presenting data on the properties of a substance, production and use volumes, areas of usage, and a provisional risk assessment based on intended uses. The Commission envisioned a three-step registration process for existing substances. First, chemicals sold in more than 1,000 metric tons every year would be registered (estimated 2,600 substances). Second, chemicals sold in over 100 metric tons would be registered (estimated 3,000 substances), followed by chemicals sold in over one metric ton (estimated 25,000 substances). About 70 percent of new chemicals are marketed in quantities of more than one metric ton annually.

Evaluation: The dossier compiled by industry for each substance subject to registration would be submitted to a central database. Under the guidance of a new European Chemicals Bureau, designated authorities in member states would evaluate those chemicals used in the greatest quantities or those of particular concern to assess the need for risk reduction measures. The Commission estimated that 5,000 chemicals would initially be subject to evaluation. Chemicals produced and imported in quantities over 1,000 metric tons would be tested and assessed by 2010. Chemicals above 100 metric tons would be tested and assessed by 2012, and chemicals exceeding one metric ton would only be subject to spot checks and computerized screening.

Authorization: Chemicals identified to be of great concern would have to undergo an authorization process where a company would require specific permission before they can sell and use a chemical subject to authorization. Companies that want to continue using such a chemical would have to demonstrate that it can be used safely or that the chemical is necessary for a particular use and that there is no viable alternative. The Commission estimated that authorization initially would apply to approximately 1,400 substances that are known or highly suspected to be harmful to the environment and human health, including substances that are carcinogenic, reproductive toxicants, mutagens, or endocrine disrupters.

The Council of Ministers and the European Parliament responded to the Commission's White Paper with both support and criticism. Environmental ministers of several northern member states, including Denmark, Sweden, the Netherlands, Germany and the United Kingdom continued to support the Commission's work and its REACH proposal. They did so in part hoping to export their already stricter national standards to the European level. Many of these countries are moreover continuing to strengthen domestic regulations parallel to the development of REACH with the goal of phasing out production and use of the most hazardous substances (Geiser and Tickner 2003). For example, Sweden is working towards its goal of a "toxic free environment;" Denmark is working on its "generational goal;" and the Netherlands seeks to develop its "strategy on management of substances."

In the European Parliament, the Committee on the Environment, Public Health and Consumer Policy, under the leadership of its rapporteur Inger Schörling (Green-Sweden), issued a Committee report to the full Parliament in October 2001. This report welcomed many of the proposals by the Commission (Schörling and Lund 2004). The full Parliament Resolution on the White Paper from November 2001, however, was more cautious (Resolution A5-0356/2001). The Resolution acknowledged the need for a revised Community chemicals policy, but also noted concerns over the extensive nature of the Commission's proposal and the economic costs of the REACH proposal. These concerns were expressed by many parliamentarians and were shared by the European chemical industry, which strongly opposed many of the Commission's proposals for expanding data collection, assessment and regulation (Montfort 2003).

Together with Green parliamentarians (Schörling 2003; Schörling and Lund 2004) European environmental NGOs came out in support of the Commission's White Paper (WWF 2002; EEB 2002). Many of these, such as the European Environmental Bureau, the World Wide Fund for Nature, and Friends of the Earth had addressed chemical issues for a long time, although European chemicals management was not a top priority during much of the 1990s. The release of the 2001 White Paper, however, resulted in more NGO attention being paid to European chemicals issues. Many NGOs vocally supported efforts to introduce more stringent regulations, but also expressed hesitance that expanded assessments would result in increased animal testing, something that they wanted to avoid.

The main European association of chemical producers, CEFIC, representing some 27,000 companies, welcomed the proposal to streamline EU chemicals legislation, assessment and regulation, but argued against many of the Commission's main proposals. Some of the largest members of CEFIC, including Bayer, BASF and Shell Chemicals, opposed the idea of setting up a common registration, evaluation and authorization scheme for existing chemicals (Montfort 2003; CEFIC 2003a). Together with other critics, they believed this would be too burdensome for companies and threaten their competitiveness (Petry, Knowles and Meads 2005). They argued that if existing chemicals should be assessed, a more selective mechanism should be designed based on exposure and risk rather than volume.

#### Commission's Re-drafting, 2001-2003

The Commission began re-drafting its REACH proposal in the fall of 2001 based on comments by member states, the Parliament, and environmental and industry advocacy groups. During these revisions, DG Enterprise, in collaboration with the chemical industry, took a much more active role. To solicit comments on their revisions, the Commission organized a large internet consultation in May and June 2003. Responses to this consultation were dominated by industry organizations and chemical companies, which continued to be critical of the proposal's main goals. In addition, political leaders of several EU members, many with large chemical industries, began to publicly voice more concern even though their environment ministers earlier had expressed support for REACH.

For example, the British Prime Minister Tony Blair, the French President Jacques Chirac and the German Chancellor Gerhard Schröder in a joint letter to Romano Prodi, President of the Commission, shortly before the Commission were to present its revised proposal stressed that a EU chemicals policy must not endanger the international competitiveness of the European chemicals industry. They believed that the proposed registration procedure was "too bureaucratic and unnecessarily complicated" and did not "prioritize sufficiently between the handling of substances" (i.e. too many substances were proposed for registration). Focusing on the economic aspects of REACH, they stated that the Commission's proposal was "a long way from being the fast, simple and cost-efficient procedure that was promised."

As a result of the concerns emanating from the chemical industry and its political supporters, the revised REACH proposal that was presented by the Commission in October 2003 relaxed several requirements compared with the White Paper from 2001. *The Economist* (2003) noted that "Plans to regulate the chemicals industry in Europe approved by the European Commission on October 29<sup>th</sup> amount to a minor triumph for industrial lobbyists over environmental campaigners." In particular, the revised proposal by the Commission proposed changes in four main areas.

- First, the White Paper proposed a 'no data – no market' scheme for all substances. The revised proposal relaxed many data requirements and lowered registration requirements for substances produced and used in quantities of less than 10 metric tons per year (approximately 20,000 substances on the market).

- Second, the revised proposal introduced fairly broad exemptions on polymers (material constructed of smaller molecules of the same substances that form larger molecules) and substances that were already subject to other Community legislation.
- Third, the White Paper envisioned a scheme where chemicals with inherent hazardous properties would be replaced with safer alternatives. The revised proposal reduced some of these substitution requirements for old substances by new substances.
- Fourth, the White Paper introduced far-reaching information rights to downstream users (both industrial and public consumers) about chemicals. The revised proposal introduced broader confidentiality rights for producers.

Member states expressed mixed reactions to the revised and relaxed REACH proposal. While several of the ministers who met in the Competitiveness Council in November 2003 welcomed the changes made by the Commission, Spanish and Italian industry ministers still criticized the REACH proposal. They argued that it remained too complex, too costly for industry, and expressed fears that it would lead to substantive job losses (Carstens 2003). In contrast, many environmental ministers continued to support efforts to increase data collection and promote substitution of chemicals with intrinsic hazardous characteristics. For example, the Swedish and German environment ministers wrote an op-ed in a German newspaper, in effect arguing against other German ministers and industry representatives in favor of a strong REACH (Sommestad and Trittin 2004).

Several Greens in the European Parliament expressed disappointment that the Commission had lowered many data and regulatory requirements compared to its 2001 White Paper. They argued that these changes largely went against the recommendations by the Parliament in its Resolution from November 2001 (and even more so the report by Committee on the Environment, Public Health and Consumer Policy from October 2001) (Breyer 2003; Schörling and Lund 2004). These concerns were generally shared by environmental NGOs, including the European Environmental Bureau. In contrast, Conservative members of the European Parliament and CEFIC joined the industry ministers who argued that the Commission's proposal still placed unduly costly requirements on the chemical industry (Florenz 2003; CEFIC 2003b).

In contrast to the strong opposition to REACH from associations of chemical companies and major chemical producers, a growing number of downstream buyers and users of chemicals have come out expressing support REACH. In general, these downstream users support the attempt of the EU to generate more public data about chemicals that they use during manufacturing and include in their goods. Several downstream users expressed disappointment that information requirements were reduced in the Commission's new proposal. This disappointment stemmed from a fear among downstream users that they may be held liable for damages from chemicals that they use and for which they have only limited data, as well as public support and pressure from consumer groups for removing hazardous substances from manufacturing and goods.

The direct and indirect costs and benefits of REACH have been hotly debated and estimates have differed greatly. The Commission estimated an additional cost of €2.1 billion over 11 years for the chemicals industry (equivalent of an annual cost of €200 million) (European Commission 2001). In contrast, industry estimated its total additional cost to €7.8 billion (Nordbeck and Faust 2003). A report by the consulting firm Arthur D. Little (2002) commissioned by the German chemical industry and released shortly after the White Paper moreover predicted 2.35 million job losses and a 6.4 percent reduction in German Gross Domestic Product. A similar study by Mercer Management Consulting (2003) estimated that REACH would cost the French chemicals industry €29 to €54 billion over ten years and eliminate 670,000 jobs.

These reports, however, have been widely attacked as being based on ‘false economics’ when calculating direct and indirect costs (ICS 2004; Schörling and Lund 2004). In an assessment of the revised REACH proposal that was issued by the Commission in October 2003, Ackerman and Massey (2004) estimate that the total cost for REACH over 11 years would be €5.25 to €8.05 billion, or less than 0.1 percent of the chemical industry’s sales revenues. In addition, defenders of REACH stress that environmental and human health benefits must be included in any cost-benefit analysis, even if these are notoriously hard to quantify (Pearce and Koundouri 2004). They argue that not enough attention has been given to the benefits from improved environmental and human health protection as well as benefits of industry innovation and reduced costs of clean-up of contaminated sites and wastes from more proactive regulation.<sup>11</sup>

#### Co-decision Procedure, 2003-

After the Commission’s final proposal in October 2003, REACH became subject to the co-decision procedure involving the Council of Ministers, the European Parliament and the Commission. As the co-decision procedure began, there was much debate which Council and which Parliament Committee that would address REACH as coalitions of stakeholders continued with their disagreements.

Table 3. Key events during the co-decision procedure.

• December 2003	Member states decide that the new Chemicals Bureau overseeing REACH will be located in Finland
• October 2005	Parliament’s Environment Committee votes on REACH with eight other committees giving opinion
• November 2005	Parliament Opinion, i.e. First Reading
• December 2005	Council adopts a common position on REACH
• 2006	Parliament Opinion on Council common position, i.e. Second Reading
• 200?	Possible reconciliation between Council and Parliament
• 200?	Possible adoption by Council and publication of REACH regulation

<sup>11</sup> One assessment estimates that European costs of PCB decontamination alone could be as high as €15 to €75 billion (Kemikalieinspektionen 2004).

Most pro-REACH member states preferred discussing REACH in the Environment Council, which had been the primary Council on efforts to revise EU chemicals management since the late 1990s. In contrast, several other member states and the chemical industry worked to instead have the Competitiveness Council as lead council, which they believed would be more sympathetic to its concerns. Based on an Italian last-minute proposal during its presidency in 2003, which took many member states by surprise, the Competitiveness Council was made lead Council during the co-decision procedure. In practice, however, both the Environment Council and the Competitiveness Council debated REACH in parallel during the co-decision procedure, but with the Competitiveness Council as lead council.

A similar struggle to the one in the Council over which committee that should be the main committee during the co-decision procedure was visible in the Parliament. Parliamentarians in support of REACH and environmental NGOs pushed for the Committee on the Environment, Public Health and Consumer Policy to continue to be the main committee in the Parliament. Industry organizations and Parliamentarians who feared that the Environment Committee would be too green, however, attempted to move the handling of REACH to the industry and/or the internal market committees. Nevertheless, these efforts were resisted and the Committee on the Environment, Public Health and Consumer Policy continued to be the lead committee in the Parliament with eight other committees giving opinion.

During the co-decision procedure, many of those conflicts that were present during the development of the revised Commission proposal 2002-03 resurfaced. As before, the Greens in Parliament were strong supporters of a demanding REACH, as were several parliamentarians in other ideological groups from leader states. The rapporteur in the Environment Committee, Guido Sacconi (Socialist-Italy), moreover, sided with the Greens and other pro-REACH parliamentarians on many critical issues (Beunderman 2005). When the Environment Committee voted on October 4, 2005, 40 committee members voted in favour of the proposal designed by Sacconi, 19 voted against, and 2 abstentions.

However, concerns about the costs and requirements for industry and member states prompted leaders from the center-right and the socialist party grouping to relax a number of requirements in the proposal drawn up by Sacconi. In particular, many German conservative parliamentarians led “the attack against earlier pro-green versions of the legislation” (Beunderman 2005). These efforts were largely successful and a compromise proposal agreed upon by the leaders of the center-right and socialist grouping passed during the plenary vote on November 17, 2005. This compromise proposal reduced the amount of information that industry have to supply, reduced the number of substances in the 1-10 ton bracket that would require tests for registration, and reduced testing requirements for substances in the 10-100 ton bracket (Beunderman 2005; Mason 2005).

In the Council, coalitions across old and new member states were formed for different parts of the REACH proposal. The negotiations among member states mirrored many of those in the Parliament with many northern member states pushing for a strong REACH

while other member states adopted a position closer to that of the industry. A scheduled vote in the Competitiveness Council in late November was postponed by German request so that the new German government could have more time to assess the proposal. A vote, however, is scheduled for an extra session of the Competitiveness Council in mid-December. If the Council's common position differs from the proposal passed by Parliament, the co-decision procedure will continue with a Second Reading in Parliament and possible reconciliation between the Council and Parliament.

## Transatlantic Politics and REACH

Much early research on EU environmental politics paid little attention to linkages between EU policy making and external institutions (Selin and VanDeveer 2003). More recently there has been growing scholarly interest in transatlantic relations and the role of EU in international environmental politics (Vig and Faure 2004). Transatlantic cooperation and competition on chemicals management are partially a result of the economic importance of chemicals and the chemical industry; Europe accounts for over one-third and the United States accounts for one-fourth of global production of chemicals (European Commission 2001; ACC 2005). The United States government and the US chemical industry have been greatly involved in Brussels and in capitals of individual member states and have been critical of many of the policies proposed under REACH.

Whereas US chemicals policy in the 1970s and the early 1980s often acted as an inspiration for European policy making, the EU has overtaken the role as leader in chemicals policy development (Vogel 2004; Brickman, Jasanoff and Ilgen 1985). US government action against REACH is heavily influenced by the views of American chemicals associations and companies such as the American Chemistry Council, the Synthetic Organic Chemical Manufacturers Association, the American Plastics Council, DuPont and Dow Chemicals (United States House of Representatives 2004). The American Chemistry Council moreover has worked closely with the American Chamber of Commerce in Brussels, as well as with CEFIC and other European industry counterparts.

Opposition to REACH from the US government and the US chemical industry are related to *regulatory*, *financial*, and *market* based concerns (Selin forthcoming).

*Regulatory* cultures are different across the Atlantic (Brickman, Jasanoff and Ilgen 1985; Wiener 2004). In Europe, policy making and regulation are generally outcome oriented. Community policy makers, national governments and stakeholders often seek agreement around broad goals and guiding principles for environmental policy and work to specify regulations and practices during implementation. In contrast, American policy making and regulation are more process oriented and US environmental legislation and regulation are structured around detailed sets of rules and procedures for implementation in which controversial issues can ultimately be addressed judicially. As a result of these transatlantic cultural differences, American officials and industry representatives argue that REACH in its current form is too vague (United States 2004).

American critics moreover argue that the planned expansion of data gathering under REACH is largely unnecessary; that is, they question the need for more data gathering and possible testing of ‘existing’ substances (ACC 2003; United States House of Representatives 2004). Community regulation, moreover, is tiered and automatically requires additional testing of high-volume chemicals. In contrast, US regulators under the Toxic Substance Control Act negotiate testing requirements with producers on a case-by-case basis. REACH therefore is expected to accentuate EU-US differences over data collection and testing of high-volume chemicals. In addition, REACH is attempting to incorporate a higher level of precaution than what is currently the situation in American legislation and regulation on industrial chemicals and pesticides.

The United States has also opposed REACH on *financial* grounds related to American skepticism of the need for more data gathering and testing. US legislation, as in Europe before REACH, makes a fundamental distinction between ‘existing’ and ‘new’ chemicals and focuses on the regulation of ‘new’ chemicals. Under a REACH-like system, the responsibility and cost for generating data for registration will largely fall upon the chemicals industry while European authorities will have to bear much of the costs of evaluation and authorization. American critics in the public and private sectors argue that the financial costs for REACH, including for existing substances, are too high for both chemical companies and regulatory agencies. In addition, US chemical companies oppose the broader requirement to generate data for existing substances.

American *market based* concerns are tied to transatlantic competition over standard setting. These concerns are based on the fact that a strengthening of European standards for chemicals assessment and regulation are likely to affect production and product standards also outside of Europe. Traditionally, many product standards for consumer and environmental protection were set in America because of the size of the American economy and the United States’ political importance. Recently, however, “the locus of policy innovation with respect to many areas of consumer regulation has passed from the US to Europe” (Vogel 2004). With its expanding total population and economic weight as a result of enlargement, the EU is increasingly replacing the United States as the *de facto* setter of product standards (Pohl 2004).

Transatlantic market based controversy also includes intense debates around trade implications of REACH for the export of chemicals and products containing chemicals to Europe (ACC 2003; United States House of Representatives 2004; United State 2004). The United States argues that REACH violates rules under the World Trade Organization (WTO). The WTO allows countries to take human health and environmental protection measures into account in legislation as long as they are “proportionate” to their aim and do not create unnecessary obstacles to free trade. The European Commission claims that REACH is designed to be consistent with WTO (European Commission 2001, 2003). The United States, however, argues that many of the data collection and testing requirements under REACH are disproportionate and trade restrictive (ACC 2003; United States 2004).

The United States’ government filed a formal comment with the WTO Committee on Technical Barriers to Trade in June 2004 (United States 2004). The comment outlines

several issues regarding the workability and trade disrupting nature of the REACH proposal. Specifically, the United States expresses concern about the effects on a majority of the US exports to the common market through trade in chemicals and goods that include one or several chemicals. The United States estimates the total value of the US export to the 15 EU members in 2003 at over \$150 billion. US export to the common market further increased with the EU enlargement to 25 countries in 2004. As such, REACH may be another issue where the EU and the US clash over trade related implications for a protracted period of time.

### Concluding Remarks

EU environmental policy is guided by EU's commitment to sustainable development, the precautionary principle and the polluter pays principle. The development of the REACH program is part of a larger EU policy making effort on risk management that is driven by past failures to protect public health, European political and public demand for more risk-adverse regulation, an expansion of the regulatory authority of EU institutions, and interests of leader states. REACH will be one of the largest pieces of EU legislation on environment and public health ever to be adopted. REACH sets out an ambitious agenda for revising and improving European chemical safety and management. However, proof will be in the implementation and it is too early to say if these ambitions will be realized during the implementation phase likely to begin in 2007.

Instead, this paper examines those factors that lead to the initiation of the REACH process as well as those factors that have shaped the politics of REACH. REACH is an example of the recent trend in EU environmental politics where controversies are played out among different coalitions of actors across European institutions, governments and interests groups, rather than between institutions at different governance levels. The strongest supporters of REACH include environmental ministers in northern European member states, DG Environment, Green parliamentarians, and environmental and public health NGOs. Critics of many aspects of REACH include the chemical industry, politicians from countries with large chemical industries and many conservative parliamentarians. In addition, DG Environment and DG Enterprise repeatedly have been involved in tough negotiations.

The politics of REACH, moreover, has a strong transatlantic and international dimension. While the European Commission keenly promotes REACH in North America, US federal agencies have actively worked with the US chemicals industry against European efforts to create a REACH program. As discussed above, US government and chemical industry criticism of REACH focuses on issues of regulation (including data collection, precaution and regulation), financial costs (costs of expanded assessment and regulation) and markets (standard setting and trade). Diverging transatlantic positions on chemicals management may also lead to growing polarization on chemicals issues outside the transatlantic region as the EU and the United States transfer their differences to global chemicals cooperation and agreements.

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