

Most of the fish being sold in supermarkets and restaurants in Europe would be banned for sale if fish had the same maximum permitted levels of toxins as meat, eggs, milk or chicken. See page 23.

Three Sages by Bente Christensen-Ernst.



(2) The obligation of enterprises to submit a preliminary risk assessment would provide the authorities with comprehensive information on whether or not the chemical substance in question could be handled safely, avoiding unacceptable risks for workers, the population at large and the environment. Thus, for the large majority of substances (estimated at more than 80 percent), there would be no need for further assessment. In the minority of cases where there is need for further assessment, it would be clear where the further assessment should be focussed. The gain in time would be substantial compared to the present system.

(3) Under the new system, the industry would be responsible for preliminary risk assessments and assume responsibility for the safety of its products. It would be under an obligation to cooperate on the establishment of Community Risk Assessments where these were considered necessary. The delays encountered under the present system, where Member State authorities assume full responsibility for risk assessments without the necessary means at their disposal, would be eliminated.

(4) Targeted risk assessments would in most cases replace the comprehensive risk assessments of today. The latter are the main cause of delays under Regulation 793/93 as they require consideration of all dangerous effects, all exposed populations and all environmental compartments.

Accelerated Risk Management

According to the Commission, REACH also contains two factors that would contribute to an acceleration of the legislative process:

(1) The precautionary principle would be invoked whenever the risk assessment process is unduly delayed and where there is an indication of unacceptable risk. In particular, should a producer of a given substance delay the filing of information or test results, the authorities would be entitled to conclude the assessment. It would then pass the dossier to the Commission with a recommendation to apply

the precautionary principle and to proceed to risk management measures to the possible extent of a total ban.

(2) A further acceleration is needed in order to proceed to risk management decisions for other substances in a reasonably short time frame. Thus, the Commission should be authorised to use the Committee procedure under Directive 76/769 more extensively than in the past. This approach would take account of the full range of implications of possible restrictions.

Responsibility

While industry has the formal responsibility for the safe use of chemicals in the current regulation, authorities have the responsibility for performing risk assessments of chemicals that the industry produce. This is very impractical and imposes considerable burden on the authorities, as well as high costs.

In the new strategy however, this responsibility is shifted to industry. Producers, importers and downstream users become responsible for carrying out risk assessments and providing data to the authorities as well as to users and consumers.

Timetable for Existing Substances

The testing and evaluation of the large number of existing substances on the market has a phased approach in REACH. Precise deadlines would be established for the submission of registration dossiers for existing substances. In general, substances produced in higher volumes would have to be registered first. However, the system is intended to be flexible enough to allow for earlier registration of substances of concern (e.g. intended for consumer use or having particular proven or suspected hazardous properties) produced in lower tonnage. Under these presumptions and given rapid progress in adoption of the revised legislation, the suggested deadlines for submission of registration dossiers were basically:

- substances exceeding a production volume

of 1,000 tonnes - at the latest by the end of 2015,

- substances exceeding a production volume of 100 tonnes - at the latest by the end of 2008, and
- substances exceeding a production volume of one tonne - at the latest by the end of 2012.

Dossiers drawn up in the context of the voluntary initiative on the part of the International Council of Chemicals Associations (ICCA) which comply with the OECD procedure would be valid for this purpose. However, the information contained in these dossiers would have to be supplemented in order to meet the requirements in REACH.

The strategy also included a tiered approach for the testing and evaluation of high production volume existing substances. Level 2 testing should be completed for substances above 1,000 tonnes by 2010 and Level 1 testing of substances above 100 tonnes should be completed by 2012.

A Central Entity

The Commission proposed to establish a central entity for the administration of the REACH system and the provision of technical and scientific support. Building on its existing experience, the entity would be the receiving body for the registration dossier, and forward the copies of the registration dossiers to the Member State authorities; establish and maintain a comprehensive central database on all registered chemicals and perform spot-checks and computerised screening of the registered substances for properties raising particular concern. It would also support Member State authorities in the evaluation of substances.

Public Access to Information

Today there is no central tracking system by which the public can determine whether regulatory measures are in place for individual chemicals. There is a lack of public awareness of the requirements of chemicals legislation. There is also little knowledge in the public sphere about the risks posed by chemicals.

The Commission acknowledged consumers' "right of choice." Information should enable the consumer to make a judgement on whether alternative products on the market are more favourable in terms of their intrinsic properties and risks.

The new strategy intended to increase the public understanding of the regulatory system and, furthermore, to give the public access to information about the chemicals being used. Better public access to information on chemicals would increase public awareness and lead to greater accountability on the part of industry and authorities.

The Commission believed that industry, including downstream users, should be responsible for providing this information to consumers. Information must be presented in such a way that it enables a person to understand the risks and to develop a sense of proportion in order to make a judgement on the acceptability of those risks.

Other Issues

The White Paper also touched briefly on other subjects:

- **Stimulating Innovation:** The Commission proposed to increase the current thresholds for notification and testing of new substances, to extend the conditions for derogation for research and development and enable test data to be used and submitted in a flexible way.
- **Substitution:** A key aim of the White Paper. The increased accountability of downstream users and better public information was expected to create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.
- **Non-animal Testing:** To maximise the use of non-animal test methods, testing requirements would be met as far as practicable through use of existing non-animal test methods. The development of new non-animal test methods would be encouraged. Measures to increase testing thresholds and more flexible test regimes would limit the need for testing.
- **Trade Barriers:** The new policy should not



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Humans, birds, arctic mammals and other animals have persistent man-made chemicals in their blood and tissue. Scientists refer to it as our "body burden". See pages 21-25.

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discriminate against imported products. In that respect, the EU should conform with Article 2.1 of the WTO's Technical Barriers to Trade, which sets out that imported products shall be accorded treatment no less favourable than that accorded to like products on national origin.

- **Complying with OSPAR:** The Convention for the Protection of the Marine Environment of the North East Atlantic aims to prevent and eliminate pollution and to protect the maritime area of the North East Atlantic against the harmful effects of human activities (e.g. land-based sources, off shore sources, dumping and incineration of wastes). The strategy supports this aim, in particular through the proposals for improved controls on downstream users of chemicals.

Costs

The Commission pointed out that it is very difficult to give a reliable estimate of the "cost of action" implied, such as for the testing of existing substances where availability of test data generated earlier is largely unknown. However, a first estimate was given:

- Testing costs for existing substances: €2.1 billion over 11 years = €0.2 billion/year, to be borne by the chemicals industry.
- Human resources for a new entity: A staff of 190 people at the European Chemicals Bureau (ECB) to provide the technical and administrative framework.
- Public human resources in the Member States: Member States will relocate their current staff. Extra resources will be allocated to evaluation of existing substances. These resources will be freed from their current tasks by the following measures:
 - Computerised screening and spot checks will replace the current general conformity check for new substances below 100 tonnes.
 - Risk assessments will generally be carried out by industry rather than authorities.
 - Industry human resources: an estimate is hardly possible because an increase can be expected for processes such as the authorisa-

tion process, but a reduction can be expected because of:

- notification of substances between ten kg and one tonne/year/manufacturer,
- less strict requirements for certain substances such as intermediates with low exposure,
- less strict requirements for R&D (research and development) substances.

Benefits

According to the Commission, the main benefits of the proposal were:

- Better protection of the environment and human health through appropriate risk management based on adequate information about the dangerous properties of chemicals. This would reduce the incidence of certain diseases related to chemicals (such as cancer or allergies) and reduce the risks that chemicals can pose to the environment (such as through the accumulation of persistent chemicals in the food chain). The main difficulty is that neither the dangerous properties nor the uses of chemicals are sufficiently known. The influence on allergies is an example.
- Allergy treatment costs are estimated at €29 billion/year in Europe. Chemical substances are considered to play a major role in inducing allergies either directly or by increasing susceptibility to natural allergens (e.g. pollen). For example, a US study has shown that asthma cases have risen by 40 percent since the 1970s. If the new strategy makes even a small reduction in the €29 billion cost of allergies, this will outweigh the costs of the strategy.
- Improved framework for innovation in the chemicals sector which will contribute to the development of novel chemicals that may substitute current chemicals of concern thus decreasing the risks from chemicals.
- Strengthen the competitiveness of the EU chemicals industry.
- Increased transparency and better access of the public to information, thus enabling more informed choices.

General Advantages

The REACH system was described by the Commission as having many advantages compared to the current regulation. The main issues were:

- A single coherent system for all chemical substances.
- All substances, existing and new, produced in volumes above one tonne per year would be covered.
- Acute and long-term toxicity would be tested.
- Waiving of testing on due justification, and all available test data used and registered.
- Reduced testing for low exposure substances and R&D (research and development) substances.
- Limited in vitro testing for substances between one and ten tonnes.

REACTIONS ON THE WHITE PAPER

Overview

The White Paper outlining the new strategy was sent to the Council and European Parliament (EP) for consideration. The Council reacts by adopting conclusions while the EP adopts a resolution. These are then sent back to the Commission for the drafting of a legislative proposal based on the opinions of the Council, EP and other stakeholders.

The Council adopted conclusions in June 2001 while the Parliament adopted its resolution in October the same year. Both were positive towards REACH but also asked for amendments, in general making the system stronger in protection of the environment and human health, animal protection, consumer protection, etc., but also requiring it to be simplified.

Simultaneously, the Commission held conferences and stakeholder meetings to get feedback from other stakeholders. The Commission also set up working groups consisting of experts to provide advice on specific areas, enabling the Commission to draft legislative proposals for the implementation of REACH.

Beside these formal channels, many stakeholders reacted through media and initiated lobbying campaigns. The chemicals industry and trade unions, as well as political, environmental, consumer and animal protection groups, increasingly made their voices heard in support or defiance of the REACH system. Eventually even government officials and Heads of State from major industrial (chemical) countries engaged in the debate.

The Commission was also divided internally between the interests of health and the environment on the one hand - represented by DG Environment - and the interests of the chemicals industry, represented by DG Enterprise, on the other. Both Directorates had been involved in the process of drafting the new chemicals policy.

With the call for a new chemicals strategy coming from the Environment Council to increase the protection of human health and the environment, DG Environment had the initiative through the initial stages of drafting the strategy. However, as critique against REACH from the chemicals industry and powerful industrial countries increased, DG Enterprise took the initiative, increasingly turning the focus of the strategy toward competitiveness, downplaying the reason for developing a new strategy in the first place: to increase protection of humans and the environment.

Council

The European Council, consisting of the EU Heads of State, adopted conclusions on the White Paper at a meeting on 7 June 2001. The Council welcomed the White Paper and generally supported the REACH system as proposed. The Council also called on the Commission to present a proposal for a regulatory framework by the end of 2001.

However, the Council also had a number of concerns where they called for clarification and amendments, mostly with the aim of further increasing protection of human health and the environment. Thus the Council invited the Commission to:

- More deeply study the relationship to legislation in other areas and consider measures to avoid duplication of legislation work and to achieve coherence and the same level of protection in all fields of Community legislation.
- Study the case for introducing within the REACH system a simple register including substances produced in volumes below one tonne, with the aim of allowing, if possible, prioritisation of substances of concern.
- Study how to develop screening procedures to effectively identify chemicals with potentially harmful properties or uses of concern for the purposes of prioritising substances for which further information is urgently needed and those requiring accelerated risk management.
- Study how to develop criteria for classifying substances in categories of concern and explore the use of decision trees to apply consistent control measures, based on hazard criteria and use patterns, in line with a prudent and precautionary chemicals management.
- Further study the data requirements for substances produced in volumes below ten tonnes in order to ensure that the information provided will be sufficient for classification and labelling and to assess the need for risk reduction measures. The data sets must also provide appropriate information for handling cases of unintentional releases and to enable the protection of the health and safety of workers while ensuring a minimum of animal testing.
- Develop procedures that can be used both by authorities and the industry to simplify the identification of the relevant testing strategies and reduce the need for animal testing, including the use of decision trees and specific screening methods for all chemicals, such as validated computer modelling and testing to identify chemicals that are persistent and that bioaccumulate, taking into account the cost of testing requirements.
- Exploit, in order to limit the costs and efforts involved in the novel authorisation procedure, all realistic means of simplifying the procedure and of making use of available informa-

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tion; to this end authorisations that have an impact on the internal market should have general validity and be taken on the Community level.

- Add PBT (persistent, bioaccumulative and toxic chemicals) and VPVB substances (very persistent, very bioaccumulative chemicals) to the groups of substances of very high concern that will be subject to authorisation as soon as the necessary criteria for their identification are established.
- Envisage the addition of known endocrine disrupters to the authorisation system when agreed scientifically valid test methods and criteria are established, and study whether other substances with properties of concern, such as sensitizers and chronic toxic substances, need to be included in the authorisation system.
- Co-ordinate in co-operation with member states the input into the international work on the Globally Harmonised Classification and Labelling System (GHS) and also analyse its implications for the Community legislation

and consider, as appropriate, the need to submit proposals for its implementation.

- Further investigate how a central entity such as an expanded ECB (European Chemicals Bureau) or other body should best be organised and financed to avoid duplication of tasks as well as how fees, funds and other means of financing can support the resources of such an entity as well as the tasks carried out by member states and to assess and minimise the overall costs for their public administrations, with the aim not to exceed, if possible, the costs implied by full implementation of the existing legislation.
- Develop mechanisms and define practical rules, to be operational when the system is implemented, through which the industry makes testing data and other information available in order to avoid duplication of tests and market distortions, while ensuring an equitable sharing of costs taking due account of the property rights of the party who generates the data.
- Investigate ways to ensure the effective implementation and study the adequacy of

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industry's data quality assurance system, and the enforcement of the new legislation, including provisions for a review of its implementation to allow for adjustments if the objectives are not being met.

European Parliament

In the European Parliament, the White Paper was considered by the Environment Committee, based on the Schörling Report by the Rapporteur Ms. Inger Schörling. The Committee welcomed, as did the Council, the White Paper and agreed with the REACH system in general, but also called for changes to strengthen the proposal, in many cases on the same issues as the Council had called for changes.

On 17 October 2001, the Environment Committee motioned for the adoption by the Parliament of a resolution supporting the Commission's plan to establish a single system for the registration, evaluation and authorisation of both existing and new chemicals but called for a more proactive, preventive approach.

According to the motion, a key aim of the new policy must be to phase out substances as soon as they are shown to be of "very high concern" unless their use and their hazardous properties are shown to be essential and there is no safer alternative.

To this end, the Committee wanted the range of chemicals subject to authorisation to include persistent and bioaccumulative substances, endocrine disrupters and substances that are carcinogenic, mutagenic and toxic to reproduction.

The motion also called for the inclusion of imports into the EU and chemicals present in manufactured goods. Substances deemed to be of very high concern must, it said, be banned from consumer products by 2012 and products must be labelled to warn consumers of dangerous substances contained in them.

Chemicals in volumes of less than one tonne should also be included in the new regime and registered, under a simplified pro-

cedure, by 2012 unless they were shown, as a result of screening carried out before 2008, to be of potential concern in which case they must be subject to full registration.

The motion also set out that effects of chemicals on children's health must be taken into account and it also wanted animal testing banned where recognised alternative tests are available.

The motion was debated and adopted by the Parliament on 15 November, 2001. The Rapporteur had tried to find compromises for the amendments with her colleagues and shadow rapporteurs from the different party-groups. Although some successful compromises were achieved, the PPE voted against the Resolution in the final vote. The motion was adopted by 242 in favour, 169 against and 35 abstentions.

Most of the proposals from the motion remained, although some points were taken out or rephrased, while some additional points were inserted. In the end, the Parliament vote on the Resolution required the strengthening of REACH on many points. Among the key issues were:

Objective: The Parliament stressed that protection of human health and the environment must have priority, that the new policy must cover the entire life-cycle of chemicals, and aim to achieve the generation goal of the OSPAR Convention (see *Esbjerg Declaration* and *OSPAR Convention* on pages 45-46).

Animal tests should be reduced to an absolute minimum and prohibited where recognised alternatives are available.

Duty of Care: industry should have a Duty of Care for chemicals irrespective of the production volume.

The Substitution Principle and the promotion of safer practices and substances to replace hazardous practices and substances must be implemented as a key aim of the EU chemicals policy, and as primary risk reduction option. The substitution principle should apply to all chemicals of concern.

Registration of substances below 1 tonne: contradictory votes were adopted. A PPE amendment asking for the rejection of such a register was adopted narrowly with support from the UK Labour Party. At the same time, the original paragraph 17, that asked for comprehensive minimum information on all chemicals, irrespective of tonnage, was maintained.

Scope of substances of very high concern: (substances to be phased out, unless they are specifically authorised): Calls from the Rapporteurs for an extension of the scope was rejected with the adoption of amendment from PPE, again with the votes of UK Labour. The result was the same as the Commission proposed, substances that are carcinogenic, mutagenic and toxic to reproduction categories 1 and 2 and POPs to be included, inclusion of other substances that are of high concern, such as substances that are persistent, bioaccumulative and toxic to reproduction are to be considered.

Authorisation: Strong wording from paragraph 34 was adopted with a request that industry must prove that the use of the substance in question is really needed and that there are no alternatives, and that the hazardous properties of the substance are needed for the intended purpose.

Public availability of data: key information such as production volumes, use patterns and exposure sources were requested to be made publicly available in addition to information on the properties of chemicals, and requests for comprehensive labelling.

Chemicals in consumer products: Parliament asked that imported articles should be treated the same way as articles produced in the EU and for labelling provisions for substances of concern in consumers products.

Cefic

While the Council and Parliament were supportive but asked for more, the chemicals industry opposed the new system on many grounds. On 13 February, Cefic issued a press

release stating that the chemicals industry supported the objectives of the proposed new strategy. These are defined as to protect human health, safety and the environment, assuring coherence of the internal market, giving the public access to information and enhancing the competitiveness of the European chemicals industry.

However, Cefic did not believe that REACH would work in practice or that it would achieve the objectives. Furthermore, the association asserted that it may even damage the competitiveness of the European chemicals industry. The main critique from Cefic was that chemicals regulation should be based on risk assessment. The requirement for authorisation of substances based on their intrinsic properties, such as persistence and bioaccumulation, was considered of particular concern, as it could lead to arbitrary restrictions and bans with potentially serious effects on the chemicals industry.

Cefic also pointed out that the proposed system would increase bureaucracy and result in more tests having to be performed on more chemicals, which would slow down progress. Instead Cefic wanted to see a streamlined testing programme, speeding up the risk assessment process.

The increased testing would also mean that more animal testing would have to be done by the chemicals industry. Cefic wanted the test programme to focus on the substances which give the greatest cause for concern.

The registration process for new substances was also considered inadequate. Cefic wanted it improved in order to regenerate innovation. Finally, Cefic said that it will continue its commitment to the voluntary HPV programme, which is scheduled to provide basic information on 1,000 HPV chemicals by the end of 2004.

Cefic Thought Starter

In September 2001 Cefic launched a "Thought Starter on REACH - an Initial Proposal for Translating the REACH System into

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Forty-four percent of sampled vegetables and fruit contained at least one pesticide. One hundred percent of sampled rain contained phthalates, softeners used in PVC plastic. Alkylphenols, ethoxylates and synthetic musks were found in almost all samples. Brominated flame retardants were found in 30 percent.

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Practice.” In a 21-page paper, Cefic presented its own version of REACH where the requirements of the chemicals industry had been met. In summary Cefic proposed the following:

Registration: should only be required for non-polymer substances which are placed on the market in volumes exceeding one tonne per year. Cefic specified a “core information set” for necessary information as related to likely exposure and tonnage. Documentation of data should be the responsibility of industry and be accessible to authorities.

Evaluation: Cefic proposed that if the available data and information are insufficient for an appropriate risk assessment, the regulators have the ability to require the consortia or company concerned to provide the required information. If there are indications of unacceptable risks, regulatory action can be taken.

Evaluation must take place within a “reasonable” and definitive timeframe to enable the enterprises involved to plan for the future and for the system to work effectively.

Authorisation: Authorisation should apply only to those substances which match criteria, and which have been through the registration and evaluation procedure. Substances, which are controlled by other legislation, should not need authorisation under REACH.

It is the view of Cefic, that substances of “very high concern” should be very limited in scope, restricted to CMRs of Category 1 and 2, and POPs (characteristics laid down in the Stockholm Convention on POPs).

If the substance is not already “adequately controlled,” industry should be required to provide further information within an agreed timeframe. Unless the substance gives rise to severe concern due to exposure, the enterprise may continue to market the substance in the interim.

Cefic wrote that all decisions on authorisation for specific uses should be based on:

- a risk assessment,
- a full socio-economic analysis,
- the availability and the impact of alternative substances (substitutes), and

- risk reduction measures to minimise exposure to acceptable levels.

Uses which do not give rise to concern or which are already controlled would be exempt from this procedure.

Non-Government Organisations (NGOs)

Many NGOs, mostly environmental and consumer groups, had been watching what was going on since the Council had called on the Commission to draft a new strategy for a chemicals policy in 1998. They were also trying to have an influence in the debate, supporting a strong and pro-active legislation for the protection of human health and the environment. Since 2000, some of them had joined the statement in the Copenhagen Chemical Charter.

When the White Paper was presented, most of the international environmental groups, such as The European Environment Bureau, Friends of the Earth, Greenpeace and WWF, welcomed it as a step in the right direction. However, they had many reservations (see *Differing Views*).

STAKEHOLDER'S CONFERENCE

In April 2001, the Commission organised a conference to launch the new chemicals strategy as introduced in the White Paper and to gather input from key stakeholders on its implementation. The Conference was opened by the Commissioner for the Environment, Margot Wallström and the Commissioner for Enterprise, Erkki Liikanen.

Stakeholders gave their input during two workshops. The first workshop addressed the process and how to implement the new policy in the most cost-effective way. The second concentrated on major stakeholder contributions.

Stakeholders agreed on a wide range of subjects, such as the objectives of the strategy, the need for a scientific approach, that a single system was preferred to the current regu-

lation, to increase efforts to communicate and that international cooperation is essential.

However, there was vast disagreement on many complex issues and basic principles. Some elements of the proposed strategy were judged inappropriate by certain stakeholders.

Industry and trade union representatives considered the authorisation process as unnecessary in view of the registration and evaluation steps, and would prefer a system that uses restrictions rather than authorisation. Moreover, the time schedule proposed in the White Paper was, according to industry, too tight, in particular for the in-depth testing requirements. Further, it was pointed out by some stakeholders that the White Paper did not take into account socio-economic consequences.

The trade union representatives disagreed with the fact that substances should be banned solely on the basis of intrinsic properties. They thought that the policy should include assessments of risks and benefits before bans are decided, and risks of alternative options must also be considered.

The environmental NGOs viewed the strategy developed in the White Paper as too narrow and as catering too much to industry self-interest. As it stands, they believed that it was not adequate to protect human health and the environment.

The consumer NGO representative requested downstream liability in industry - the new chemicals policy should set out the minimum requirements for all other sectors. Several member states expressed concerns about the resources that would be necessary to implement the new strategy. Representatives from small and medium-sized enterprises (SMEs) and some downstream users expressed similar concerns about the proportionately high costs that they might have to face.

Stakeholders also held diverging views on the scope for authorisation, some calling for inclusion of other categories than CMR and POPs. NGOs and some Member States called for a prudent approach, particularly concern-

ing testing requirements in the one to ten tonne range because most of the in vitro tests have yet to be developed.

TECHNICAL WORKING GROUPS

In order to assist the Commission in its development of legislation to implement REACH, a number of working groups of technical experts were convened from October 2001 to February 2002. The working groups were made up of stakeholder experts on particular topics covered by the White Paper, who came from authorities in the member states, industrial associations and NGOs.

Eight working groups were established assessing different aspects of REACH and the legislative context. During the first meeting, tasks were assigned to the members of the groups. The papers that were produced as a result of this assignment were presented and discussed during the second meeting. The working groups covered the following areas:

- testing, registration and evaluation,
- risk assessment,
- substances of very high concern,
- classification and labelling,
- risk management,
- substances in products, and
- information through the supply chain.

The final documents were presented to the Commission as stakeholder input to the initial drafting of a regulation.

BUILDING BLOCKS

Based on the Council Conclusions, the EP Resolution, reports from the Technical Working Groups and input from various conferences and meetings with stakeholders, the Commission initiated the task of drafting legislation to implement REACH into EU regulation.

The work was organised under eight headings, similar to those of the Working Groups, which together would form the entire legislative proposal. Each heading was called

Snow, ice and water from Alpine regions contain DDT, PCB, brominated flame retardants, HBCDs, chloroparaffins, phthalates, toxaphenes and chlorinated dioxins and furans.

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a Building Block. These were drafted from June to October 2002.

The Building blocks were internal working documents which contained the detailed suggested wording of the proposal. In November 2002 an early draft of the authorisation block leaked from the Commission. This draft shows that there was considerable disagreement between DG Environment and DG Enterprise on many issues, e.g. regarding which substances would be banned and require authorisation for production. DG Environment wanted to include PBT and vPvB substances, required specification of which uses the authorisation would cover and time limits for the authorisation if granted. In the draft, this view was not shared by DG Enterprise. Drafting of the legislative proposal went on into spring 2003. In the meantime, a number of studies concerning specific aspects of the regulation were performed.

THE DRAFT REGULATION

Overview

Since the White Paper was presented in February 2001, there had been a major political, media and lobbying battle in the EU regarding the future chemicals regulation. Initially industry opposition came mainly from individual large chemicals industries, but when the presidency of Cefic went to the BASF top-gun Eggert Voscherau in summer 2002 things really started to heat up (see also *Behind the Scenes*).

The entire chemicals industry was mobilised and came out aggressively against the content of the White Paper. Moreover, the industry put pressure on DG Enterprise and created an increasing internal split within the Commission. They even managed to have Heads of State from Member States - who had recently requested stronger provisions in REACH - to come out against REACH. Furthermore, unions, employer organisations and animal welfare organisations were attacking different aspects of the strategy.

As if these forces were not sufficient, in March 2003 the European Council had expressed that “competitiveness must once again be centre stage” in the EU. To this end, the new Competitiveness Council was requested to be involved in the REACH process.

Also the US chemicals lobby ACC, the global chemicals federation ICCA and the US government joined the battle. The campaigns against REACH were among the most aggressive ever experienced in the EU.

The result of these campaigns was that the Commission backed down. The requests put forth by the European Council and European Parliament for strengthening the strategy were mostly left out. Instead the Commission began to water down the White Paper.

The Internet Consultation

The Commission decided to present the Draft Regulation to stakeholders and the general public in a consultation, inviting comments on the content before finalising it and sending it to the European Parliament and Council for consideration. On 7 May 2003, the entire draft was presented on the Internet.

The purpose of the Internet consultation was to test the workability of the proposals with stakeholders. There were about 1,200 pages of legislative text, largely made up of technical annexes that were not new requirements, as well as a range of new procedures. The Commission wanted feedback on the drafts before finalising its` proposal.

The Draft

The Draft Regulation, which would replace over 40 existing directives and regulations, intended to implement the proposals set out in the White Paper. The legislation aimed to place a duty on companies which produce, import and use chemicals to assess the risks arising from their use, requiring new test data to be generated and to take the necessary measures to manage any risks they identify. This would reverse the burden of proof from public authorities to industry for putting safe

chemicals on the market. Testing results had to be shared to reduce any likely animal testing. Registration of information on the properties, uses and safe use of chemical substances were also said to be an integral part of the new system.

Main Features

The main features of REACH in the Draft Regulation were similar to the White Paper:

Registration

A mandatory registration of existing and new chemicals produced in volumes above one tonne per year and producer. The registration procedure required that the producer or importer provide a technical dossier containing data and information about the substance in question to the authorities. A substance may not be marketed until it was registered.

Evaluation

The dossier and the substances that apply for registration would be evaluated by authorities in the Member States. The evaluation followed prioritisation criteria to be elaborated by the new agency (see below).

Authorisation

Substances of very high concern may only be produced and marketed if the Commission gave permission - authorisation. The authorisation must be granted if the applicants show that the risk generated from its use were "adequately controlled." If this was not shown, the authorities may grant an authorisation if it was shown that the socio-economic benefits outweighed the risk to human health and the environment and that there was no suitable alternative substance or technology. Such an authorisation would normally be time-limited.

Scope

The registration requirements varied depending on the volume in which a substance was produced, and on the likelihood of exposure to humans or the environment. A phased-in system lasting up to 11 years was foreseen.

Higher tonnage substances would require the most data, and would have to be registered first. The latter provisions were intended to reduce the regulatory burden on small and medium sized enterprises.

Tighter controls would be introduced for the chemicals of highest concern. Thus, certain types of substances such as carcinogens, mutagens and reproductive toxicants (CMRs), persistent, bioaccumulative and toxic substances (PBTs) and very persistent and very bioaccumulative substances (vPvBs) would be subjected to the authorisation regime and would be registered early. In certain cases also other substances, for example with endocrine disruption effects, could be included on a case by case basis within the authorisation system where it was shown that they give rise to the same level of concern.

Each use of such substances would have to be authorised for a specific use. Decisions would be based on a risk assessment and consideration of other socio-economic factors.

Others, such as polymers (chemicals used as raw materials for plastics and detergents and a wide variety of other products), and substances used as intermediates would be subject to substantially lighter registration requirements. In many cases, where there is little risk of exposure, polymers and intermediates will be exempted from registration.

The Commission expected that around 80 percent of all substances would only have to be registered, the rest would have to undergo evaluations for safety and subsequent authorisation.

The member states would be responsible for the evaluation of substances by examining certain registration dossiers, as well as checking the application of REACH within their own territories. They would also be able to suggest restrictions on the use of substances based on a structured risk assessment - where they consider that EU legislative action is necessary, although the final decision on such restrictions would be taken by the Commission.

The Commission would grant authorisations after taking into account the views of the agency on the risk and on the socio-economic aspects. Authorisation decisions would take into account the guarantees provided by the applicant firms and available information on alternative substances and processes that may reduce the risk posed. To simplify the system and to reduce costs, an authorisation would be valid for enterprises further down the supply chain as long as they abide by the conditions for the intended use and inform the Agency.

A New Agency

A new chemicals agency was also proposed to manage REACH. The agency would have the task of ensuring the efficient operation of the new system, including providing advice to the Commission, and guidance to Member States and to enterprises, including SMEs. Non-confidential data generated by REACH would be made available to downstream users of chemicals and to the general public in a publicly accessible database.

Research and Innovation

Research and innovation would be encouraged by allowing research and development to take place without registration for five years, extendable to ten years, an extension of existing provisions. In order to keep the need for animal testing to a minimum and to keep costs down, a system of data sharing among companies was proposed. In addition, important elements of flexibility were proposed within the testing requirements, allowing industry to use alternative sources of information to fill data gaps, or to argue that certain tests were unnecessary because of a lack of exposure.

Changes from the White Paper

Albeit the European Council and European Parliament had requested significant changes to the strategy as proposed in the White Paper, it was difficult to see that this had any major impact on the Commission. Instead the Draft Regulation became weaker than the White

Paper in many details. But there were two severe cutbacks.

The first concerns the substitution of hazardous substances with less hazardous substances. This is one of main aims of the new strategy according to the White Paper and it had provisions calling for the substitution of hazardous substances when less hazardous alternatives exist. In the Draft Regulation, this had been reversed; the availability of safer alternatives was explicitly ruled out as reason enough to decline authorisation of a hazardous substance.

The second cutback concerns the ambition in the White Paper that producers or importers of products that can lead to significant exposure of humans and the environment to chemicals should provide relevant information about the chemicals released. In the Draft Regulation, the Commission abandoned this ambition and foresaw registration of substances released in volumes above one tonne and that are likely to cause harm.

REACTIONS TO THE DRAFT Overview

The consultation went on from May to July 2003 and resulted in some 6,500 responses, mainly from the chemicals industry, its employees and associated organisations, but also from a wider group of stakeholders. All comments are available on the Commission Website. Below are some examples but all the comments may be downloaded or viewed on the Commission Website <http://europa.eu.int/comm/environment/chemicals/whitepaper.htm>.

In addition to the comments received via the Internet and e-mail, the Draft Regulation was widely commented on in media by politicians, academics, industrialists, activists and other stakeholders. Notably, even heads of Member States, the US government and governments in Asia voiced concern and critique against the Draft Regulation.

Chemicals Industry

The chemicals industry was very critical of the Draft Regulation presented for consultation, even though they had won considerable alleviation on the issues of substitution and chemicals in products. The main issues of concern for the industry were:

Scope: Under the REACH system, chemicals may be regulated on their intrinsic properties, such as persistence, bioaccumulation and toxicity (PBT), or if they are very persistent and very bioaccumulative (vPvB) toxicity is not required for regulatory action to be taken. This approach is opposite to the current concept that exposure can be predicted and used as a determining factor. The chemicals industry also opposed required authorisation of endocrine disrupters and potentially carcinogenic substances.

Further, they stated that all substances already covered by other EU regulation should be excluded from the scope of the regulation. Information and management: The proposal was considered too bureaucratic, demanding too much documentation and information. Industry also wanted to put more responsibility and decision-making power with the new central agency, avoiding individual member states starting substance evaluation on suspicion.

According to Cefic, the problems identified above would lead to serious effects for the European chemicals industry and ultimately the EU economy as a whole. The following effects were predicted:

Workability: The REACH system as proposed was not workable because of the high demands. It was considered unscientific, over bureaucratic and unmanageable and may collapse up front.

Competitiveness: The lack of workability and the restrictions regarding what substances would be allowed in production would put the European chemicals industry at a serious disadvantage compared to its main competitors in the US and Japan. Sales, especially outside the EU, were threatened. Since the chemicals

industry is the largest industry in Europe, this would have repercussions throughout the whole European economy.

Costs: While the White Paper estimated that the increased costs to be borne by the EU chemicals industry would be about €2.1 billion over 11 years, other studies, commissioned by the chemicals industry, claimed that costs would be immensely higher. In France alone the costs, including loss of GDP growth, could be up to €88 billion.

Jobs: The ultimate consequence of the lack of workability, reduced competitiveness and high costs is, of course, jobs. The chemicals industry claimed that REACH would lead to massive unemployment across Europe, especially in countries with large chemicals industries such as Germany, France, Italy and the UK. In France, up to 670,000 jobs would be lost according to a report commissioned by the French chemicals industry. A report commissioned by the German industry had previously claimed that 1.8 million jobs could be lost in Germany.

In August, the European Federation of Chemical Distributors (FECC), an organisation very close to Cefic, let its' national federations in France, Germany, Italy and Ireland write letters to the Heads of State. The letters outlined the concerns for financial problems to the chemicals businesses throughout Europe and ensuing unemployment. FECC urged the governments to act against REACH. :

George W. Bush Administration

The US government ran an aggressive lobby campaign to influence the development of REACH since the White Paper was presented in February 2001 (see also *Behind the Scenes*, page 101). The campaign was mainly orchestrated by the American Chemistry Council (ACC) and its global counterpart ICCA where ACC held the rotating presidency. In fact, the US lobbying was so strong that it prompted a letter of protest from 68 medical, healthcare, academic, scientific and environment NGOs in the US.

The prime concerns of the US government were that the new approach to regulation of chemicals could:

- Disrupt US exports of chemicals and consumer products containing hazardous substances to the EU and distort global trade in tens of billions of dollars in chemicals and downstream products - from autos to textiles.
- Influence REACH-like policies to spread to other regions and be embraced by the United Nations for regional or global regulation and treaties (e.g. SAICM).

In April 2003, while the Commission was having internal negotiations regarding the Draft Regulation, US Foreign Secretary Colin Powell sent a cable to US embassies in the EU (see *US action Cable* in the Appendix.) Echoing the concerns voiced by the chemicals industry, the cable outlined the concerns of the Bush administration and requested that the embassies should act by presenting these concerns to all relevant Commission Directorates General (DGs), as well as all Ministries of Environment, Trade, Industry and Foreign Affairs in the EU member states. The talking points listed and ways of presenting them were inter alia:

Workability: The approach outlined in the White Paper raises questions about its workability and thus its ability to effectively achieve its health and environmental policy objectives. The focus on tens of thousands of chemicals is too broad and lacks prioritization. Implementation may prove problematic.

Scope: Regulatory resources should focus on chemicals posing the greatest risks. Certain low risk types of chemicals should be excluded - such as certain polymers and intermediates where exposure is negligible - and most constituents of articles. An additional benefit of a more focused approach would be reduced animal testing - an outcome which would be consistent with EU animal welfare objectives.

Costs and Competitiveness: The costs to implement REACH are substantial. The Commission's own cost estimates for REACH total

Typical Industry Arguments

A study of industrial argumentation made by The Stockholm Environment Institute in 1999 shows that there are four arguments that are typically raised by industry in opposition to new environmental regulation:

1. The proposed policy may be counterproductive, adding to costs as well as failing to yield environmental benefits, i.e. a lose-lose situation.
2. The environmental goal may be valid, but the proposed instrument is inefficient in that it imposes unnecessary costs.
3. The proposed instrument may lead to changes in competitive conditions which may disadvantage important sections of industry or place industry at a disadvantage compared to those in other countries or regions.
4. There is an irresolvable conflict between society's desire for higher environmental standards and a company's goal of adding to shareholder value.

€18-32 billion and do not take into account effects on prices, international competitiveness and employment. These costs of compliance may negatively impact innovation and development in the EU of new, more effective, and safer chemicals and downstream products.

Trade: The proposed approach would adversely impact production and transatlantic trade in tens of billions of dollars in chemicals and downstream products - from autos to textiles. There is concern that the economic implications are not adequately assessed.

Considering the content of the Draft Regulation presented one month later by the Commission, it seems that the Bush administration had some success on key issues, e.g. the exclusion of polymers and most constituents of articles. Nevertheless, the Bush administration was not pleased.

In May 2003 the Draft Regulation was criticized in an official comment from the US government. Key points were similar to the lines that had been communicated throughout

the campaign. The Draft Regulation:

- may be unworkable,
- departs from ongoing international regulatory cooperation,
- imposes substantial costs while providing uncertain benefits,
- adversely impacts small and medium sized companies,
- disrupts global trade,
- adversely impacts innovation,
- creates market uncertainty,
- is unclear regarding administrative coordination and consistency, and
- raises concerns regarding consortia and data sharing.

In conclusion, the US government strongly encourages the Commission to:

- 1) Reduce the scope of aspects of the regulation to better focus EU resources on substances that are likely to pose the highest risks;
- 2) Develop an EU approach which supplements - and does not supplant - ongoing international cooperative efforts to effectively address the risks posed by existing chemicals;
- 3) Clarify and simplify the process by which regulatory decisions will be made; and
- 4) Ensure that the impacts of the EU regulation - both positive and negative - are fully and transparently assessed. The Commission should also ensure that its final proposal is fully consistent with the EU's international obligations.

Blair, Chirac and Schroeder

The governments of the UK, France and Germany submitted comments on the Draft Regulation. The comments voiced concern regarding the same issues as the chemicals industry and the US government brought up: bureaucracy, lack of workability, loss of competitiveness for the EU, jobs, trade effects, etc., as has been previously described.

On 20 September 2003, as the Commission was again redrafting the regulation after the comments from the Internet consultation, the Heads of State of these nations went further. In a joint letter to Romano Prodi, the Presi-

dent of the Commission, Prime Minister Tony Blair, President Jacques Chirac and Chancellor Gerhard Schröder reiterated their concerns.

They pointed out that in March 2003, the European Council has sent out a clear signal for strengthening the competitiveness of the industries in the EU and to reduce the bureaucracy facing these companies in order to achieve economic growth and comply with the Lisbon Strategy.

They clearly state that "a future EU chemicals policy must be designed in such a way as to ensure environmental, health and consumer protection without endangering the international competitiveness of the European chemicals industry." The concerns of the three Heads of State can be summarised as:

- the Draft Regulation is too bureaucratic,
- it may be unworkable,
- it does not prioritise the substances of most concern, and
- it may have an impact on competitiveness.

The letter in itself, the context in which it was written and the specific demands was clearly a very strong statement from the three major chemical producing nations in the EU. The implicit meaning is that economy is the priority if protection of the environment, health and consumers is not compatible with international competitiveness.

Environmental NGOs

The four largest environmental NGOs - the European Environment Bureau, Friends of the Earth, Greenpeace and WWF - submitted a joint document in the consultation. The groups welcomed REACH and wrote that the Draft Regulation goes part of the way towards phasing out the production and use of hazardous substances. The NGOs particularly welcomed that PBT and vPvB substances, as well as EDCs are covered by the scope of the authorisation stage and that substances will not be allowed to be marketed if there is insufficient data.

However, they also identified a number of crucial flaws in the Draft Regulation:

Substitution: Continued use of the worst chemicals, even when safer alternatives are available. The new system will identify the worst chemicals - those of very high concern - but, as currently designed, industry would be able to get permission to carry on using them, even if safer alternatives are readily available. In the view of the NGOs, the use of chemicals of very high concern (such as those that accumulate in breast milk) should only be allowed if industry demonstrates an overwhelming societal need, that no safer alternatives are available and that risk reduction measures will be put in place.

The NGOs stated that progressive, step-wise substitution of hazardous chemicals with safer alternatives is necessary to achieve the goal of phasing out use of the worst persistent, bioaccumulative and toxic chemicals. They also wrote that consideration of availability of alternatives as an integral part of an authorisation application is necessary to prevent the authorisation system from becoming bogged down with applications for unnecessary uses of chemicals of very high concern.

Transparency: Secrecy remains. The current proposals would allow industry to keep a large amount of information confidential regarding the production and use of chemicals. The NGOs wrote that this is against the interests of consumers, workers, downstream users and retailers.

Untested chemicals in consumer products: The current proposal would allow imported products to contain untested chemicals, presenting unknown hazards to Europe's consumers.

Unclear definitions: The NGOs point out that, a number of key concepts were not sufficiently defined and/or explained. This includes adequate control, socio-economic assessment and exposure scenarios. They noted that poor definition of such concepts leaves many aspects of the REACH system open to interpretation, particularly by the agency and its Committees. This would not prevent political horse-trading in controlling chemicals and

The Lisbon Strategy for Economic, Social and Environmental Renewal

The Lisbon Strategy is a commitment to bring about economic, social and environmental renewal in the EU. In March 2000, the European Council in Lisbon set out a ten-year strategy to make the EU the world's most dynamic and competitive economy. Under the strategy, a stronger economy will drive job creation alongside social and environmental policies that ensure sustainable development and social inclusion.

The Lisbon Strategy touches on almost all of the EU's economic, social and environmental activities. The European Commission's annual Spring Report examines the Strategy in detail. The Spring Report is the only document on the agenda of the Spring European Council, where EU Heads of State and Government assess the progress of the strategy and decide future priorities in order to realise the Lisbon targets.

continue the current cumbersome and ineffective decision making.

Inconsistency between treatment of different chemical properties of very high concern in authorisation and registration. The Commission's inclusion of substances with PBT, vPvB, CMR and endocrine disrupting properties in the authorisation scheme was welcomed. However, it was pointed out that in several places in the text relevant for the authorisation and registration procedure, CMRs are dealt with as a priority or specific arrangements have been provided, without considering the new scope of authorisation.

In addition, a number of specific comments were given by the NGOs in the order required in the Commission's guidance for the Internet consultation.

Consumer Organisations

The consumer organisations support the introduction of a more protective regulation on chemicals, especially concerning chemicals

Berlin, 20 September 2003

Dear President,

On our initiative on 21 March 2003, the European Council sent out a clear signal for strengthening the industrial competitiveness of the EU. We agreed that we had to reduce the bureaucracy that European companies encounter and decisively improve the regulatory framework within which our companies, faced with strong competition, must manoeuvre.

To achieve this, we must ensure we do not place unnecessary burdens on industry. We continue to call on the Commission to conduct an analysis of current market and competitive conditions. We will therefore suggest to our partners that the Commission present a report to the European Council at its December meeting containing suggestions for the optimization of industrial framework conditions in order to avoid risks of de-industrialisation.

It is also essential to comprehensively assess all important Community projects with respect to their potential effects on industrial competitiveness.

The review of EU chemicals policy provides the first concrete opportunity to apply the described principles in a manner that could serve as an example for other areas of industry.

A future EU chemicals policy must be designed in such a way as to ensure environmental, health and consumer protection without endangering the international competitiveness of the European chemical industry. We would also want the new regulatory system to keep animal testing to an absolute minimum.

The Consultation Document published by the Commission in May 2003 contains certain positive elements in this regard. However, the ideas currently being considered give us cause for concern. In particular, we consider the envisaged registration procedure to be too bureaucratic and unnecessarily complicated. We are concerned in addition that the proposed regulatory system does not prioritise sufficiently between the handling of substances, that it will as a result not be workable in practice and that it will be difficult to convince stakeholders that we have created

an effective system for targeting and handling those substances which present real safety or environmental concerns. It is still a long way from being the fast, simple and cost-efficient procedure that was promised.

For this reason, France, Germany and the United Kingdom have brought forward comments on the workability and impact of proposals made in the consultation document. We made suggestions for substantial changes to the proposals so that they can be an effective approach for sustainable development.

We are also concerned about the potential impact of the new requirements on the competitiveness of EU businesses exporting to Third Country Markets, and about the position of EU businesses competing in the EU with Third Country suppliers able to avoid these requirements when sending products to our markets.

We must ensure that the proposals do not disadvantage legitimate EU business interests in the global market by imposing requirements which are not pertinent to protecting health and environment. With this in mind, the Commission should carry out a full evaluation of the concrete effects of the planned regulations on the European chemicals industry, as well as on the economy, taking account of the effects throughout the supply chain. The proposals presented to the European Parliament and the Council should create an effective framework which allows EU business to continue to thrive.

To this end, the Commission must work with the Presidency of the Council to ensure that the Competitiveness Council - in accordance with the European Council decision - plays an effective role in the handling of this legislation.

We would be grateful if you could take up these proposals and help contribute to making the planned new regulation of the chemicals regime a successful example of our joint efforts to strengthen the industrial competitiveness of the EU.

Yours sincerely

Tony Blair
Jacques Chirac
Gerhard Schröder

used as constituents of articles (the regulatory name for consumer products in the draft). The two largest organisations - The European Consumers Organisation (BEUC) and EuroCoop - strongly support the draft REACH regulation, but are very critical of some key aspects, as summarised below.

The European Consumers Organisation (BEUC)

According to BEUC the EU needs to establish horizontal minimum requirements for all chemicals being produced and used in the EU, but it is unclear to which extent the Draft Regulation would effect sectorial directives concerning chemicals in paints, pharmaceuticals, cosmetics, toys and food. They want REACH to be clarified and strengthened in this respect.

BEUC is very critical of the lack of clear provisions concerning chemicals in consumer products. Chemicals in products will mainly be considered by the REACH system if they are registered and if they are released in "sufficiently high amounts to cause adverse effects on health and/or the environment." BEUC points out that this leaves an important question unanswered: how is substantial exposure to be defined and who will define it?

BEUC states another problem is that the provision only covers products containing substances which are already known to be hazardous. Substances which are produced in volumes below one tonne per year per producer within the EU will not need to be assessed even when used in consumer products and even if the total amount is substantially higher than one tonne per year. Chemicals in imported products will not be controlled at all unless there is substantial exposure due to chemicals released from these products.

According to BEUC the proposed system will not enable consumer organisations to provide meaningful information to consumers on the chemical content of everyday consumer products.

EuroCoop

EuroCoop points out that REACH lacks a mechanism to deal with the potential of synergistic effects from a mix of chemicals. As a result there is a risk that chemicals will be authorised despite the fact that there may be a problem if a number of chemicals appear as a "cocktail" in the air, water or soil.

EuroCoop stresses the need to include the necessity for a simple, easy to understand labelling system. Their position is that consumers have a right to know the constituents of products in order to be able to make an informed choice.

They also believe that retailers will need the information in order to be able to advise their customers and consumers. In the Draft Regulation there is no system in place to secure the flow of information from producers to downstream users and consumers.

While EuroCoop demands labelling, they also stress that labelling must not be used by industry to put the responsibility on consumers. Industry must remain responsible for the content, and carry out correct use and disposal of their products.

EuroCoop also wants to strengthen the proposal in terms of how to deal with chemicals in imported goods. They state that as the proposal stands now it is too weak compared to the requirements for domestic products.

EuroCoop also believes that the precautionary principle and the principle of substituting for safer alternatives need to be further developed and more clearly expressed in the proposal. They do not want the system to act as a license to continue using risky chemicals. Their position is that the intention must be to ban risky chemicals except in those cases where it can be proven that there is a public need and no safer substitute.

Animal Protection NGOs

One of the controversial issues regarding the REACH system - or any other strategy to assess the vast amount of untested chemicals being produced and used throughout the world

- is animal protection. By necessity these chemicals must be tested in different ways for their effects and the traditional way of testing often implies using animals. Thus, it has been widely discussed how many tests will be necessary, how many animals will need to be killed and how this can be avoided or at least minimised. Therefore animal protection groups have engaged in the discussions about the REACH proposal.

European Coalition to End Animal Experiments (ECEAE)

The organisation represents animal rights organisations in 12 European countries and is the largest animal rights organisation in Europe campaigning solely on the issue of animal experiments. Established in the 1990s, initially to lobby the European Parliament over the issue of cosmetics testing, the ECEAE proved such a success that the campaigning alliance was continued.

While not taking any clear position on the REACH system, the ECEAE supports the aim of properly identifying and controlling chemicals that may be hazardous and have effects on humans and wildlife. However, the ECEAE opposes animal testing as part of the strategy and identifies seven steps to avoid or minimise such tests:

Eurogroup for Animal Welfare

Eurogroup represents 20 animal protection and welfare groups in Europe. The group was set up in 1980 with the aim to influence and promote the introduction of EU animal protection legislation, with member organisations in all EU member states.

As ECEAE, Eurogroup for Animal Welfare shares the concern of environmental and consumer organisations about the effects of some widely used chemicals on the health of both human and wildlife populations and supports their call for tighter control of existing chemicals. However, Eurogroup is concerned that the existing testing strategy will still be the underlying principle of new Community chemicals legislation.

The proposal in the Draft Regulation that low production volume chemicals could be registered after in vitro testing only is very much welcomed. However, they want the EU to thoroughly review its risk management policy with greater emphasis on the use of non-animal tests in all testing strategies, together with more positive support for the development of non-animal tests. Eurogroup recommends:

Eurogroup points out that the White Paper gives little indication of how the development and validation of alternative methods is to be fostered. They believe immediate action is imperative if significant progress is to be made in time to impact the testing for chemical registration. They note that a substantial amount of funding will be required, and the work must be focused on tests with the greatest potential to save animals that might be used in the registration of existing chemicals. They want the Commission to make funding of development and validation of alternative methods a priority in the Sixth Framework Programme for Research.

Other NGOs

A joint declaration from July 2003, signed by 429 organisations and over 22,000 individuals, was submitted as a comment to the Draft Regulation in the consultation. The signatories represent environment, consumer and health interests. Specifically, the call states:

“We, the undersigned, 429 organisations and 22,464 citizens around the world, from Australia to Zaire, wish to ensure that our health and that of the environment will be properly protected from hazardous chemicals.

We therefore ask the European Commission to ensure that the new chemicals legislation enforces:

- An obligation to phase out chemicals that accumulate in wildlife, humans or the environment, and those that disrupt hormones. Restricted uses of such chemicals should only be permitted temporarily, if safer alternatives

are not available, and the use is essential to society;

- A full right to know, for both consumers and businesses, including what chemicals are present in products; and
- A requirement that products imported into the EU have to conform to the same safety standards as those made in the EU.

The draft legislation does not implement these three points. We consider that the new system will not be workable, and will not effectively protect future generations, unless these measures are taken.

Please take this declaration as our submission to the Commission's consultation on the workability of the chemicals legislation."

Non-chemicals Industry

Unice

The European industries and employers are organised in national federations which are represented at the EU level by the Union of Industrial and Employers Confederations of Europe (Unice). Unice has 35 member federations and four observers from 28 countries in Europe.

Unice has a history of close connections to the chemicals industry. The fact that the chemicals industry is the single largest industry in Europe undoubtedly gives the chemicals sector a certain clout within Unice.

Mirroring and further enhancing the position of the chemicals sector as the prima donna of the European industry, Unice's current president, Jürgen Strube, is chairman of the board of the German chemistry giant BASF, the largest chemicals producer in the world (BASF also holds the presidency of Cefic through top executive Eggert Voscherau). Strube was quoted in the Los Angeles Times in March 2004 saying "What Europe needs is more entrepreneurship, less regulation". His predecessor as president of Unice, Georges Jacobs, was chairman of the executive committee of the Belgian giant chemicals group UCB. The chairman of Unice, Philippe de Buck, has a long history as a top executive in

the Belgian industry federation Agoria where the chemicals industry also has a strong position.

Thus it comes as no surprise that Unice unreservedly takes the same position on REACH as the chemicals industry. In its position paper and press release from July 2003, Unice expresses concerns about bureaucracy, competitiveness, costs and trade, pointing out that these issues have not been sufficiently assessed and/or considered by the Commission. In short, Unice calls for:

- Prioritisation of the most problematic substances.
- Basing test requirements on the risks involved, not on hazardous properties; and clear and straightforward exposure categories.
- The scope to be limited to marketed substances, and exemptions given for products and substances regulated under other EU legislation, polymers and intermediate products.
- Simple and rapid procedures, safeguarding competitiveness and protection of confidential business information.
- Careful evaluation of all costs, pilot projects on the effects on SMEs, and benchmarking with USA/Japan.
- Consistency with other regulations - no duplication of requirements, e.g. in workplace health and safety.
- Centralised decision-making, enhanced legal certainty for registered uses of substances.

Other Non-chemicals Industries

Non-chemical industry have been represented by Unice and have mostly followed the official line. However, there are some companies that believe REACH could bring advantages to their business and hold a more radical position than Unice. Among them are producers and retailers that want to be able to supply their clients with information regarding the chemical contents of the products they are producing and/or selling. For example, the large retail chains Marks & Spencer and Boots supported the Draft Regulation.

Another industrial sector that sees ad-

vantages with the Draft Regulation is the construction sector. Many large construction companies had experienced PCBs and asbestos being built into buildings and other structures, putting them in a situation potentially leading to financial disaster. Many of them, such as the Swedish global construction company Skanska, welcomed the provisions of substitution, information and clear political objectives brought forward in the White Paper. In the Internet consultation, many of them were critical that these provisions had been weakened and requested that they be reinstated.

Unions

Many trade and worker unions commented on the Draft Regulation in the Internet consultation. While the vast majority were represented by ETUC (see below) some organisations chose to make individual comments. Below are some examples.

The European Trade Union Confederation (ETUC)

The trade and worker unions of Europe are mainly represented by The European Trade Union Confederation (ETUC). The confederation consists of 77 member organisations from 35 countries in Europe. In total, ETUC represents some 50 million individual members across the continent.

ETUC called on the European Commission to hold on to a high level of ambition implementing REACH. In its contribution to the public Internet consultation procedure, ETUC pointed out that such a system must ensure a high level of protection of workers in all workplaces against dangerous substances.

The main objective of REACH is the protection of human health and the environment against adverse effects of chemicals., ETUC pointed out, and in their view the exposure of workers to chemical substances in a wide range of workplaces should be a priority for attention.

Important elements in the Draft Regulation

were the general “Duty of Care,” requiring producers of chemicals to ensure that they can be used safely; the obligation to make a chemical safety assessment for every chemical put on the market; and a central registration of safety data of all chemicals marketed in higher volumes (over one tonne/year). Thus the burden of proof would lie on the shoulders of industry, where it belongs, and a huge amount of safety information will become available that is essential for the proper functioning of existing legal instruments for Workers’ protection.

The ETUC accepts that exemptions be made, particularly on intermediates and polymers. However, for those substances, they require some essential information on workers’ safety in order to prevent existing legislation from being undermined. The ETUC calls on the Commission not to weaken the approach.

In the view of the ETUC, REACH has the potential to give a strong impulse to the protection of workers against dangerous substances and to sustainable development of the European chemical industry:

IG Metall, ver.di and IG Bau

The German unions IG Metall, ver.di and IG Bau jointly support the development of a more progressive chemicals policy. Therefore they demand that the new EU chemicals policy be urgently developed in order to put an end to the current organised lack of responsibility. The three unions see the need for manufacturers and suppliers to build up their knowledge on the effects of their chemicals, provide their customers with comprehensive information on the dangers and provide them with tailor-made safeguards.

According to the unions, the chemicals industry is not opposed to this reasoning and also accepts the essential features of the definitions given, as shown by their expert opinions. However, the chemicals industry tries to convey the opposite impression in its media campaigns against REACH.

The dual strategy is designed to cause the

European legislation on the new chemicals policy to fail. If the industry were serious about “responsible handling,” which is often mentioned, it should help to quickly find solutions for the weak points still causing trouble from the first draft law, and implement the central elements of the new policy:

- General liability of the manufacturer and user for ensuring that all substances and preparations can be made and used safely so that there will be no negative effects on human health or the environment for foreseeable uses - such producer responsibility is par for the course in other areas of industry.
- The requirement that a risk assessment be carried out for all substances (regardless of the quantity produced) and that this be documented.
- Plugging gaps in knowledge of substances already on the market and registering them.
- Automatic ban on the use of particularly hazardous substances with the exception of uses which have been specifically approved (authorised).
- Public access to available data.

The unions also point out that the earlier the legislation enters into force, the quicker existing knowledge deficits can be systematically rectified and the sooner protection against undesirable effects of chemical substances can be improved. They believe that the result of these efforts, which will definitely take more than a decade to emerge, will benefit not only workers but also consumers and the environment in general. :

EMCEF

The European Mine, Chemical and Energy Workers’ Federation (EMCEF) is a pan-European organisation representing hundreds of thousands of workers. The chemical workers are of course the most vulnerable group if the apocalyptic predictions made by some stakeholders about job losses would become reality.

Already in 2001 EMCEF had entered into dialogue with Cefic regarding REACH.

In 2002 Cefic formed a European Chemical Industry Employers Group (ECEG) to accommodate talks about issues of mutual interest, such as the EU chemicals policy review, between industry and unions. The cooperation developed in a positive way, eventually culminating in joint statements and press releases.

The EMCEF comment to the Draft Regulation is remarkably neutral considering the issues at stake (health and jobs) and the cooperation with ECEG and Cefic. EMCEF points out that social issues are, beside ecological and economic aspects, the third vital leg for achieving sustainable development. Thus, the social conditions for the chemical workers need to be considered in the new regulation.

For EMCEF, main areas of social impact are not only the number of jobs, but also: quality of work, training and education, health, safety and workplace environment, motivation of employees, and reduction of existing research and development. They believe that these are commitments of the social partners that need support of the EU decision-making bodies to give social aspects a more important role in the Lisbon vision.

EMCEF welcomed the introduction of access to information for workers and the public and also the inclusion of PBT and vPvB substances into the authorisation scheme. However, they did not agree that such substances need to be phased out if they are adequately controlled, and they wanted a clearer definition of the substitution mechanism.

THE ROYAL COMMISSION

Starting in 2000, the highly renowned Royal Commission on Environmental Pollution in the UK had carried out a wide-ranging study on the long-term effects of chemicals. The report was presented in June 2003 and gave echo throughout Europe.

The Royal Commission clearly recognised that there were problems with releases of persistent and bio-accumulating substances and

that the current system was not addressing these concerns. “Where synthetic chemicals are found in elevated concentrations in biological fluids... and the tissues of humans... regulatory steps should be taken to remove them from the market immediately.”

The Royal Commission also thought that the new EU chemicals strategy REACH was insufficient in that the phase-out of persistent and bio-accumulating substances would take too long. It believed such substances should be substituted for safer substances within one decade. An important tool in this work would be the precautionary principle.

THE CHANCELLOR’S SPEECH

In June 2003, in the middle of the ongoing Internet consultation, the German Chancellor Gerhard Schröder turned up and gave a supportive speech at the Cefic General Assembly in Hamburg.

In his speech, the Chancellor praised the successful lobby efforts made by Cefic and warned that “*other viewpoints are dominating industrial issues, which cannot and should not be the case.*” He also praised Commissioner Liikanen of DG Enterprise, who was also present at the Assembly, for raising the industrial thinking in the Commission and achieving positive changes to REACH.

“We do of course agree in principle that the attempt to promote a new comprehensive body of legislation for chemical politics in the sense of health or environmental protection should not meet with any objections. But it is equally clear that the competitiveness of the European chemical industry should not be left behind in achieving this.”

The Chancellor continued by identifying problems with the Draft Regulation and then asked Commissioner Liikanen and the Commission to review the Draft Regulation accordingly “*in the interest of innovation and employment in Europe.*”

This speech was remarkable in itself. However, the fact that the Chancellor had been one

of the Heads of State requesting stricter provisions and a quick implementation of REACH at the European Council meeting in June 2001, made it astonishing.

COSTS

The cost of implementing REACH has been an issue of discussion, and has been exaggerated since the White Paper was first introduced in February 2001. While the Commission then estimated that the costs for increased testing would be some 2.1 billion over 12 years, industry pointed out that the total costs would be much higher.

Several reports were commissioned during 2001-2003 by the Commission as well as by Member States and industry. However, it was clear that any estimate produced before the arrival of a more comprehensive proposal would be uncertain. The White Paper did not contain enough detail to perform any credible estimates of the total costs or benefits.

This created a situation where “anything goes” and parts of the anti-REACH lobby felt free to use their imagination and creativity. Some studies presented impact scenarios showing that the whole EU was threatened by mass-unemployment and financial recession.

The first studies with some relevance came shortly after the Draft Regulation had been presented, since this was the first time any credible assessment was possible. Nevertheless estimates of the associated costs continued to vary greatly, from some €3 billion to hundreds of billion (see *Costs: the Facts and the Figures*). All of the cost estimates, except those from the Commission, ignored the potential socio-economic benefits, estimated to be tens of billions.

ANIMAL TESTS

REACH requires that substances produced in volumes above one tonne per year are registered and provided with data regarding toxicity and other properties. Over the years

the chemicals industry and scientific society by tradition have mainly used and developed test methods including animals. Thus, when authorities demand more data, there is considerable risk that this will mean an increase in the number of animals used for testing, regardless of what strategy is used.

One of the aims of REACH is to minimise the use of animal testing. To this end there are provisions requiring computerised test-schemes, development of non-animal testing methods etc. Nevertheless the concerns remain.

In April 2001, just two months after the White Paper had been presented, it was estimated by the Institute for Environment and Health (IEH) in the UK that as many as 12 million animals would be needed to test all of the existing substances in production. This estimate was widely criticised and in March 2002 the IEH presented a revised estimate saying that some six million animals would be required.

Also this lower figure has been criticised. Other stakeholders pointed out that these estimates were done on the basis of the White Paper which lacked details, making any estimate very difficult and uncertain.

Also the estimates did not fully consider the development of non-animal testing methods, the provision for industry to share data information, the alleviations concerning data requirements for substances produced in volumes below one tonne per year and underestimated the volume of data already available within the industry.

However, the main point from the pro-REACH stakeholders was that the current situation, with tens of thousands of untested chemicals being used and released to the environment, is a much larger test including enormous numbers of animals and humans which also includes future generations. Data are required promptly and it is not acceptable to wait for non-animal testing to become fully developed. In the meantime, it is imperative that authorities invest heavily in the develop-

ment of non-animal testing to minimise the use of animals. Most animal welfare organisations agree with this position.

THE PROPOSAL

Overview

Based on the responses on the presentation of the Draft Regulation, the Commission began finalising the official Proposal for a new regulation. The proposal was adopted on 29 October by the Commission. The bulk of the proposal was similar to the Draft Regulation from May 2003.

Again, few of the requirements from the European Council and Parliament from 2001 were introduced. Moreover, none of the impairments introduced in the Draft Regulation had been restored. On the contrary, the Commission introduced some new changes making the regulation even weaker.

The chemicals industry and its allies reacted positively to the new provisions, although still complaining that all of their requirements had not been met, while environment, health and consumer NGOs were furious about the watering down.

Changes from the Draft Regulation

While the Proposal outlined a regulation which is a vast improvement compared to current regulation, it is a watered down version of the Draft Regulation, which in turn was a watered down version of the White Paper. And even the White Paper was weak compared to what the European Council and Parliament requested in 2001. Moreover, in its present state, the Proposal also represents some serious impairments even when compared with current regulation. The main impairments in the Proposal were:

Registration (Scope)

The Draft Regulation required that data regarding the properties of substances produced or imported in volumes over one tonne per year per producer/importer be submitted to the authorities if industry wanted to continue

to put the substance on the market. In the Proposal, the data requirements for substances below ten tonnes per year had been reduced.

The Draft Regulation also required that a Chemical Safety Report (CSR) should be produced for all chemicals produced in volumes above one tonne per year and distributed to downstream users. In the Proposal, CSRs only had to be produced for substances above ten tonnes, and communication to downstream users became limited to the safety data sheet.

About 65 percent of all the existing substances on the market belong to the category 1-10 tonnes and would thus not be affected by the reduced Registration and reporting requirements.

Furthermore, some 90 percent of the new substances also belong to this category. In the current regulation, new substances produced in volumes over ten kilograms are required to submit such data. For new substances, REACH will actually mean lower requirements than today. It must also be pointed out that the Council in their Conclusions from June 2001, requested the Commission to consider registration of all substances, even those produced in volumes below one tonne.

The Draft Regulation had excluded certain kinds of polymers from the Registration process. In the Proposal, this exemption had been extended to include all polymers, representing many thousands of substances.

Responsibility (Duty of Care)

The White Paper and the Draft Regulation contained an important general provision about the industry's responsibility, called Duty of Care. It was stated that all actors should have a basic responsibility for the safe management of chemicals, regardless of more specific requirements. These provisions on Duty of Care disappeared in the Proposal.

Authorisation (Substitution)

The White Paper had provisions calling for the substitution of hazardous substances for less hazardous substances when such alter-

natives were available. This requirement had been reversed in the Draft Regulation presented in May - the availability of safer alternatives was explicitly ruled not to be reason enough to decline an authorisation. This caused an outcry from various stakeholders, notably the environment, consumer and health NGOs. Though this explicit clause had been removed in the Proposal, substitution remains subordinate to a vague concept of "adequate control", allowing the continued production and use of a very hazardous substance to be authorised, even if there are safer alternatives on the market.

Consumer Products

As regards substances in products that can lead to significant exposure of humans and the environment, the White Paper proposed to set up a working group which would identify the product categories (e.g. toys and textiles) the relevant exposure situations and all other practical implications. On the basis of the findings of this working group, producers or importers should be requested to identify products containing such substances and provide any information as appropriate.

The Draft Regulation foresaw registration of hazardous substances in articles that may be released in volumes above one tonne and that are likely to cause harm. In the Proposal, registration was only required when hazardous substances are intended to be released from the products in quantities above one tonne. This clause is virtually empty since hardly any products would fall under this definition that would not already be covered by the requirements for preparations. If such substances may be released, all that is required is a notification in that respect.

Transparency

An important principle introduced in the White Paper was the Right to Know. It was conceived that the general public had the right to know what chemicals were in the products they bought and consumed, and what the risks

with these substances were.

This general principle was translated into a general requirement for producers and users to provide such information to the public. The European Council and Parliament requested even more transparency than proposed in the White Paper. The chemicals industry objected and the provisions were reduced in the Proposal by introducing a list of information that should be confidential, such as the name of registrants.

REACTIONS TO THE PROPOSAL

Overview

The Draft Regulation had prompted some 6,500 comments and thus most stakeholders felt they had already expressed their view. However, the stakeholders mostly concerned, the chemicals industry and the environment and health NGOs, were still on top of the issue. The amendments on the Scope of REACH made to the Proposal were known by the chemicals industry and other stakeholders well before the presentation of the Proposal. On 16 October the Commission presented a revised impact assessment where most changes were discussed.

Chemicals Industry

If Cefic and the rest of the chemicals industry allies were pleased with the watering down of the Proposal, they did not spill it. On 16 October, when the Commission presented the changes to the Scope of REACH at a presentation of the new Impact Assessment, Cefic commented by saying:

“Whilst an encouraging move on the Commission’s part, this latest analysis, in Cefic’s view, does not meet the request made by the three Heads of State and Government Chirac, Schröder and Blair, in their recent letter to Commission President Romano Prodi.”

On 29 October, the same day the Proposal was adopted by the Commission, Cefic cautiously commented: “The challenge is always to strike a balance between protection of hu-

man health and environment, and the competitiveness of the European industry. Given our concerns about workability, we now have to analyse the final proposal to see whether it meets the objectives.”

The UK chemicals federation CIA was unimpressed but more aggressive. On 8 October 2003, CIA Director General Judith Hackett acknowledged the improvements but wanted more: “The Commission have completed half the job in reducing the scope of the proposals. If REACH is to be workable the Agency has to be established and given the power to prioritise, make decisions and manage the system. Failure to do so will result in the REACH monster consuming us all.”

The French chemicals federation UIC kept a similar tone: “If some lightening brought in the field of application and for some requirements of tests are noted, UIC nevertheless deplores that the proposed text remained bureaucratic and unnecessarily complicated, and that it presents serious threats on the competitiveness of the French chemical industry and downstream industries.”

The US chemicals industry, represented by ACC, was even less enthusiastic about the Proposal as they “expressed disappointment that the proposed scheme remains unworkable and could lead to a new trade conflict.”

ACC President and CEO Greg Lebedev said “a few tweaks do not change a fundamentally flawed proposal” and repeated his concern that the proposal also may be at odds with World Trade Organization (WTO) rules. He added: “Some Commissioners have said they want to sell the REACH scheme across the globe. The world doesn’t want or need European regulatory colonialism, and the EU’s trading partners won’t buy a scheme that puts them at a competitive disadvantage and is more complicated than a Rubik’s cube.”

Environment and Consumer NGOs

As the Proposal had been watered down further, the environment and consumer NGOs were furious. In December 2003 the Euro-

Support for and Opposition against REACH and Tighter Regulation

Since the first presentation of REACH in the White Paper in 2001, most stakeholders have declared that they agree with the main objectives of REACH, to increase the protection of human health and the environment. But agreeing with the objective is one thing, and agreeing with the details of the Proposal is another. Thus, the positions on the strategy differ dramatically. Many stakeholders promote tighter regulation on chemicals and support REACH, although most of them want the regulation to be tighter than proposed. Others believe REACH goes too far and want to streamline regulation and solve the problem through voluntary measures from the industry. The table below shows the positions of some stakeholders. See also *Differing Views*.

Support REACH - Tighter Regulation

The European Council
The European Parliament
Some Member State Governments
European Workers' Union
Some Industries
Environment NGOs
Consumer NGOs

Oppose REACH - Voluntary Measures

The Chemicals Industry
The US Government
Some Member State Governments
Industrial Federations

pean Environment Bureau (EEB) published a review of the proposal. The report points to a number of impairments and in the summary EEB expressed its disappointment at how the initial aims of the White paper had been watered down:

“Unprecedented interference by the chemicals producers’ in Europe and the US, has led the Commission to considerably weaken the proposal and to tip the balance away from environmental and public health protection towards the self-interests of business, which seems to fear public exposure and claims serious negative economic impacts.

As a result the proposed REACH is a shadow of the original plans, which were supported by the European Parliament and the EU Member States. Loopholes, flawed approaches and bureaucratic procedures have been introduced after the Commission’s internet consultation before summer 2003, some of which are a reversal of standards already achieved. Instead of moving away from chemicals of very high concern their continued use is accepted under a toothless and flawed ‘adequate control’ obligation. Relevant safety information, like what chemicals are found in consumer prod-

ucts, will not be made available at all, or, as with company names and use categories, only after time-consuming administrative red tape. Above all, the scope of REACH has been reduced, which will only ensure an appropriate safety assessment for about 10% of existing chemicals, and leave most chemicals entering the EU via consumer products largely untouched.

Despite all these problems REACH still holds its position as the right framework, which the EEB supports. EU governments and parliaments now have the responsibility of closing those gaps and correcting flawed procedures to realise its benefits for society and the environment.”

While these are the words of EEB, they are used in this book to summarize what other environment and consumer organisations said.

ETUC

In a somewhat delayed response to the Proposal, the Executive Committee of the European Trade Union Confederation (ETUC) adopted a Declaration regarding the REACH proposal at its’ meeting in Brussels on 17-18 March 2004. The Declaration represents a

similar position to that taken by ETUC in the Internet consultation in June 2003 (page 91).

In the Declaration, ETUC expresses the opinion that the proposed REACH system would constitute a significant contribution to sustainable development, improving protection of the environment and human health, and that it will foster innovation in Europe.

ETUC pointed out that the final regulation may be improved by re-instituting the Duty of Care for substances produced in volumes below 1 tonne per year, introducing certain tests and a requirement for a Chemical Safety Report for substances produced in volumes between one and ten tonnes per year and by including sensitising substances in the authorisation process. ETUC also suggests the creation of an "aid plan" from authorities to facilitate the implementation of REACH, especially for small and medium sized companies and downstream users.

SHIFT OF COMPETENCY

Overview

Since the first calls for a new strategy on chemicals came from the Council of Environment Ministers in 1998, they had the lead competency on the development of the new strategy. Other Councils were consulted but the responsibility was on the Ministers of Environment since it was an initiative to increase environmental and human safety. In Parliament, the lead on REACH was in the Committee on Environment. For those opposing REACH, it was of key importance to shift competency and have industry allies take the lead.

Council

Following the adoption of the Lisbon Strategy (see box on page 85) the European Council decided to create a new "super-Council" to ensure that the objectives of the Strategy were met, the Competitiveness Council (CC). The CC, consisting mainly of Ministers of Industry and Energy, should inter alia have a hori-

zontal role, examining the proposals of other Councils from an economic and competitiveness perspective.

Already at its spring meeting in March 2003, the European Council had requested that the CC become more involved in the drafting of the new chemicals regulation. This request was repeated by Schröder at the Cefic General Assembly in June 2003, and then jointly by Blair, Chirac and Schröder in their letter to President of the Commission, Romano Prodi in September 2003 (see page 86).

At a meeting of the European Council on 16-17 October 2003, it was decided that the CC would take over the lead responsibility for the REACH proposal, due to be adopted by the Commission within two weeks, from the Council of Environment. In its conclusions, the European Council wrote:

"The Council and the Commission must address the needs of specific industrial sectors, especially the manufacturing sector, in order for them to enhance their competitiveness, notably in view of their essential contribution to economic growth. EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas.

To this end the Commission is invited to take into account the consequences of proposed EU legislation on enterprises through providing a comprehensive impact assessment. The forthcoming proposal on chemicals, which will be examined by the Competitiveness Council in coordination with other Council configurations, will be the first case for implementing this approach, taking in particular into account its effects on SMEs."

From then on CC had the lead on REACH. The consequences remain to be seen. Though the CC meetings are usually attended by Ministers of Industry, Competitiveness, Energy etc, Member States are free to send whichever Minister they prefer. Thus they may, in theory, send their Ministers of Environment to discuss REACH at the CC meetings.

The European Parliament

A similar takeover was also attempted in the European Parliament. REACH had been handled by the Committee on Environment since the White Paper was presented in 2001. In December 2003 the REACH Proposal was officially allocated to the Committee on Environment by the President of the Parliament, Pat Cox. However, the Committee on Industry and the Committee on Legal Affairs each claim they should have the lead competency since the competency had been moved in Council. Nevertheless, the Committee on Environment defended its lead on the issue in letters to the President.

The decision on which committee should have the lead was delayed since PPE and ELDR had not yet decided on their opinion. In January, the Chair of the Committee on Environment, Caroline Jackson, blocked the discussions of the draft report produced by the Rapporteur Guido Sacconi (see below). The reason for blocking the discussions was that there had been no decision regarding which Committee should have the lead. In effect, this stopped the adoption of the draft report until after summer 2004, when a new Parliament will start working on the issue again.

In February it was finally decided that the lead would stay with the Committee on Environment.

The Sacconi Report

Although there was an on-going dispute regarding which committee should take the lead on REACH in Parliament, MEP Guido Sacconi had been appointed Rapporteur by the Environment Committee and he pursued the task.

The Sacconi Report was debated in the Environment Committee in Strasbourg on 29 of March and in Brussels 6 of April. It was clear from the beginning that it was a draft report without time for amendments from other Members. The draft report simply mirrored the view of Mr Sacconi. Mr Sacconi focused on certain priorities relating

especially to the functioning and functionality of REACH.

On Registration he restricted himself to two types of amendments of the Commissions proposal: establishment of a single registration system for substances contained in articles, and the further relaxing of the obligations to be imposed on downstream users as regards the provision of indications to suppliers of chemical substances or preparation.

On the Evaluation Mr Sacconi stressed that The Agency should be given the job of drawing up the list of priority substances for evaluation and the simplification of the procedure.

On the Authorisation and Substitution the Rapporteur's view was that the link between Authorisation and the Substitution Principle needed to be made clearer and more forceful. Overall, Sacconi asked for the New Chemical Agency's role to be strengthened.

FURTHER DELAYS

During the lively debate in the Environment Committee, the timetable became more obvious. The Commission presented a draft proposal on further work regarding assessment of the impact from REACH on business throughout the supply chain, on innovation and on accession countries, as demanded by industry. Further delays were apparent. The working groups were scheduled to start their work in April and present results in November or December 2004. Further, a high level group consisting of principal stakeholders and representatives of Parliament, the Council, as well as the Commission, would oversee the work and give overall direction to the exercise. This group is scheduled to start work in autumn 2004.

Some members of the Committee voiced concern that the work would delay the process and questioned why the impact assessment only addressed potential impacts on business and not included impacts and benefits to the environment and on social issues.

Summary of Part Two and Final Remarks

SUMMARY OF PART TWO

The production and use of chemicals remained virtually unregulated throughout the world until only some forty years ago, when the petro-chemistry boom flooded society with new substances and articles used for a multitude of purposes and the negative consequences first became obvious. When regulations eventually started, it was limited and focused on acute exposure.

The current regulations in the EU were created with free trade and the internal market in mind. They provide insufficient protection for human health and the environment against the hazards of persistent and bio-accumulative substances.

The REACH Proposal, presented by the Commission in October 2003, was born as an initiative to increase the protection of human health and the environment. The strategy also aimed to achieve a sustainable European chemicals industry, living up to the commitments of the EU and all Member States according to the Rio Declaration, Agenda 21 as well as the obligations of OSPAR States to reach the generation goal.

The same governments that had supported REACH and requested even tighter provisions in the European Council meeting in 2001, were during 2002 and 2003 convinced to turn around and oppose the regulation. The US chemicals industry joined the battle, eagerly supported by the Bush administration.

Under the vicious attacks from one of the largest industrial sectors and four of the most powerful governments in the world, the Commission backed down. The Proposal is undoubtedly a watered down version of the initial ambitions and drafts.

FINAL REMARKS

The Proposal is not perfect. It will not provide the level of protection it aimed for. Nevertheless it is still much better than current EU regulation and a great example for others to

follow and to build on. This is also the main worry of the chemicals industry, especially in the US.

REACH has been the subject of an unprecedented aggressive and sustained attack from one of the largest industrial sectors in the world and it has been slashed and denounced by four of the most powerful governments.

However, REACH has also been supported by many politicians, agencies, scientists, NGOs, industries, down-stream users, unions and governments. Unfortunately these stakeholders have no-where near the same political power or the same resources as those allocated by the global chemicals industry and the governments of France, Germany, Great Britain and the USA.

The anti-REACH lobby have undoubtedly taken the initiative. In a "political coup", the President of the European Council even handed over the responsibility for REACH, one of the most important environmental and health protection initiatives of our time, to the Ministers of Industry, Internal Market and Energy in the Competitiveness Council.

But the process is nowhere near its end. The fight over REACH will go on for years and once adopted it will be attacked over and over again. In this process it is crucial that people and organisations aiming to protect human health and the environment do not lose their perspective, that they do not get lost in the labyrinths of chemicals policy, drown in technical discussions or forget their priorities when mesmerised or scared by the anti-REACH lobby.

REACH must be seen for what it is: an initiative to protect human health and the environment against hazardous chemicals and a way of living up to the commitments made in Rio de Janeiro 1992, OSPAR 1998 and WSSD 2002. I must be safeguarded against the attacks of the chemicals industry as well as governments and politicians with short-term perspectives.

**PART THREE:
BEHIND THE
SCENES**

Deadlock

A look at what has been going on behind the scenes is useful when trying to understand why a perfectly reasonable political objective, such as REACH, turned into a political deadlock. It may also explain why a regulation intended to increase protection of humans and the environment is being watered down in the name of competitiveness.



It would prove to be the rainiest month of April in Chester, Great Britain since 1818 and the coldest for ten years. When the 15 Ministers of the European Council met for an informal two-day meeting on the 25th and 26th of April 1998, the temperature was only a few degrees above zero.

The Ministers had several important issues troubling them and creating friction. Climate change was at the top of everybody's minds after negotiations in Kyoto resulted in an emerging conflict between Europe and the United States. The European governments were now discussing transports and national reduction goals. There was also an evolving conflict with the US regarding the import and acceptance of genetically manipulated organisms. However, the conflicts in these areas would later be dwarfed by another issue on the agenda now: a review of the EU chemicals policy. Few, if any, of the Ministers present realised the magnitude of the conflict they were starting.

In preparing for the meeting, five of the governments present had adopted a paper setting out the need for a review of the chemicals policy. The paper had been developed after discussions with experts in the field and laid out the problems and effects of the current regulations. It also proposed some specific ways of addressing the problems. The paper was tabled and discussed. For decades the problems of the past had been haunting them and their predecessors. All the tens of thousands of chemicals that had been registered in the EU before 1981 were still not examined for their effects on human health and the environment. Further, about 95 percent of all the chemicals being produced and used were such "existing" substances. There was a process on how to assess some of them, but it had proved excruciatingly slow and inefficient. To date not one of the substances had gone through the process.

But there were additional problems. Even if authorities wanted to restrict or ban a substance because it was considered dangerous, their hands were tied. Restriction could only be taken after lengthy processes, often taking years, and the outcome was uncertain. In the meantime the substance could stay on the market. These problems had become evident over the past year, when the governments in the EU tried to ban the use of some toxic softeners in soft PVC toys.

The personal concerns of the Ministers were enough in themselves. But chemical security, in particular endocrine effects, had become an issue of broad public concern. Moreover, the crisis over mad cow disease had taught them the potential costs - economic as well as political - for not taking a precautionary approach. Finally, the Environment Ministers of the EU Member States party to OSPAR were committed to cease all releases of hazardous chemicals to the marine environment before 2020 as was to be agreed two months later in the OSPAR Convention. Since all pollution eventually ends up in the marine environment, this commitment had a greater meaning than the wording itself.

The time had come to address the problems. The Ministers agreed to request that the European Commission review EU chemicals regulation and propose a strategy that would be better equipped to protect human health and the environment.

There are many regulations concerning chemicals in the EU. Some lie under DG Environment and others under DG Enterprise. When Council requested a review of the chemicals regulation in 1998, and later provided fundamental guidelines in 1999, it became a joint task for these two DGs in the Commission to do the work. However, since the initiative came from the Council of Ministers of Environment and the objective was to increase security of human health and the environment, the main responsibility in the Commission was put on DG Environment. Once the Commission had presented a proposal, it would be handed over to Council and the European Parliament in a co-decision procedure.

Although the Commission was burdened by internal conflicts, accusations of corruption and even resignation in 1999, the need for the development of a new chemicals policy remained high on the agenda. In February 2001 the Commission delivered a proposal for a new chemicals strategy in the European Union in the form of a White Paper. The stage was set for what German media has called the greatest lobbying battle ever: REACH.

The Prima Donna Awakens

In the modern corridors of the European Chemical Industry Council, Cefic, on 4 Avenue E. Van Nieuwenhuysse in Brussels, the representatives of the European chemicals industry are used to being listened to. They work hard to make things smooth for their members, creating streamlined regulations and, when necessary, going out of their way to fight regulation or costs that may stifle growth.

Few industrial sectors on Earth are as economically important as the chemicals industry. The size of their global annual sales are difficult to imagine, amounting to some €1,500 billion and growing quickly. While only a third of the size of global oil, sales of chemicals are bigger than those of automobiles, weapons, food, agriculture and most other industrial sectors in the world. Chemicals are big business and the chemicals industry is used to being treated accordingly. This is especially true in Europe where the chemicals industry has a stellar status. It is not only the biggest European industry, it is also the globally most expansive, out-competing US and

Asian companies and creating 75 percent of the European trade surplus. It is the crown jewel of European industry - the Prima Donna.

While the European Commission was busy drafting a new chemicals strategy in 2000, Cefic watched carefully. The then newly elected president of Cefic, Jean-Pierre Tirouflet, comes from the French speciality chemicals manufacturer Rhodia, a company that safeguards its reputation. He believed that improving the image of the chemicals industry was a priority for Cefic. Gaining public confidence was essential to the survival and development of the industry. In this sense, he has continued the tradition of his predecessor, Bryan Sanderson, who preferred openness, dialogue and cooperation with other stakeholders rather than being seen in an open conflict.

At an early stage, Mr. Tirouflet and his colleagues in Brussels were of course aware of the political movement to improve regulation and they realised that this could become a problem. However, they did not want to be associated with high-profile opposition to environmental regulation. Subtlety was of essence. The strategy they decided on was to let the Commission understand their opposition to any dramatic regulatory changes. Simultaneously, they would highlight all the positive things that the industry was doing and stress the need for a dialogue where Cefic and the industry would take a positive note. And to some extent it worked. The Commission was so divided on the issue that, even when the White Paper was presented in February 2001, the text was not available for several days and there were still uncertainties regarding for example which substances should be subject for authorisation.

Nevertheless, the arrival of the White Paper sent shivers through the entire chemicals industry. The principles of the new strategy would significantly alter the playing field, setting new and extended demands on industry. But Cefic was not taken aback. They had been consulted and informed by the Commission. Besides, being the largest industry in the EU gives certain clout and access to the political salons of Brussels. But they simply had not believed the Commission would pursue their task as requested by Council, once Cefic had let them know that industry preferred things just the way they were.

The White Paper was clear evidence that the Commission was not listening and Cefic raised its voice, but only slightly. As a reaction to the proposal, they assured the Commission that they supported the objectives but had doubts about practical issues. Of particular concern to Cefic at this point was the alleged proposal in the White Paper to ban or restrict substances based on their intrinsic properties. This could have severe consequences for the chemicals industry. Though concerns were raised, the tone was still civil and opposition subtle.

Enter the Hood

But the splash created by the White Paper had also awakened others and subtlety has never been their hallmark. In the offices of the United States Mission to the European Union (USEU) on Rue Zinner in Brussels, Ambassador Rockwell Schnabel

and his staff were deeply worried about the development. For the United States the proposed new European chemicals regulation would be of great political and economic concern.

Firstly it threatened US exports of chemicals and products to the EU. The US chemicals industry was fighting an uneven battle with the European industry, losing ground day by day, but exports from the US to the EU were still worth billions of dollars. Not only could these exports be threatened, the EU chemicals industry could even enhance their competitive advantage if European chemicals were considered safer than US chemicals. Secondly the principles in the new strategy could spread to the US and other regions and find its way into international treaties, setting a new global agenda which the US industry would not be prepared for and was ill equipped to handle. The Commission had already stated that spreading the principles in REACH to other regions and global political fora was an ambition. Finally, there are many US-owned chemicals industries in the EU and most of them are low-tech production facilities, often in Eastern Europe, which could have great difficulties adapting to the new regulation.

The USEU reported back to Washington D.C. where the government put together a team of experts from the Environmental Protection Agency (EPA), State Department, Commerce Department and the Office of the Trade Representatives (USTR). The team had meetings with the American Chemistry Council, the American Plastics Council and individual companies to solicit their views on the EU strategy and the impact it could have on chemicals trade.

From the beginning the goal seems to have been to intervene and change the direction of the new regulation before it could be finalised. While the team was working in Washington D.C., the USEU met with a number of US chemical producers based in Europe. After these meetings the USEU reported back to the US government that it was imperative that they begin a dialogue with the EU as soon as possible with the hope of influencing the draft text.

This was not the first time the US government tried to intervene in European chemicals policies. In 1997 and 1998, the State and Commerce Departments mounted a sustained lobby effort on behalf of the US chemicals and toys industries to derail European efforts to limit the use of softeners in soft PVC toys. One year down the road, after right-to-know request in the US had revealed the extent of the lobbying by the US, the interventions provoked a letter from Congressional Representatives Waxman and Miller asking if it was administration policy to lobby against public health legislation in foreign countries. Their letter prompted Vice President Al Gore to ask the Commerce and State Departments to stop the lobbying. Gore

“We recognize and respect each nation’s right to set legitimate public health and environmental standards and to take appropriate precautionary action.”

Al Gore, Vice President USA, 1998

wrote: "We recognize and respect each nation's right to set legitimate public health and environmental standards and to take appropriate precautionary action."

Another stakeholder with a reputation of being somewhat unsophisticated in exercising its considerable power was also waking up. The German chemicals industry is by far the biggest in Europe and the two largest chemical producers in the world are German. They were now increasing pressure on the authorities on their own, using a more confrontational approach.

While the US government was once again building a strategy to interfere with European chemicals policy and the German industry began to act on its own, Cefic maintained its subtle tone. Concerns were raised that the subtle approach was not working and another major setback to the industry was soon to come. In June 2001 the European Council discussed the White Paper at its meeting in Gothenburg, Sweden. Industry was hoping that the Ministers would have a different, more industry-friendly, perspective than the Commission had shown so far. However, they were to be disappointed. In fact, the Council thought the provisions in the White Paper were too weak and demanded even more.

At the Cefic General Assembly one week later, on 15 June 2001, Jean-Pierre Tirouflet proclaimed that REACH had become the most important legislative issue facing the European chemicals industry. He was concerned that the new regulation focused too much on health and the environment and called on the Commission to improve the workability of the proposal. Cefic's main concern was still the element which made it possible to ban or restrict substances on the basis of their intrinsic properties, such as persistence or bio-accumulation. Cefic feared that decisions could be made to ban substances unnecessarily and arbitrarily.

But Tirouflet also criticised the chemicals industry and possibly the evolving US involvement: "It is not good enough for us to simply complain... We must take a more positive and creative approach. We must be more innovative in our thinking and come up with workable solutions... which are acceptable to everyone. It is in this spirit that Cefic is organising its response and involvement in this regulatory area."

Time is Running out

Things were not going well for the chemicals industry. First the Commission had proposed a new strategy that was not to their liking. Then the European Council had adopted conclusions requesting stronger provisions, and soon the European Parliament was scheduled to comment by adopting a Resolution on REACH. All the signs showed that Parliament would follow the Council in its call for stronger provisions, or maybe go even further.

In the Parliament, the Committee on the Environment, Public Health and Consumer Policy was in charge of developing the position on the White Paper. Additionally, it was decided that the Committees on Industry and on Legal Affairs would provide opinions.

According to the procedure, the Committee appoints a political group responsible for producing a report on the issue at hand. The group which gets the responsibility then appoints a person to be Rapporteur. Since a rapporteur has considerable influence, there are often several groups who want the responsibility for important files. Thus there is a system where the political groups are given a certain amount of points each year according to their political strength. These points are used to “buy” the responsibility for a certain issue. Which group is given the responsibility for a report depends on who is next in line and has points left to pay with. The groups who do not become Rapporteur appoint a Shadow Rapporteur who follows the issue and co-operates with the Rapporteur.

When it was time to appoint a Rapporteur for the White Paper, the Conservatives and the Green group were particularly interested in handling the report. For a long time the Greens had saved points and abstained from seeking to become Rapporteur on other issues, and were next in line when the White Paper finally came and were thus given the responsibility to handle the issue.

The Green group appointed Ms Inger Schörling to be Rapporteur. She was to produce a report that would form the basis for the opinion of the Committee. After discussions and possible amendments, the report would be submitted to the rest of the Parliament as a draft resolution from the Committee. The draft resolution would then be discussed and possibly also amended by Parliament before being voted on in plenum.

Changing the Tone

The chemicals industry was deeply worried. Ms Schörling represented the Greens and was not likely to promote the views of the chemicals industry on this issue. On the contrary, they assumed that her report would contain some very far-reaching provisions. But such a report would ultimately need the support of a majority in the Parliament. Thus, the German chemicals industry and Cefic intensified their lobbying and focused on the Members of Parliament, aiming to stop approval of further demands.

A campaign directed toward the parliamentarians was rolled out. It included seminars, workshops, meetings, lunches, dinners, letters, mailouts, phone-calls, visits to plants, media releases and any other component that could be used. The prime targets of the campaign were parliamentarians from Germany, UK, France and Italy - all big producers of chemicals. Especially German Social Democrats supporting REACH were targetted with allegations of being anti-industry and complementary arguments that easily find their way into the hearts of most politicians: costs and jobs.

As expected, the Schoerling Report, presented to the Committee in August 2001, had a number of recommendations which were even stronger than the requirements of the European Council in June. Reacting to the report, Cefic said that it would have serious effects on the European chemicals industry if implemented.

Again, the most serious problem according to Cefic was the use of intrinsic properties as a basis for decisions on restrictions. While the Schoerling Report argued that “full risk assessment has proved to cause paralysis by analysis” Cefic considered continued reliance on risk assessment to be key: “Risk assessment based on sound science is the corner stone to an acceptable and successful regulation.”

On 16 October, while the chemicals lobby was mapping out the opinions of the German Social Democrat parliamentarians, sending concerned letters to their constituencies and publishing advertisements, the Environment Committee took a vote on the recommendations of the Schoerling Report. There were more lobbyists and stakeholders than Members of Parliament present, the room was filled with people who wanted to follow the debate and proceedings. Many of the large chemicals industries were present, particularly watching what the German parliamentarians were saying and how they were voting. There were more than 300 amendments to discuss and vote on. Finally, most of the recommendations from the Schoerling Report were endorsed for the draft Resolution.

Cefic was in shock, but the upcoming vote in Parliament was still an open affair and could be influenced. The campaign intensified as Cefic and environmental NGOs sent letters to parliamentarians asking them to vote in certain ways on specific parts of the Resolution. The German chemicals lobby VCI published a series of advertisements in *The European Voice*, *Der Spiegel*, *Frankfurter Allgemeine* and other prominent newspapers, requesting parliamentarians not to vote for the Schoerling Report. German media reports were filled with critiques against REACH, Commissioner Wallström and MEP Schörling.

Nevertheless the Greens managed to build political support by the majority of the European Parliament. But the United European Left/Nordic Green Left and The Greens/EFA were the only groups that were totally united in voting for the resolution. While almost all of the Socialists and Liberals also supported the final resolution, they were split on several key issues. The Conservatives on the other hand were almost united in voting against the resolution in the final vote. One of the key points where the UK Labour members voted with the Conservatives was for example on the registration of substances below one tonne.

The rejection of such a register was adopted narrowly, 242/215 votes. Another key issue was the scope of substances of very high concern, where the same alliances of Conservatives and UK Labour managed to weaken the scope. After the final vote, 242/169 with 35 abstentions, the resolution still remained strong but not as strong as it could have been.

Not only industry was involved in the lobby before the EP vote. Also Governments and trade unions had sent their messages to the MEPs. When the vote in plenum finally came, on November 15, the chemicals industry was relieved. Though the Resolution was still unacceptable to them, some of the provisions from the original motion had been weakened. Maybe more important was the fact that it had only been adopted with a small majority, making it politically weaker.

Chemistry in Dialogue

Unbalanced EU proposals for chemicals legislation

Can we afford even less growth?

The German chemical industry wants efficient and practicable rules for the production and use of chemicals throughout the EU. The proposal for a Regulation developed by the Environment and Enterprise Directorates General of the EU-Commission does not meet these criteria.

The proposed provisions are excessively bureaucratic, remote from practice and too expensive. In particular small and medium-sized enterprises will be unable to fulfil such requirements.

These provisions do not only affect the chemical industry but also all downstream users, e.g. the automotive, mechanical engineering, electronics, textile and construction industries. The impacts on the overall economy would be devastating. French and German studies do confirm this.

An implementation of the proposals would result in a situation where many chemicals can be no longer manufactured and processed in Europe. Millions of jobs are at stake in the European Union.

The German chemical industry has made numerous proposals to improve the current system. We need practicable rules suitable for daily business and we are willing to cooperate to achieve such results.

The German Chemical Industry

For more information about the subject "Chemicals Policy" write to
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Our full position is available in the internet: www.vci.de



Despite the intensive lobby from the chemicals industry, there was now a broad political unity. The Commission, the European Council and the European Parliament all requested stronger chemicals regulation to increase the protection of human health and the environment.

How Swede it is...

At this point the chemicals industry must have realised that a substantial lobby- and media campaign was needed if they wanted to stop or soften the new chemicals regulation. The campaign had already started with the vote in Parliament and was now stepped up and directed with more long-term strategies.

One specific strategy was to be patronising and portray the White Paper as a somewhat naive proposal from people who did not really know what they were talking about. Sweden had played an important role throughout the process. It had been one of the five Member States initially requesting a review of chemicals regulation in the EU. The Commissioner of DG Environment was a Swede. The content of the White Paper was similar to a national Swedish regulation that had been developed over years in one of the most extensive committee investigations on chemicals ever. Sweden had prioritised the issue during its presidency in 2001, the green Rapporteur was Swedish and the Swedish Chemicals Inspectorate, KemI, had been involved in the preparations of the White Paper.

The anti-REACH lobby pointed out that Sweden did not have a chemicals industry of any real importance. "What do Swedes know about the importance of chemicals industry?" Additionally, many of the Swedish key persons in the issue were women. Commissioner Margot Wallström, MEP Inger Schörling and the DG Environment Head of Chemicals Unit Eva Hellsten were portrayed as a trio trying to demolish the chemicals industry and were even referred to as "The Swedish Witches" in Germany.

Right-wing and non-regulation think-tanks attacked one of the fundamentals of REACH, the precautionary principle, and described it as a "good idea" that had been taken too far by the Swedes. For example, in an outrageous article under the headline "How Swede it is" in TechCentralStation, a free-market writer, Roger Bate, described the Swedish focus on environmental and health protection as being dangerous to innovation, jobs and progress: "Unless the Swedish folly with misuse of science and precaution is exposed, other countries may follow down its path."

Finding Friends

Though reacting late, the anti-REACH lobby was taking form and gaining speed. At the center was Cefic with its nice manners and unwillingness to take a direct and open confrontation. On one side of them were a number of large chemicals producers, national federations and sector groups running their own race, often being more confrontational. On their other side they had the US government and chemicals industry as well as the global chemicals organisation ICCA. They were also

lobbying old friends to join the fight and finding new ones, from workers unions, academics and industry-funded “green” NGOs to governments in Southeast Asia and South America.

Winning public and political support for global chemicals industries can be difficult. Huge chemical plants and transnational corporations are unsympathetic entities to many people. However,

small and medium-sized companies are more personal and “cuddly”. A lot of the REACH debate focused on the impact that the new regulation could have on smaller companies, the “downstream users”, and this was a winning concept. In 2001, seven sector groups within the chemicals industry joined forces and formed the Downstream Users of Chemicals Co-ordination Group (DUCC). The only aim of this organisation was to influence the political REACH process. The seven member organisations of this group of “downstream users” were large associations representing producers of aerosols, detergents, paints, inks, photographic chemicals, cosmetics, etc as well as the chemical distributors FECC. The companies within the seven Member organisations have an annual turnover of €115 billion. From the outset, DUCC adopted a policy on REACH which was identical to that of Cefic, though not as elaborate. Cooperation and liaison with Cefic was also one of the three strategies of DUCC.

The influence of the UK unions on the vote of Labour MEPs showed that the unions and the workers in the plants were powerful and had political influence. Over one million people work in the European chemicals industry and they constitute a substantial force that Cefic wanted on their side. Talks about REACH had been going on between Cefic and the chemical workers union EMCEF for some time. In December 2001, these talks were intensified as Cefic announced that they had formed a new organisation - ECEG - to open dialogue with the trade unions of Europe. The aim was to facilitate talks on national levels between federations of chemical producers and workers unions.

Impact Assessment - the Industry Way

On the other side of the Atlantic, things had been a bit tense. The US government was eager to start lobbying against the new EU proposal but needed the assistance and input of the US chemicals industry. The industry was also concerned, but acted slowly. Tired of waiting for industry to get their act together, the US government drafted a preliminary set of questions which they sent to the EU Commission in December.

In January 2002 the US government and the chemicals industry became closer as the American Chemistry Council, ACC, drafted a paper outlining the possible

“For many reasons, the future of the European chemical industry is at stake. It is time for us to move a step further to strengthen our cooperation with social partners.”

Eggert Voscherau, Vice President of Cefic,
December 2001

impact on US exports of the proposed EU regulation. Details and conclusions from this impact study would later re-surface as official US policy in the infamous “non-paper” as well as in communication from Colin Powell to US embassies.

One of the most widely used figures from the ACC impact study is that “Examination of just four commercially important chemicals on the EU authorization list shows that \$8.8 billion worth of U.S. exports are at risk.” This figure is as un-scientific as it can get. Here is how the ACC reasoning goes:

1. Acrylonitrile is used in ABS plastic.
2. Acrylonitrile is carcinogenic and would require authorisation in the EU.
3. If there is no acrylonitrile due to authorization, then there will be no ABS plastic.
4. If there is no ABS plastic there will be no more computer sales to the EU.
5. Computer sales worth USD 7.5 billion are threatened. ACC used similar reasoning for the other three chemicals studied in the impact assessment.

The same month, the US government also attended a two-day meeting at the headquarters of the ACC in Arlington, Virginia. The government representatives were welcomed by CEO Fred Webber, who was also a “Pioneer” fundraiser for the George W Bush election campaign since he had raised more than US\$ 100,000 to, as he said, “give industry access to a leader that’s ready, willing and able to listen.” The government and ACC agreed that the US should become more active and push for greater influence in the making of the new EU chemicals policy. The meeting was also attended by representatives of the EU, who responded positively to US “assistance to the initiative”. In this time of building alliances and bonding, the US government also had meetings to discuss the EU proposal with other chemical producers and federations, such as DuPont, Dow Chemicals, The American Plastics Council and the Synthetic Organic Chemical Manufacturers Association.

Colin Powell and the Non-paper

With the help of the US chemicals industry, the US government had reached a more detailed position regarding REACH and it was now possible to become more aggressive. On March 21, 2002, Secretary of State Colin Powell sent an “action request” cable to the US embassies in EU Member states and 35 other countries. The cable outlined the arguments against the EU proposal. It also called on the Embassies to distribute a paper outlining the US views to officials of the Ministries of Environment, Trade and Foreign Affairs, as well as local business communities. The cable refers to this paper as the “non-paper” indicating that no government agency wanted to take responsibility for it.

The non-paper effectively adopted the viewpoint of the US chemicals industry. For example it quotes the ACC impact study almost word for word, saying that “Examination of just four commercially important chemicals on the authorization list shows that \$8.8 billion worth of downstream products are at risk for bans or severe restrictions under the new system.” This figure would become frequently quoted by politicians and media in the US and elsewhere.

US Government and Industry Take a Trip

A few weeks before the embassies in the EU member states began lobbying Ministries of Environment, Trade and Foreign Affairs on behalf of Colin Powell and the US chemicals industry, the German government received special treatment. Representatives from the US embassy, the Environmental Protection Agency (EPA) and ACC met with German government officials and industry representatives on 8 March. One objective of the meeting was to promote the US regulatory system as a better alternative to REACH. Ironically, the weak US system resembles the EU policy that REACH is designed to replace.

At the meeting, the US team attacked the substitution principle, argued for voluntary regulation of chemicals and claimed it was necessary to narrow down the scope of regulatory engagement.

Initially, the German Ministry of Environment's Deputy Assistant Secretary, Wilfried Mahlmann showed disbelief that voluntary regulation could work. But the US government and industry team was animated when he demonstrated an openness to US positions.

Apparently the US initiative was warmly received. A US report from the meeting states that the Ministry of Environment responded with interest to the US positions, while the Ministry of Economics took a decidedly pragmatic and pro-business stance. One heading of the report is entitled, "Little opposition from Ministry of Environment". The lobbying of Charlie Auer from the EPA received the gratitude of a chemical industry representative who "praised EPA's presentation and asks that EPA organise seminars to educate government officials in Germany and Europe on how the EPA review system works. To help clear up misconceptions about the efficacy and efficiency of the US approach."

In the opinion of the US State Department, the lobbying trip was successful. A German joint government, industry, and trade union position paper from 11 March echoed many of the US positions. The US was gratified to see the recognition of the need for a "workable, affordable, and not overly burdensome solution..." in accordance with chemical industry interests.

US Speaks Out

Following up on the lobby activities, US Ambassador to the EU, Rockwell Schnabel, spoke out against REACH at a speech at the European Policy Centre in May 2002. He stated: "The implications of this for industry are massive. We warned businesses over a year ago that they needed to watch carefully how these rules develop... We are now working with industry to ensure that the EU

"If we fail to get our needs accepted, the resulting conflicts can be protracted, sometimes politically nasty - and always economically costly for business."

Rockwell Schnabel,
US Ambassador to the EU, 2002

United States Non-paper on REACH

I. Background: The European Commission adopted a White Paper in February 2001, which outlines a new policy for chemicals regulation called "REACH": registration, evaluation, and authorization of chemicals. REACH seeks to close information gaps in both existing and new chemicals data (in total over 30,000 chemicals). It also extends data requirements to downstream users of chemicals. Virtually every industrial sector could be impacted by the new policy.

The European Council and the Parliament endorsed the White Paper, and Leaders requested implementation by 2004. The Commission is expected to propose draft legislation this Summer, which will be subject to co-decision. The Commission established working groups to advise on matters related to the legislation. While a diverse group of stakeholders participated, there is a perception that some views have not been heard by key policymakers.

II. U.S. Position: While the United States fully supports the EU's objective to protect human health and the environment, there are concerns that the new policy could have significant trade implications for U.S. chemicals and downstream products. The EU's White Paper outlines what appears to be a costly, burdensome, and complex regulatory system, which could prove unworkable in its implementation. The system could present obstacles to trade in chemicals - 9% of total world trade - possibly distorting global markets for thousands of products. The United States is also concerned that the White Paper approach represents a move by the EU away from greater coherence of chemical regulatory approaches among OECD countries.

III. Concerns with the EU policy include:

- Increased costs: Testing costs (average \$250,000 per chemical) - which would apply to all chemicals, even those on the market for decades - will total Euro 9 billion, according to a UK Institute for Environment and Health study. Costs will increase not only for businesses, but also for government regulators.
- Unrealistic time lines for testing: The UK study estimates that the EU would need to extend its time line by 36 years, to 2048, to accomplish the minimum level of testing.
- Unwarranted increases in animal testing: The same UK study estimates that nearly 13 million animals will be required for testing under the proposed system.
- Adverse impacts on innovation and competitiveness: The EU's proposal would make Europe the most expensive place to bring a chemical to market - and keep it on the market - which could divert innovation offshore and further reduce the competitiveness of the EU industry. Four times as many new chemicals are brought to market in the United States as in the EU each year.
- Negative impact on jobs: Increased costs and administrative burdens for marketing chemicals in the EU could disrupt product lines and/or result in plant closures, endangering the millions of EU jobs in this sector.
- Reduced Consumer Choice: Authorization component could remove useful chemicals

from the market, which could in turn impact hundreds of products. Examination of just four commercially important chemicals on the authorization list shows that \$8.8 billion worth of downstream products are at risk for bans or severe restrictions under the new system.

- **WTO inconsistency:** The EU approach, particularly the suggestion to regulate chemicals contained in products manufactured outside the EU (e.g., dyes used in manufacturing textiles), raises significant concern with regard to World Trade Organization (WTO) rules, and may prove more trade restrictive than necessary.

- **Disproportionate impacts on small and medium businesses:** SMEs, which account for 96% of the European chemical industry, generally produce specialty chemicals in smaller volumes. SMEs could end up paying more per ton produced to comply with the new system than large multinationals that sell in huge volumes. Increased administrative burdens are more difficult for SMEs to deal with as well.

- **Arbitrary discrimination:** Under the new policy, authorities may force substitution of certain chemicals for others that have been deemed “safer.” It is unclear whether this could be implemented without resulting in arbitrary discrimination.

- **Overly narrow exemptions:** While the R & D exemption is improved over current EU practice, it could be expanded further to encourage innovation, particularly in more environmentally friendly products. It is unclear if provisions will be available to exempt polymers and other low-risk chemicals from the new requirements.

- **Movement away from international regulatory harmonization:** The EU proposal goes further than any other OECD country’s chemical regime, and appears to require new and additional testing of chemicals beyond current OECD initiatives. This move could undermine efforts to create a coherent scheme for international chemicals management.

- **“Precautionary principle:”** Invocation of the “PP,” particularly where data are unavailable or delayed, could provide cover for politically-motivated bans and other severe restrictions.

- **Developing countries:** While most developing countries are net importers of chemicals, many are major exporters of products that contain chemicals. Toys and textiles are two such products that the EU appears to be targeting under its new proposal. Developing country exporters may have difficulties complying with the complex new requirements.

IV. U.S.-EU Cooperation: The United States government and interested stakeholders are working closely with the European Commission to ensure transparency and to effect a balanced regulation that protects the environment and human health without unnecessary distortions to trade and competitiveness. We are also interested in engaging the EU member state authorities in discussion on the new chemicals policy, as member states will maintain regulatory authority. We seek increased coordination among U.S. and EU regulators and more coherent regulatory approaches. The United States is hopeful that increased cooperation and dialogue early on in the EU legislative process will lead to more effective, protective, and balanced regulation in the end.

doesn't reinvent the wheel and that the regulatory process follows those principles I laid out."

A month later in a speech at the Los Angeles World Affairs Council, Schnabel quoted the \$ 8.8 billion figure from the ACC impact study and issued a threat; "If we fail to get our needs accepted, the resulting conflicts can be protracted, sometimes politically nasty - and always economically costly for business."

Money Talks

While the US government and chemicals industry were using the \$8.8 billion figure to legitimise their opposition to REACH, their European counterparts used the same tactics and arguments. Since there were few details in the White Paper, estimating the costs was not easy. This lack of detail was used by the chemicals industry who started making claims about the costs. In the absence of data, anything goes. Cefic estimated that the costs for testing substances would be some €8 billion over a ten-year period. However, an impact study commissioned by the EU, presented to industry at a workshop in May 2002, showed that the costs for testing would be between €1.4 and 7 billion with a best estimate around 3.6 billion over 11 years. Cefic reacted to this by saying that it showed their €8 billion estimate was correct. The chemicals industry also claimed that the costs for testing were not the only costs. In total, REACH would cost industry some €20-30 billion. The Commission responded by saying costs would probably be lower and moreover they would be dwarfed by the socio-economic benefits which would be much higher. Later, the chemicals industries in France and Germany would hit back with new studies showing impacts of apocalyptic dimensions.

BASF Takes Over Cefic and Sets a New Agenda

Within Cefic, spring and summer 2002 was a time of change. Over the past two years, the presidency had been held by the French specialty chemicals producer Rhodia, but in June 2002 the German giant and world leader BASF would be taking over. Under the presidency of Rhodia, Cefic had prioritised image-building and avoiding open conflicts. However, BASF had other priorities and adopted a more confrontational style of doing business. Producers of high volume chemicals, like BASF, have more at stake. Thus Cefic's opposition toward REACH would become more aggressive. The new president was the former Cefic vice president and BASF top-gun Eggert Voscherau.

Already in his opening speech on 14 June 2002, Voscherau started to set a new agenda. Gone were the phrases calling for cooperation and dialogue. Gone was also the self-criticising and calls on the chemicals industry to be more positive. Proclaiming that the creation of a level playing field for the chemicals industry, inside and outside Europe, was his priority, Voscherau attacked the EU authorities and demanded action.

Notably, he did not attack REACH, instead he sidetracked the issue by

demanding a coherent industrial policy for all sectors in the EU based on the Lisbon strategy to make the European economy the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion.

Doing this, he created a whole new playing field, lifting the issue to a higher level, and found many friends. While REACH was still an unacceptable proposal, it was now an example of a regulatory proposal that did not comply with the Lisbon strategy and needed to be stopped if the over-arching goals were to be reached. This also showed the need for industry-friendly policies in general in the EU, an issue that needed the attention of heads of state. Eventually, this was also what happened.

At the time, the German and French governments were under great pressure from the Commission because their public deficits were above the three percent agreed in the EU stability pact. Italy was also close to the limit. As a consequence, the governments risked paying fines as stipulated by the pact. The last thing the governments of these countries wanted to see was a new regulation that, according to the industry, threatened to increase the deficit.

More Non-papers

Governments around Europe and elsewhere were now in the process of developing positions on REACH. In the US, the government had more or less adopted the position of the US chemicals industry into the “non-paper” which was not acknowledged as being an official position but nevertheless used as such. In the UK the government took a similar approach. But instead of adopting an industry paper, they borrowed Liz Surkovic from the UK Chemical Industry Association (CIA). In August 2002 Surkovic was given the task to help formulate the UK government position on REACH. Working in the Department of Environment, Food and Rural Affairs, she sought advice and proposals from the US government and EPA on how to adopt the US system in Europe. While drafting the UK position, Surkovic promised to send drafts to Charlie Auer, the US EPA representative who joined the lobby-trip to the German government in March 2002. She referred to these drafts as “non-papers”. The UK position paper was presented in December 2002 and was an echo of the demands from Cefic and chemical industries, requiring *inter alia* REACH to become more streamlined and simple and take greater consideration to competitiveness. The position paper was hailed by the CIA although they pointed out that they were disappointed that the UK position was still more demanding than they wanted it to be.

Competitiveness!

Following the adoption of the Lisbon Strategy, competitiveness became the word of the day. Everything was to be considered from a competitiveness perspective and anything that could threaten the competitiveness of the European industry

was evil. To ensure that political initiatives in the EU did not endanger the Lisbon Strategy, the European Council decided to create a new Competitiveness Council to work horizontally and oversee the activities and proposals being drafted by other Councils, such as the Council of Environment Ministers. Basically, the Competitiveness Council consisted of Ministers of internal market, industry and research who were now given a control function over other Ministers. The new Council held its first meeting in September 2002.

More Costs

Cost predictions are generally a favourite subject of the industry when opposing new environmental regulation. In mid November 2002, the first major study commissioned by industry of the costs of REACH arrived. The consultants Arthur D Little had been commissioned by the German industry federation BDI to estimate the impact of the proposed regulation on the German industry and economy. Since the White Paper was still the only basis for estimation the report gave a wide scope of results under three different scenarios, named "Clouds", "Storm" and "Hurricane" depending on the gravity of the outcome. The study shows that, in the best case scenario, REACH will mean a production loss of 1.4 percent for the German manufacturing industry and a loss of 150,000 jobs in Germany alone. The worst case scenario, "Hurricane", predicted a production loss of over 20 percent and that 2,350,000 jobs would be lost in Germany.

The report was widely criticised by independent economic experts for having fundamental methodological flaws. Even though the critique came from a panel brought together by the German Environment Protection Agency as well as from the top Environment Advisory Council appointed by the government, the report provided the chemicals industry lobbyists with exactly what they needed: figures of costs and unemployment. What's more, the report predicted gargantuan impact not only on the industry but on the German economy as a whole. The report quickly became the favourite piece of reference and the figures were used widely. It was welcomed the Director General of the UK chemicals lobby Judith Hackitt with the words "When we talk about the threat to competitiveness, we mean the threat to the employment of 100s of 1000s people employed by the industry EU-wide – and the threat to the kind of innovation which has so enhanced people's standard of living and quality of life in recent decades."

Industry Plays the Animal Card, the Costs Card, the Jobs Card...

In the past, Cefic and the US chemicals lobby ACC had not been close. However, over the past months they seem to have bonded. In November 2002 they participated at the Trans Atlantic Business Dialogue meeting in Chicago and issued joint statements against REACH. Mostly it was a repetition of the concerns for costs, loss of competitiveness, trade barriers, unemployment etc. However, Cefic also played a new card: animal tests. They claimed that the tests prescribed by the REACH

proposal would require some 12 million animals for testing. This figure was based on a report from the Institute of Environment and Health in the UK, dated April 2001. However, the report was so widely criticised for its false base assumptions, that IEH was forced to review it. In March 2002, five months before the Trans Atlantic Business Dialogue meeting, IEH had published new estimates showing a need for less than half of the original

figure. Many stakeholders claim that also this figure is far too high, but nevertheless, the figure 12 million was already in the air and raised an outcry from the animal protection NGOs, especially in the UK and Germany. Cefic had made some new, highly unexpected, friends. Over the coming year or two, the animal test issue would become a very important political aspect of the REACH proposal, and the figure 12 million is still used regularly by NGOs.

Continuing to use disproven figures, Cefic and ACC went on to say that the cost of testing was estimated at €7 billion, although the estimate in the impact assessment from May 2002 said that the cost would be between 1.4 and 7 billion, with a best estimate of 3.6 billion.

In December 2002, the Cefic initiative from 2001 to make friends with the chemical workers unions across Europe started to pay off. In a joint statement given at an annual conference organised by the Cefic group ECEG, the UK chemicals lobby, CIA, and four UK trade unions urged unions and industry in other European countries to step up their lobbying against REACH.

But more was to come. Another large group of friends had been approached and told of the evils of REACH: the downstream users representing all the companies that depend on chemicals in some form in their manufacturing process, i.e. all manufacturing industries. Most of them were organised under the European industry federation UNICE, which, incidentally, was led by another BASF top-gun: Jürgen Strube. UNICE was to come out hard against REACH.

The Tide Turns

The tide had definitely turned for Cefic. The US government was lobbying heavily on their side together with the US and European chemicals producers, chemical workers unions and industry groups. Animal protection groups attacked REACH from another side. Reports predicting economic disaster were rolling in. The calls for industry-friendly policies and the portrayal of REACH as being incompatible with the Lisbon strategy had reached the ears of the European Ministers of Enterprise. Governments across Europe were questioning REACH and there was an increasing focus on competitiveness. There was an increasing split in the Commis-

“ When we talk about the threat to competitiveness, we mean the threat to the employment of 100s of 1000s people employed by the industry EU-wide.”

Judith Hackitt,
Director General CIA, 2002

sion between DG Environment and DG Enterprise.

On March 10, only little more than a week before the meeting of the EU Heads of State at the European Council spring meeting, Cefic and its new ally EMCEF, the European chemical workers union, held a joint press conference in Brussels. The topic of the press meeting was to announce that the two organisations called for a coherent industrial policy as recently proposed by Commissioner Likkänen of DG Enterprise. Cefic president Eggert Voscherau spoke of the need to meet the objectives of the Lisbon strategy, the importance of a competitive industry and the dangers of regulation overkill. Reinhard Reibsch of EMCEF warned that excessive regulation could threaten jobs and economy.

Whether the calls of Cefic and EMCEF were heard by the Heads of State is uncertain, but there was definitely movement in the political arena. On 20-21 March 2003, the EU Heads of State met in Brussels at the annual spring meeting of the European Council. On the initiative of Tony Blair, Jacques Chirac and Gerhard Schröder, reviewing progress and setting objectives to meet the Lisbon strategy was at the top of the agenda for the meeting. This must have been especially important to Chirac and Schröder who were under pressure from huge deficits in excess of the EU stability pact and desperate to increase economic growth in their countries, where chemical production was key. Indeed, the Council meeting concluded that economic growth was the main objective. To this end it was considered necessary to raise employment, promote innovation and entrepreneurship and strengthen the internal market. Echoing the calls from industry, the Ministers proclaimed that "Competitiveness must once again be placed centre stage".

Although the Council conclusions set the priorities for the EU as a whole, they were intended to be applied to all sectors, also to the regulation of chemicals. To this end, the Competitiveness Council - consisting mainly of Member State Ministers of Industry and Energy - should be consulted by the other Councils on all issues that could possibly have an impact on European Competitiveness. Soon the Blair-Chirac-Schröder trio would make this point very clear.

Powell Sends Another Cable and Schnabel Goes into Denial

In the US, the government lobbying against EU policy making had created some turmoil. In December 2002, in a letter to President George W. Bush, some 70 US environmental, public health and labour organisations came together to denounce their governments efforts to derail the REACH proposal. However, this did not stop Colin Powell from continuing to lobby for the US chemicals industry. On 29 April, just days before the REACH proposal was due to be released for public comment, Powell sent another cable, this time to the governments of the EU Member States and EU Candidate States as well as to the US mission to the EU. The cable mainly repeated industry objections to REACH, including predicted costs, objections to the precautionary principle, the wide scope and the complexity of the regulation. Instead, Powell promoted a US-style regulation. The cable also complained about

the length of the proposed 5-week comment period and supported to have it extended as demanded by the chemicals industry.

Press reports in the US and EU described the US opposition against REACH and reported about the lobbying. In May, these reports prompted a letter from Rockwell Schnabel, US Ambassador to the EU and

one of the most prominent US lobbyists against REACH, to the International Herald Tribune. Despite two years of lobbying, and numerous public appearances on the issue, Schnabel denied that the US had criticised REACH or identified it as a problem and added that the government had not yet had time to study the proposal. The denial from Schnabel prompted a response from MEP Schörling and the debate was heated.

However, only a few days later, William Lash, Assistant Secretary of Commerce, commented on REACH in media. He admitted that US officials had met with EU leaders on several occasions to express their concerns about the proposal. Lash described REACH as being a barrier based on un-sound science or non-existent risk analysis that would damage US exports. In addition, the Commerce Department announced their intention to hold a series of public town hall meetings to organise US opposition to REACH.

The ACC was even more outspoken about the US role in shaping European chemicals policy when they, almost a year later, in January 2004, presented their main achievements of 2003 in the report "2003 in Review." ACC not only confirms the extensive US involvement, they see it as one of their main achievements and consider themselves as being instrumental: "ACC rallied opposition to the draft proposal, including a major intervention by the U.S. government, and ACC actively supported the European industry's advocacy efforts with the leaders of Britain, France and Germany, and many Southeast Asian nations. These efforts helped to build an aggressive position worldwide, and brought about significant concessions in the draft now being considered by the European parliament."

Waiting

Spring 2003 was a tense time for all stakeholders as they waited for the detailed REACH draft proposal from the Commission. It was five years since the first calls from the Council meeting in Chester, UK, to develop chemicals regulation that provided safety for humans and the environment. The REACH system, presented by the Commission in the White Paper 2001, had been approved by the European Heads of State in Council as well as by Parliament, with requests of further strengthening. But since then the chemicals industry had run an aggressive campaign directed against REACH, gaining support from high places and it was no secret that the issue had created a great split in the Commission. While DG

"ACC rallied opposition to the draft proposal, including a major intervention by the U.S. government."

2003 in Review, ACC

Environment wanted to strengthen the proposal in accordance to the requests from the European Council and Parliament, DG Enterprise saw it from the perspective of the chemicals industry.

In April the anti-REACH coalition presented another economic study of the effects of REACH. This time, the French chemicals industry and Ministries had commissioned Mercer Management Consultants to assess the costs to the French chemicals industry and society. The Mercer report, timely presented just as the Commission was laying the last hand on the REACH proposal, predicted enormous costs, unemployment and social problems if REACH - as presented in the White Paper - was implemented.

Needless to say, the Mercer study was welcomed by the chemicals industry and used extensively to discredit the upcoming proposal. The study prompted the French government to oppose strict chemicals regulation. Now the chemicals industry had the backing of four of the worlds' most powerful governments and their Heads of State in their fight against REACH: Tony Blair in the UK, George W Bush in the US, Jacques Chirac in France and Gerhard Schröder in Germany.

In May 2003 the Commission presented a Draft Regulation for Internet consultation and stakeholders, governments and citizens were invited to comment. The duration of the consultation was extended to eight weeks following requests for such extension by industry and the US. This meant that the timetable for final adoption of the proposal foreseen for July could not be met. This in turn had the knock-on effect that the time left for the European Parliament to do a first reading was so tight that it was close to impossible to be able to have a first reading.

Oddly, the entire Commission did not officially stand behind the document as would have been expected if it was a proposal from the Commission. Instead, it was presented as a document from DG Enterprise and DG Environment. Lacking the official support from the entire Commission signalled that the Commission had internal difficulties with the proposal and that there was considerable room for changes. The Commission said it would use the comments received in the consultation to finalise the proposal, which would be presented before the end of the year.

It was apparent that the anti-REACH campaign, orchestrated by the US and EU chemicals industry and the US government, had been successful. The Draft Regulation contained almost none of the improvements requested by the European Council and Parliament. Instead, several of the demands from the chemicals industry had been met and the Draft Regulation was a watered down version of the White Paper. The most obvious impairments were that the requirements for substitution of hazardous substances and the demand for assessment of all chemicals used in consumer products, also imported ones, had been effectively taken out or severely watered down.

Despite the alleviations presented in the Draft Regulation, the chemicals industry was not pleased and the internet consultation presented new possibilities

for lobbying activities. The chemicals industry mobilised its friends from around the world to send comments. Anti-REACH industry associations, governments, unions, downstream users, NGOs, academics and citizens sent thousands of comments. In the end, the Commission received some 6,500 comments, almost half of them from industry and many from citizens. Many referred to the enormous costs and high unemployment figures predicted by the chemicals industry, or the 12 million animals that they thought would be used for testing. The fact that over 90 percent of the citizens in the EU are concerned about chemicals was not reflected in the comments received by the Commission.

The Letter

While the chemicals industry continued to oppose REACH on the grounds of high costs and lack of workability, non-compliance with the Lisbon Strategy was the main argument on the higher political level. Heads of State could hardly oppose a regulation on the grounds of alleged bureaucracy or uncertain financial predictions, especially not when they had themselves identified it at the European Council in Gothenburg in June 2001 as a priority which should enter into force in 2004.

However, when the chemicals industry re-phrased their objections to REACH as it being a threat to the aims in the Lisbon Strategy, that was a different ball-game. Even the US government started talking about the threat REACH posed to the Lisbon Strategy. Why the US government should be concerned over the success of a strategy that aims to out-compete the US industry is a mystery.

On 20 September 2003, while the Commission was significantly re-drafting the Draft Regulation and making it into a Proposal, Tony Blair, Prime Minister of the UK, Jacques Chirac, President of France and Gerhard Schröder, Chancellor of Germany, sent a formal letter to Romano Prodi, President of the European Commission. In the letter they pointed out that the European Council, at its spring meeting in March 2003, had on their initiative discussed the progress in reaching the aims of the Lisbon Strategy. They had then agreed to increase the competitiveness of the European industry by reducing the bureaucracy that European companies encounter. The Heads of State went on, voicing their concern that the proposal for a new chemicals regulation would endanger this work and thus threaten the aims of the Lisbon Strategy. As if reading a script from the chemicals industry or the US government, they were particularly concerned about the registration procedure which was too bureaucratic and unnecessarily complicated. Also the scope was too wide and lacked prioritisation. Lastly they expressed concern that the new requirements would have unacceptable effects on the competitiveness of EU businesses and signed off by saying: "To this end, the Commission must work with the Presidency of the Council to ensure that the Competitiveness Council - in accordance with the European Council decision - plays an effective role in the handling of this legislation."

All of their governments had two years earlier agreed that the White Paper

needed strengthening and wanted it to have a greater scope. But now the Heads of States of the three largest chemicals producing Member States was telling the President of the Commission that the Commission was out of line and that the proposed REACH system would not be accepted. The Commission needed to take greater consideration to the economy of the chemicals industry. They demanded that the Competitiveness Council be given greater influence in the issue. The Prime Minister of the fourth chemical giant nation in the EU - Italy - had not been asked to sign the letter. However, Silvio Berlusconi, President of the European Council at the time, would soon play an important role as well.

The Move of Competency

The presidency of the European Council rotates every 6 months. When the EU Heads of State meet four times per year, the Head of State in the presiding Member State has great influence on the agenda. From 1 July to 31 December 2003, Italy was the President Member State and Silvio Berlusconi was consequently not only Prime Minister of Italy, but also President of the European Council. The first of the two European Council meetings to be held during the Italian presidency was on 16-17 October in Brussels. It would be two field-days for the chemicals industry

The focus of the meeting was "Relaunching the European Economy", how to create economic growth and a social and economic backdrop in accordance to the Lisbon Strategy. Under the heading "Creating Favourable Conditions for Growth and Employment - Enhancing the Competitiveness of the European Economy" the Council discussed REACH. If any of the Ministers present in Chester 1998 had been in the room they would probably have been astonished. Why was the European Council discussing a policy, intended to increase the safety of humans and the environment, under such a heading? They would probably have been taken even more aback as the Heads of State declared that "the Council and the Commission must address the needs of specific industrial sectors ... in order for them to enhance their competitiveness, notably in view of their essential contribution to economic growth. EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas."

Having set the priorities straight, the Heads of State continued: "The forthcoming proposal on chemicals, which will be examined by the Competitiveness Council in coordination with other Council configurations, will be the first case of implementing this approach, taking in particular into account its effects on small and medium sized enterprises." With these words, the European Council declared that the responsibility for the chemicals policy would be taken from the Ministers of Environment and was in the future going to be handled by the Competitiveness Council. No Head of State opposed the decision.

As far as the European Council was concerned, REACH was now a strategy to increase the competitiveness of the EU chemicals industry. As a result, REACH was presented by the Commissioner of DG Enterprise, Erki Liikanen, at the next Com-

petitiveness Council meeting in November 2003. Some of the Ministers expressed concern about the costs and the bureaucracy and they welcomed a decision to set up a Working Party to examine the proposal in all its aspects. They also reminded Liikanen about the words from the latest European Council: "EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas."

At last: The Proposal

The letter from Blair, Chirac and Schröder to the Commission and the decision by the European Council to move the competency to the Competitiveness Council was undoubtedly a strong signal to the Commission as they were working on the Proposal, scheduled to be released at the end of October. The European Council would not be disappointed. When the Proposal was presented the scope of REACH had also been reduced, meaning less bureaucracy, less costs, less data requirements, less reporting and less protection. Polymers had been excluded and the data requirements for other substances produced under 10 tonnes per year had been reduced. Chemical Safety Reports were not required anymore for substances below 10 tonnes. The general "Duty of Care" had been taken out and transparency had decreased. The impairments from the Draft Regulation had not been restored. By most accounts, the Proposal was another great victory for the EU and US chemicals industry.

The Block

The REACH Proposal was now scheduled to be commented on by Council and Parliament. The Anti-REACH lobby had turned the opinion of several Member States and the European Council, shifted the political responsibility from the Environment Council to the Competitiveness Council and put pressure on the Commission to give competitiveness greater importance. Thus, Council would be receptive to the arguments of the chemicals industry, making it possible to convince them to water down the Proposal further. However, since REACH was formally still an environmental issue, it is handled in a co-decision procedure, where Parliament and Council need to find an agreement. The Proposal had now been assigned to the Social Democrats by the Environment Committee and the Italian Member of Parliament Guido Sacconi was appointed to be Rapporteur. He was considered to start his work on the basis of the European Parliament's resolution from 2001.

Parliament was scheduled to start working on the Proposal right away, hoping to adopt a first reading in May 2004, before the European elections so as to give timely input to the discussions in the Council for their adoption of a common position.

In December 2003, the President of the European Parliament, Mr Pat Cox, received a letter from Mr Berenguer Fuster, the chairperson of the Committee on Industry, External Trade, Research and Energy. The letter declares that following

the shift of competency in Council, the competency in Parliament should also be changed. Therefore REACH should be moved from the Committee on Environment, Public Health and Consumer Policy to the Committee on Industry etc. Shortly thereafter, another letter with similar content arrives, this time from the Committee on Legal Affairs who also want the lead competency. The chairperson of the Committee on Environment, Public Health and Consumer Policy, Caroline Jackson, reacted by strongly defending the lead responsibility of her committee.

However, the primary purpose of these letters however was of procedural nature: by creating a conflict of competence, the work of the lead committee was to be stalled to stop the Parliament from adopting a first reading in this legislature. The Conservatives in the Environment Committee and the chair of that committee had already stated that they thought more time was required, in line with demands from industry. A key motivation may also have been to keep the issue out of the elections. The strategy worked: The unresolved conflict of competence served as the necessary pretext for the chair of the Environment Committee to block the discussions as planned in January. As a consequence, it became impossible to complete a first reading.

Once REACH was off the agenda of this Parliament, it was a smooth decision with no objections that the Committee on Environment would keep the lead competency. The Committees on Industry and on Legal Affairs were given enhanced cooperation due to a majority by the Conservatives and the Liberals. Thus it will be up to the new Parliament to carry on the fight for a regulation to protect the health of humans and the environment against hazardous chemicals.

Powell Sends a Third Cable and US Intervention is Unveiled

In March 2004 Colin Powell sent yet another cable to US embassies requesting them to act against REACH. The content of this new cable was similar to the first one and critique against the intervention of the US government in European policymaking was growing in the USA. On 1st of April, the US House of Representatives Committee on Government Reform presented a report looking into the multi-year US lobby campaign against REACH. In the report, the Bush administration is accused of working with the US chemicals industry to influence the new EU chemicals strategy. The Bush administration is also accused of basing its opposition against REACH entirely on the American Chemistry Council's assessments. The report, which was released by Henry A. Waxman, a democrat from California, found no evidence that the Bush administration had performed any own analysis of the impacts of REACH or sent the assessments of ACC for peer review.

The report contains details from e-mail correspondence between the US government, chemicals industry and US embassies in Europe. In a letter to president George W. Bush, Mr Waxman says: "I request a clear statement from you that the United States will not work to undermine environmental protections

in other nations." EU Commission spokesperson in the US, Anthony Gooch, commented the US lobby campaign "There would seem to be an inordinate weight given to only one side of a complex argument. Significant concerns about the environment and public health seem to be totally absent from their agenda." In an e-mail quoted in the report, an official of the US trade representative wrote: "But who will take on Wallstrom - the answer is only other ministers or heads of state. The US government plans to send in our ambassadors to member states and commission to make our case." Another e-mail from the US trade officials urged the chemicals industry to "get to the Swedes and Finns and neutralize their environmental arguments."

**"Who will take on Wallstrom?
The answer is only other
ministers or heads of state"**

US Trade Representative

REACH is Loose

While European leaders are caving in to the pressure from the chemicals industry and over-seas governments, REACH has embarked on a voyage of its own. Beyond the wide, but short-sighted, circles of the multinational chemical industries and their protectors, the interest for REACH is mounting. People around the world are inspired by the fact that politicians are trying to address something that concerns people in their everyday life.

While right-wing think-tanks are debating how to "confine" stricter chemicals regulation like REACH to Europe, many NGOs are studying REACH, trying to find ways of implementing it in their parts of the world.

Ironically, the aggressive lobby campaign mounted by the ACC, which was undoubtedly aimed at preventing regulation similar to REACH from spreading to the US and other regions of the world, has fuelled the interest for stronger regulation in the US. Politicians and the media are starting to question the safety of their own system, the Toxic Substances Control Act, which in many ways is similar to the current regulation in the EU.

US Democratic staff have met environmental groups to determine which parts of REACH could be incorporated into US law. On 19 March 2004, three key US senators called for investigations into whether the current US laws were enough to protect human health and the environment. The call was made in a letter to the congressional General Accounting Office, saying inter alia: "Concerns have been raised that existing statutes may not provide an effective means of responding to data indicating that substantial risk may exist."

The words sound familiar. Perhaps the distance between Chester and Washington D.C. isn't so big after all.

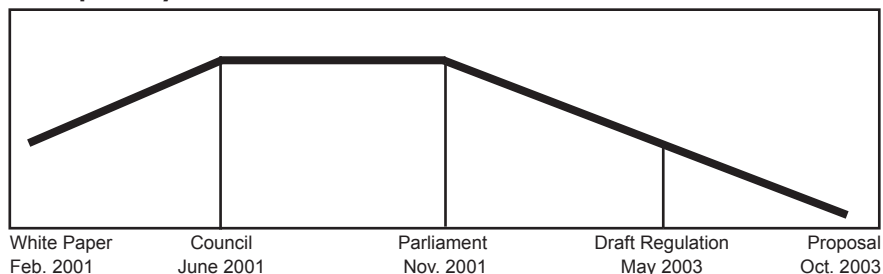


ATTACHMENTS

The Ups and Downs of REACH

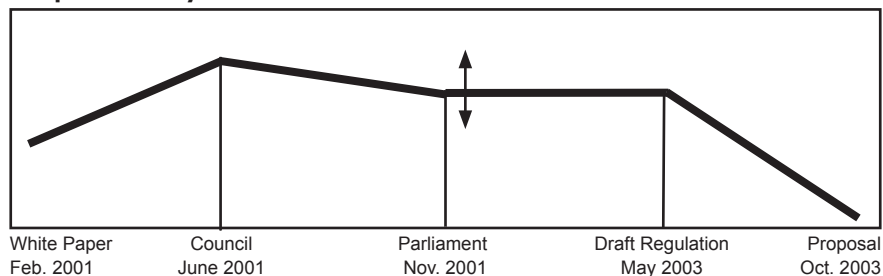
The strategy put forth in the White Paper meant substantial improvements in protecting human health and the environment against effects of industrial chemicals. However, the provisions were not enough to reach the objectives of the initial request of the Council or the European Parliament. Both of these institutions demanded changes, increasing protection further. Environmental and consumer groups were unimpressed by the proposal and requested stricter regulation. However, the Draft Regulation, presented in May 2003, contained impairments on some issues and very few improvements compared to the White Paper. The Proposal laid forth in October 2003 had even more reductions in the requirements, falling short even of the White Paper. While there are many details in the provisions, the general demise may be summarised in the following (graphs by EEB)

Transparency



The White Paper instigates an improved transparency for the public, requiring the chemicals industry to provide information regarding chemicals. However, the White Paper does not extend this right-to-know to consumer products. The Council required the Commission to improve citizens' right-to-know and the European Parliament required increased burden of information on chemical producers, extending transparency also to the labelling of consumer products containing hazardous substances. In the Draft Regulation presented by the Commission in May 2003, there were no improvements from the White Paper. In the Proposal from the Commission in October 2003 the Commission had decreased transparency further by adding a new list of information that should always be confidential, such as the names of registrants.

Scope and Duty of Care

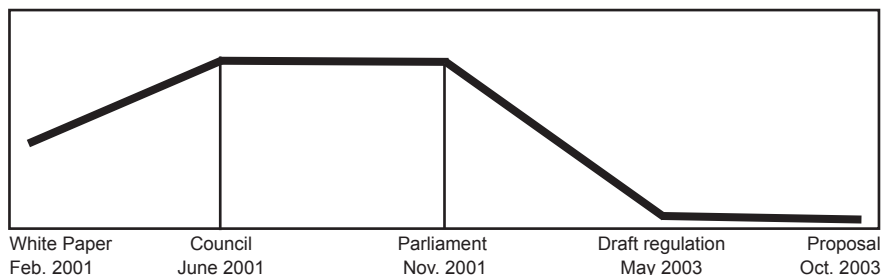


According to the White Paper all chemicals produced or imported in quantities above one tonne per year and producer/importer must be registered and required provision of certain data. The Council requested that the possibility to have a simple register also of chemicals produced or imported in volumes below one tonne per year be studied. The Parliament reacted in an unclear way. On one hand they said there should be no requirements for substances below one tonne, on the other

The Ups and Downs of REACH

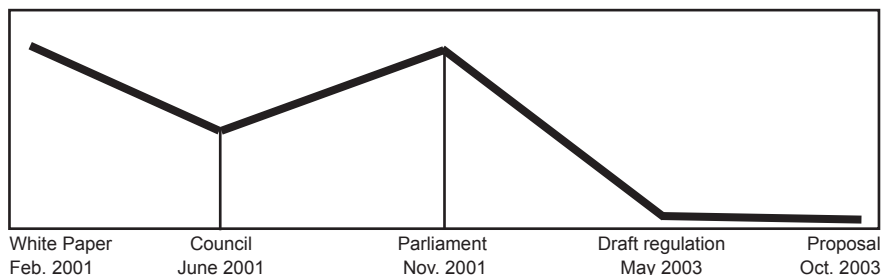
hand they also asked for a simple register for substances below one tonne. In the Draft Regulation presented in May 2003, the provisions were the same as in the White Paper. In the Proposal, the Commission introduced a severe decrease in the data requirements for substances produced in volumes from one to ten tonnes per year and also excluded polymers completely from the requirement. The White Paper also contained a general provision called “Duty of Care” which required that chemicals be produced and used in ways that would not have negative effects on human health or the environment. This duty was also disappeared in the Proposal.

Substitution of Hazardous Substances



The White Paper includes a principle aim to substitute hazardous substances with less hazardous. The Council required that this general aim be replaced by a clear duty on the downstream users to always substitute when possible. This requirement was echoed by the European Parliament. In the Draft Regulation the requirements from the Council and Parliament had not been introduced. Instead the Commission had softened the wording from the White Paper, now only requiring that hazardous substances should be substituted if they could not be “adequately controlled.” In the Proposal this remained.

Chemicals in Consumer Products



The White Paper states that all producers of consumer products have a duty to assess the safety of all chemicals used in their products and that this duty also applies to importers of consumer products. The Council softened the requirement by saying that this only applied to “substances of concern” while the Parliament agreed with the provisions from the White Paper. In the Draft Regulation the Commission had softened the provision to only apply when there are “significant releases” from the products. The Proposal has similar provisions:

Differing Views

While there was broad agreement among the stakeholders on the need to achieve sustainable development within the chemicals industry and to create a single regulatory system aiming to increase protection of human health and the environment, there were many points of differing opinion regarding the details of the new strategy proposed in the White Paper. The main points were:

Objective

Commission: Promotion of a non-toxic environment and compliance with the OSPAR generation goal.

Council: Within one generation (2020), chemicals are only produced in ways that do not lead to a significant negative impact on human health and the environment.

EP: New policy to achieve the OSPAR generational goal. 2012: no authorisation for substances of very high concern in consumer products as soon as appropriate alternatives are available. 2020: zero discharges.

Cefic: 2012/2020 goals are unrealistic. Even the benefits of products that are essential to society such as important hygiene products and medicines could be jeopardised.

NGOs: Implementation of the OSPAR generation goal. A commitment to stop all releases to the environment of hazardous substances by 2020.

Substitution

Commission: The substitution of hazardous chemicals is an important objective.

Council: Chemicals that are dangerous should be substituted with safer chemicals or technologies.

Parliament: Substitution principle should be fully applied to all chemicals of concern. Broad concept of substitution (safer substances, materials or technologies).

Cefic: Concept of substitution would lead to significant implementation difficulties.

NGOs: A requirement to substitute less safe chemicals with safer alternatives. The substitution requirement should apply to all chemicals and should include substitution with non-chemical alternatives.

Registration, Scope

Commission: Substances and preparations.

Council: All uses of concern of chemicals in products must be covered by the new system.

Parliament: Chemicals produced in, or imported to, the EU as substances, preparations, or in products.

Cefic: Substances and preparations placed on the market

NGOs: A full right to know, including what chemicals are present in products.

Registration, Tonnage Threshold

Commission: Greater than one tonne.

Council: Study the case for introducing within the REACH system a simple register including substances produced in volumes less than one tonne.

Parliament: Rejected calls for additional register for greater than one tonne but also calls for registration of all chemicals irrespective of production volume with comprehensive minimum data.

Cefic: appreciates .. that key concerns are shared ... to avoid unworkable scope for registration

NGOs: All uses of a chemical should be approved and should be demonstrated to be safe beyond reasonable doubt.

Evaluation

Commission: Supports research on improvement and simplification of risk assessment procedures.

Council: Develop procedures that can be used both by authorities and by the industry to simplify the identification of the relevant testing strategies.

Parliament: Simplified risk assessment: criteria to put substances in categories of concern based on hazard criteria and use pattern to trigger rapid risk reduction.

Cefic: Risk assessment of chemicals, where potential exposure and use are also taken into account; must form the basis for all regulatory decisions.

NGOs: Decisions need to be based on generic principles such as usage in consumer products and a simple check list of conditions.

Authorisation, Scope

Commission: CMR1+2 and POPS; decide later on PBT and VPVB.

Council: CMR1+2, POPs, PBT, VPVB; envisage addition of endocrine disruptors; and study inclusion of sensitizers and chronic toxic substances.

Parliament: CMR1+2, POPS, and study others e.g. PBT.

Cefic and VCI: Proposed extension of scope would lead to an unmanageable situation.

NGOs: CMR, PTB, vPvB, + equivalent level of concern, e.g. PT. Phase out of persistent or bioaccumulative chemicals (P or B).

Authorisation, Conditions

Commission: Risk assessment to show that use constitutes a negligible risk, conditional authorisation if justified by the overall socio-economic benefits of the use.

Parliament: Use must be essential to society. Hazardous properties essential for intended use, no safer alternative, alternatives are being developed, decisions by authorities as directly as possible on the information received from registration and evaluation steps.

VCI: Criticises that entire groups of substances of economic relevance are to be replaced merely on the basis of certain hazardous properties without considering their usefulness and their actual risks during use. Decisions by authorities as directly as possible on the information from registration and evaluation.

The German Industry Federation BDI: Criticises "societal needs" as incompatible with the objective of safe use.

NGOs: Authorisation only when there is an overwhelming societal need and no safer alternatives can be found.

Public Availability of Data

Commission: Industry list of dangerous substances to be made available on the Internet, and stakeholder access to non-confidential info in the database.

Council: Information relevant for the safe use of chemicals as well as products must be made available to all users. Stakeholder access to the non-confidential information is important but not sufficient. A general duty for manufacturers to provide comprehensive information on the content of chemicals in products and their hazard and risks and to label products appropriately.

Parliament: Data on properties of chemicals to be published, no confidentiality for production volumes, use patterns, sources of exposure. Duty of manufacturer to provide information on content and properties of chemicals in products. Toll free number for information on chemicals in products, and labelling of consumer products with regard to substances of concern.

VCI: Production volumes, and use patterns and sources of exposure should remain confidential.

NGOs: A full right to know, including what chemicals are present in products. Labeling of consumer products with information regarding the contents of hazardous substances.

Costs: The Facts and the Figures

Estimating the costs of a proposed regulation can be done in a variety of ways and using many different definitions of cost. Studies can also be limited to specific parts of the regulation, for example costs for testing, or far-reaching in their scope such as trying to assess dynamic effects down the whole business chain. Most cost assessments only look at expenses and ignore benefits, thus not showing the real cost. Below are the most important assessments of the costs of REACH.

The White Paper

The first cost estimate relating to the new strategy was presented in the White Paper in 2001. According to the Commission, the direct costs of testing chemicals would be approximately €2.1 billion over 11 years, or €191 million per year, corresponding to 0.05 percent of annual sales. Other costs to the chemicals industry, downstream users or other parts of society were not considered. The Commission pointed out that there were also substantial benefits to society in terms of health effects which were difficult to assess, but may exceed the costs many times over.

UK Impact Assessment

In May 2001 Risk & Policy Analysts (RPA) in Loddon, UK presented a partial impact assessment with a cost/benefit analysis for the UK. The report, ordered by the Department of Environment, Transport and the Regions (DETR), was limited in that it was based on the White Paper, which did not give sufficient detail for a comprehensive assessment. The result showed that the total costs for UK society could be some £0.6-1 billion over 20 years while the socio-economic health benefits, in the form of prevention of asthma, cancer, dermatitis, injuries and fatalities, were estimated to be at least £1.5-2 billion over ten years.

RPA Business Impact Assessment

In June 2002 the Commission presented an impact assessment that had been done by RPA together with Statistics Sweden. As other impact assessments at the time, it was based on the White Paper which did not give sufficient detail for a comprehensive assessment. The assessment estimated the total costs for the chemicals industry to be between €1.4 and 7 billion with a best estimate around €3.6 billion over 11 years. This would mean an annual cost of approximately €327 million or 0.08 percent of annual sales.

The Arthur D. Little Report

To examine the economic effects of the new strategy, the German industry federation Bundesverband der Deutschen Industrie (BDI) commissioned the consultants Arthur D. Little (ADL). The report, which was presented in December 2002, based its assessments on the rough strategy presented in the White Paper and presented three scenarios depending on how the strategy was to be interpreted. The result showed that the German economy would suffer substantially from the new regulation. Estimates were presented in terms of "gross value added loss," for all industrial sectors in Germany and showed that the loss would be between 0.4 and 6.4 percent and that between 150,000 and 2.3 million jobs would be lost in the German industry depending on which regulative scenario would be realised. The methodology of this report was widely criticised by economists as well as the German government.

The Mercer Study

In April 2003 Mercer Management Consultants presented a report supervised by the French chemicals industry federation Union des Industries Chimiques (UIC), several other French industrial federations as well as Ministries of the French government. The scope of the study was to assess the total costs to French society of implementing REACH. The methodology was basically the same as that of the Little report (see above). Since there was no detailed proposal at this time, the study worked with assumptions based on the strategy presented in the White Paper. The study showed that the main economic impact would be a domino effect, where non-chemical industrial sectors would be affected either by passing-on of the chemicals industry's costs or by the need to replace substances that are no longer available.

Costs: The Facts and the Figures

It was concluded that the implementation of REACH would ultimately affect the whole French economy, due to reduced business activity and lower consumption. The impact on employment was estimated to be a loss of 360,000 - 670,000 jobs, or up to 2.8 percent of the working population. The economic costs in France were claimed to be between €29 and 54 billion, and the cumulative loss of investment was estimated at between €47 and 88 billion.

RPA Combined Costs Assessment

In February 2003 RPA presented another study including the costs for administration of the new agency. The report concluded that the costs for testing substances and administration were €3.8 - 4.1 billion.

RPA Estimate of Benefits on Occupational Health

Already with the presentation of the White Paper in 2001, the Commission claimed that the economic benefits of the new strategy would be substantial. In March 2003 RPA presented a report studying the economic benefits that REACH could bring to occupational health in Europe. The report estimated that the benefits would be between €27 to 54 billion over 30 years.

RPA Revised Business Impact Assessment

In connection to the presentation of the draft regulation in May 2003, the Commission asked RPA to undertake a new business impact assessment based on the details in the draft regulation. The study was presented in October 2003 and showed that the provisions in the draft regulation were much more costly than the assumptions that had been made in the first business impact study in 2002. The proposed inclusion of polymers and the requirement of separate Chemical Safety Reports (CSR) increased costs significantly. The total costs up to the year 2020 for the chemicals industry and downstream users to implement the draft regulation were estimated to be somewhere between €14 and 26 billion. The best estimate was €12.6 billion excluding costs for testing. The Commission stated it would present a final impact assessment once the final proposal was developed.

Supplement by Arthur D. Little

Following the presentation of the draft regulation, BDI commissioned ADL to follow up on the previous report from December 2002 by assessing the effects of the proposed regulation on the German industry. The report was published in August 2003 and claimed that the "gross value added loss" to the whole German industry could be 4.7 percent and that some 1.7 million jobs could be lost as a result of implementing the draft regulation.

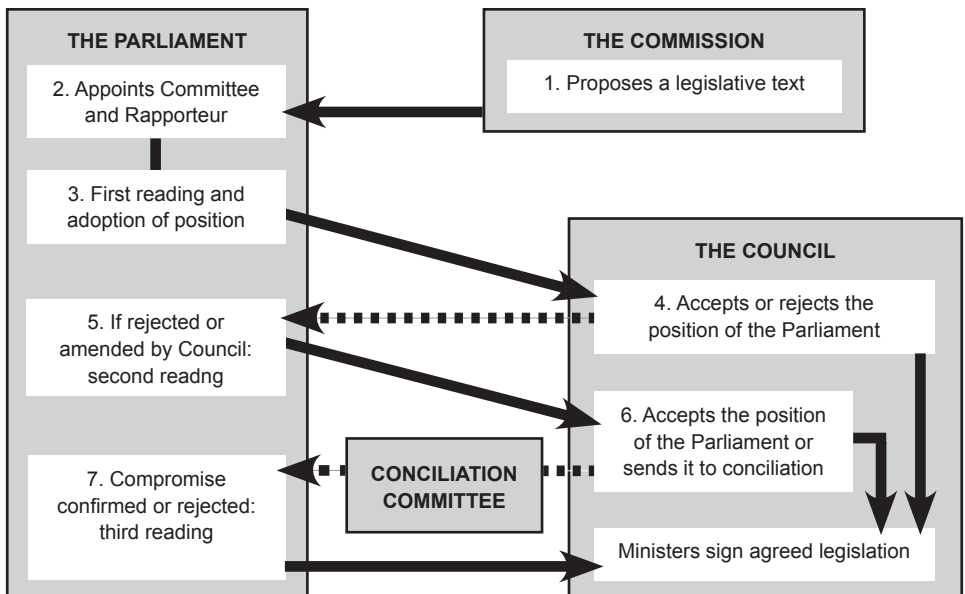
The Commission's Extended Impact Assessment

When the final Proposal from the Commission was presented in October 2003 it was accompanied by an extended impact assessment. The assessment states that the changes from the draft regulation to the final proposal brought dramatic cost reduction compared to the RPA Revised Business Impact Assessment (see above). The decision to drop the requirements for CSRs, exempt polymers, lower testing and registration requirements for substances produced under ten tonnes per year and the lighter requirements for intermediates meant that costs would be reduced by €10.6 billion. The remaining cost would be €2.3 billion. When costs were passed on to downstream users the final costs to industry would be €2.8-5.2 billion. The assessment also pointed to potential benefits of the new strategy. Concerning long-term health effects, REACH was expected to lead to economic benefits in the region of €50 billion over 30 years, although the Commission pointed out that this was not intended as an estimate. On the environmental side, benefits were stated to be even more difficult to assess, but an example given of the many economic benefits was the potential to avoid future contamination of land. As an example of the amplitude of such costs, the Commission pointed out that the costs of polluted land sites in the Netherlands alone were estimated to be €23 billion.

The Codecision Procedure - Map of the Political Process

During 2004/2005, the European Parliament will have its first reading of the Proposal from the Commission. The process then follows the codecision procedure. This procedure puts the European Parliament and the Council on an equal footing, and together they adopt legislation proposed by the Commission. Parliament has to give its final agreement. Codecision is an essential power of the European Parliament, which enhances its ability to influence European legislation. Codecision applies, among other things, to the environment, consumer protection, education, culture and health. The codecision procedure involves one, two or three readings.

1. The Commission proposes a legislative text;
- 2-3. The European Parliament adopts a position on the basis of a report by its relevant standing committee and usually suggests changes to the Commission proposal in the form of amendments. This is the first reading;
4. The Council of Ministers either approves Parliament's amendments - in which case the legislative proposal is adopted - rejects or modifies them;
5. On the basis of a recommendation by the relevant standing committee, the European Parliament delivers a position at second reading: it approves, rejects or amends the Council position by an absolute majority of its Members (314 votes);
6. The Commission takes account of Parliament's amendments and forwards an amended proposal to the Council. The Council can adopt Parliament's amendments that have been accepted by the Commission by a qualified majority, or modify Parliament's amendments only by a unanimous vote. In the event of disagreement between Parliament and the Council, a conciliation committee made up of the members of the Council and a delegation from Parliament meet for a maximum of six weeks. In the vast majority of cases the two parties reach an agreement, in the form of a joint text;
7. Parliament is invited to confirm this agreement at the third reading. If no agreement is reached, the proposal for a Community "law" is deemed not to have been adopted (i.e. it lapses).



In preparing this guide a great number of documents have been used. For practical reasons, only the most important documents are listed below. However, most documents referring to the process of creating a new chemicals policy in the EU are available on the Internet. Below are some useful links with vast amounts of information and more links. See also the Contact List at the end of the guide.

Links

European Commission websites on the Future Chemicals Policy:

<http://europa.eu.int/comm/environment/chemicals/whitepaper.htm>

<http://europa.eu.int/comm/environment/chemicals/reach.htm>

<http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/whitepaper.htm>

European Chemicals Bureau:

<http://ecb.jrc.it>

European Council Presidency Conclusions:

http://europa.eu.int/european_council/conclusions/index_en.htm

European Council Newsroom:

<http://ue.eu.int/Newsroom/Contents.ASP?LANG=1>

European Parliament Resolution on the White Paper:

<http://www3.europarl.eu.int/omk/omisapir.so/pv2?PRG=QUERY&APP=PV2&LANGUE=EN&TYPEF=A5&FILE=BIBLIO01&NUMERO=0356&YEAR=01>

The Swedish Chemicals Inspectorate (KemI) website on REACH:

http://www.kemi.se/default_eng.htm

Department for Environment, Food and Rural Affairs (UK) website on chemicals policy:

<http://www.defra.gov.uk/environment/chemicals/eufuture.htm>

Development Initiative for Chemical Industry Dependent Areas in the UK, website on chemicals policy:

<http://www.teesvalley-jsu.gov.uk/dicidauk/keyissues/chemstrat/chemstratindex2.htm>

EurActive, on-line media on European Union Policies - website on REACH:

<http://www.euractiv.com/cgi-bin/cgint.exe/1043577-444?204&OIDN=1506288&-tt=en>

Report on US intervention from House of Representatives and internal US government documents:

http://www.house.gov/reform/min/inves_admin/admin_reach.htm

Cefic website on chemical policy review:

<http://www.chemicalspolicyreview.org/>

Literature

European Commission

Industrial Chemicals: Burden of the Past, Challenge for the Future, a Stakeholder Workshop, 24-25 February 1999.

White Paper - Strategy for a Future Chemicals Policy, 27 February 2001.

Communication from the Commission on Impact Assessment, May 2002.

Building Block on Authorisation of chemical substances, July 2002.

Stakeholder Reactions on the Internet Consultation, 24 July 2003.

Proposal for a Regulation of the European Parliament and of the Council etc (REACH Proposal), Volumes 1-6, 29 October 2003.

Commission Staff Working Paper - Extended Impact Assessment, COM (2003) 644 final, 29 October 2003.

Memorandum of Understanding between the European Commission side (DG Enterprise and DG Environment) and Industry (UNICE/CEFIC) to Undertake Further Work Concerning the Impact Assessment of REACH, April 2004.

Implications of the proposal for a new chemicals legislation - REACH system - for animal testing, undated.

Useful Links and Literature

Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau:
Public Availability of Data on EU High Production Volume Chemicals, undated.
White Paper - Strategy for a Future Chemicals Policy, 27 February 2001.

European Parliament

European Parliament Resolution on the Commission White Paper on a Strategy for a Future Chemicals Policy (The Schoerling Report), A5-0356/2001 - Final Edition, November 2001.
Letter from Ms Caroline Jackson to Mr Pat Cox, December 2003.
Draft Report on the Proposal for a regulation etc, Guido Sacconi, January 2004.
Letter from Ms Caroline Jackson to Ms Karamanou, February 2004.

Council

Chemicals Policy - Council Conclusions, 7 June 2001.
Presidency Conclusions, 20/21 March 2003.
Presidency Conclusions, 16/17 October 2003.
2539th Council Meeting, Competitiveness, 10 November 2003.+++++

Industry

Arthur D. Little: Economic Effects of the EU Substances Policy, 18 December 2002.
Arthur D. Little: Supplement to the Report on the BDI Research Project, 31 August 2003.
BDI: For a Competitive and Innovation-oriented Chemicals Policy, Position Paper, September 2001.
Cefic: Key Problems on the Schörling Report as Perceived by the European Chemicals Industry, Annex, August 2001
Cefic: Draft Schoerling Report on the Commission Paper on Strategy for a Future Chemicals Policy - an Appraisal by the European Chemicals Industry, August 2001
Cefic: EU Chemicals Policy Review - Plenary Session 12-15 November, A. Perroy, November 2001.
Cefic: EU Chemicals Policy Review, September 2002.
Cefic: Assembly of Business Members: EU Chemicals Policy Review - the View of European Mid-sized and SME Chemical Manufacturers, November 2002.
Cefic: Strategy for a future Chemicals Policy - Expectations of the European Chemicals Industry: Workability and Competitiveness, January 2003.
Cefic: Consultation Document Concerning Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), Appendix 4, Summary of Business Impact Assessments of new Chemicals Policy, July 2003.
Cefic: Consultation Document concerning Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), Executive Summary, July 2003.
Cefic: Annual Reports and Press Releases 1998-2004.
Cefic: Thought Starter on REACH - an Initial Proposal for Translating the REACH System into Practice, undated.
CEPE: Annual Reviews, newsletters and press releases 2000-2003.
CIA Press Releases 2000-2004.
DUCC: Position on Future Chemicals Policy, undated.
FECC: Letter to the German Chancellor Gerhard Schröder, August 2003.
FECC: EU new Chemicals Policy - Summary of the Official Submission to the Internet Consultation, 2003.
Mercer Management Consulting: Study of the Impact of the Future Chemicals Policy, Final Report, April 2003.
UIC: Press Releases 2000-2004.
Unice: Letter to President of the European Commission Romano Prodi, 11 September 2003.
Unice/Cefic Press Release, November 2003.
Unice: Press releases 2000-2004

NGOs

- BUAV-ECEAE: Report on "The Way Forward - Action to end Animal Toxicity Testing, January 2004.
- BUAV: Response to the CSTEE criticism of the Way Forward, February 2004.+++
- Copenhagen Chemicals Charter: 5 key demands for a better EU chemicals policy, 27/28 October 2000.
- EEB, Eurogroup, Friends of the Earth and WWF: A New EU Chemicals Policy, Some Key Arguments, August 2001.
- EEB: Position on Commission Proposal for a Regulation on REACH, December 2003.
- EEB/WWF: A New Chemicals Policy in Europe, new Opportunities for Industry, January 2003.
- Environmental Health Fund: US Intervention in EU Chemical Policy, September 2003.
- Friends of the Earth, Safety Testing of Chemicals and the new EU Chemicals Policy, May 2003.
- Greenpeace: Consuming Chemicals, 2003.
- Greenpeace: Chemical Legacy, 2003.
- Vier Pfoten: Internet Comment on REACH Draft Regulation, 2003.
- WWF: Toxic Legacy, 1999.
- WWF: UK National Biomonitoring Survey 2003.

Other

- AMAP: POPs Fact Sheet #1, Arctic Monitoring and Assessment Programme, 2000.
- ECVAM, Alternative (non-animal) Methods for Chemicals Testing: Current Status and Future Prospects, draft, May 2002.
- EEA: Low Doses, High Stakes? 1998.
- EEA: Late Lessons from Early Warnings, 2001.
- ETUC Declaration on the Proposed Reform of EU Policy on Chemicals (REACH), 17/18 March 2004.
- House of Representatives (USA): A Special Interest Case Study: The Chemical Industry, the Bush Administration, and the European Efforts to Regulate Chemicals, April 2004.
- IEH: Testing Requirements for Proposals under the EC White Paper "Strategy for a Future Chemicals Policy", April 2001.
- IEH: Testing requirements under the EC White Paper 'Strategy for a future chemicals policy' - an update, March 2002.
- Royal Commission on Environmental Pollution, Chemicals in Products, 2003.
- RPA and Statistics Sweden: Assessment of the Business Impact of New Regulations in the Chemicals Sector, Final Report, June 2002.
- RPA: Regulatory Impact Assessment of the EU White paper; Strategy for a Future Chemicals Policy, May 2001.
- RPA: Assessment of the Impact of the New Chemicals Policy on Occupational Health, March 2003.
- Revised Business Impact Assessment for the Consultation Document, October 2003.
- SCF: Opinion of the EU Scientific Committee on Food on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food, 22 November 2000, 5.2.1
- Stockholm Environment Institute (SEI): Costs and Strategies Presented by Industry During the Negotiation of Environmental Regulations, April 1999.
- TNO: report R2002/606, 2002 and R2003/198, 2003.
- The Swedish Chemicals Inspectorate (KemI): Kemikalieutredningen (Assessment of Chemicals), ISBN 91-38-21380-X, 2001.
- The Swedish Chemicals Inspectorate (KemI): Main Issues in the European Commission's Proposal, 14 November 2003.
- The Swedish Food Administration, the Swedish Monitoring of Pesticide Residues in Food of Plant Origin: 2002.
- SRU: On the economic impact of the planned reform of European chemicals policy - Statement, July 2003.

List of Acronyms

ACC - American Chemistry Council
 ADL - Arthur D. Little
 AMAP - Arctic Monitoring and Assessment Programme
 Barcon - The Barcelona Convention
 BDI - Bundesverband der Deutschen Industrie, German Industry Federation
 BEUC - European Consumers Organisation
 CEE - Central and Eastern Europe
 Cefic - European Chemical Industry Council
 CEPE - European Council of the Paint, Printing Ink and Artists' Colours Industry (Conseil Européen de l'industrie des peintures)
 CFC - chlorofluorocarbon
 CIA - Chemical Industries Association
 CLRTAP - Convention on Long-range Transboundary Air Pollution, also called The Geneva Convention
 CMA - Chemical Manufacturers Association
 CMR - carcinogens, mutagens and reproductive toxicant
 CSR - Chemical Safety Reports
 DDT - dichlorodiphenyltrichloroethane
 DES - diethylstilbestrol
 DETR - Department of Environment, Transport and the Regions (UK)
 DG - Directorate General (of the European Union)
 EBFRIIP - Eurochlor and European Brominated Flame Retardant Industry Panel
 ECB - European Chemicals Bureau
 ECEAE - European Coalition to End Animal Experiments
 ECEG - European Chemical Industry Employers Group
 EDC - endocrine disrupting chemicals
 EEA - European Environment Agency
 EEB - European Environment Bureau
 EEC - European Economic Commission
 EINECS - European Inventory of Existing Commercial Chemical Substances
 ELINCS - European List of Notified Chemical Substances
 EMCEF - European Mine, Chemical and Energy Workers' Federation
 EP - European Parliament
 EPA - Environmental Protection Administration (USA)
 ETUC - The European Trade Union Confederation
 EU - European Union
 FAO - Food and Agriculture Organisation
 GDP - Gross Domestic Product
 GEF - Global Environment Facility
 GHS - Globally Harmonised Classification and Labelling System
 HBCD - hexabromocyclododecan
 HCB - hexachlorobenzene
 HELCOM - The Helsinki Commission, the governing body of the Convention on the Protection of the Marine Environment of the Baltic Sea Area
 HPV - High Production Volume
 ICCA - International Council of Chemicals Associations
 IEH - Institute for Environment and Health (UK)
 IFC - International Finance Corporation
 IFCS - Intergovernmental Forum for Chemical Safety
 ILO - International Labour Organisation

List of Acronyms

IMO - International Maritime Organisation
IPCS - International Programme on Chemical Safety
KemI - National Chemicals Inspectorate (Sweden)
LRI - Long-range Research Initiative
MARPOL - International Convention for the Prevention of Pollution from Ships
MEA - multilateral environmental agreement
MOLAR - Mountain Lake Research Project
MPD - Minimum Pre-marketing Set of Data
NGO - non-governmental organisation
NIS - newly industrialized states
OECD - Organisation for Economic Co-operation & Development
OSPAR - The Convention for the Protection of the Marine Environment of the North-East Atlantic
PBT - persistent, bio-accumulative and toxic
PCB - polychlorinated biphenyl
PCT - polychlorinated terphenyl
PIC - Prior Informed Consent
POP - persistent organic pollutant
PRTR - Pollutant Release and Transfer Register
QSAR - Quantitative Structure Activity Relationship
R&D - Research and Development
REACH - Registration, Evaluation and Authorisation of CHemicals
RPA - Risk & Policy Analysts (UK)
SAICM - strategic approach to international chemicals management
SIDS - Screening Information Datasets
SMEs - small and medium sized enterprises
TBT - tributyltin
TDI - tolerable daily intake
UIC - Union des Industries Chimiques (France)
UK - United Kingdom
UN - United Nations
UNCED - United Nations Conference on Environment and Development
UNCHE - United Nations Conference on the Human Environment
UNECE - United Nations Economic Commission for Europe
UNEP - United Nations Environment Programme
UNFCCC - United Nations Framework Convention on Climate Change
Unice - Union of Industrial and Employers Confederations of Europe
UNIDO - United Nations Industrial Development Organisation
UNITAR - United Nations Institute for Training and Research
USA - United States of America
USEU - United States Mission to the European Union
USTR - United States Office of Trade Representatives
VCI - Verband der Chemischen Industrie eV
VOC - volatile organic compound
vPvB - very persistent and very bio-accumulative
WHO - World Health Organisation
WSSD - World Summit on Sustainable Development
WTO - World Trade Organisation

Contact List

American Chemistry Council (ACC)

1300 Wilson Blvd., Arlington, VA 22209, USA
 Tel. 703-741-5000, Fax: 703-741-6000
 E-mail: webmaster@americanchemistry.com
www.americanchemistry.com

Arctic Monitoring and Assessment Programme (AMAP), AMAP Secretariat

Strømsveien 96, P.O. Box 8100 Dep., N-0032 Oslo, Norway
 Tel. +47 23 24 16 32, fax: +47 22 67 67 06
 E-mail: amap@amap.no
www.amap.no

Chemical Industries Association (CIA), UK

Kings Buildings, Smith Square, London SW1P 3JJ, UK
 Tel. 020 7834 3399, fax: 020 7834 4469
 E-mail: enquiries@cia.org.uk
www.cia.org.uk/

Chemical Reaction Website

A joint project of The European Environmental Bureau, Friends of the Earth and Greenpeace
 E-mail: info@chemicalreaction.org
chemicalreaction.org/

European Chemical Industry Council (Cefic)

Avenue E. Van Nieuwenhuysse, 4 box 1
 B-1160 Brussels, Belgium
 Tel. +32 2 676 72 11, fax: + 32 2 676 73 00
 E-mail: mail@cefic.be
www.cefic.be and www.chemicalpolicy.org

European Chemical Industry Employers' Group (ECEG)

Avenue Emile de Béco 109, B-1050 Brussels, Belgium
 Tel: +32 2 626 2180 , fax: +32 2 646 0685
 E-Mail: info@emcef.org
www.emcef.org

European Coalition to End Animal Experiments (ECEAE)

16a Crane Grove, London N7 8NN, UK
 Tel. +44 (0)20 7700 4888, fax: +44 (0)20 7700 0252
 E-mail: eceae@buav.org
www.eceae.org/

European Community of Consumer Cooperatives (Euro Coop)

Rue Archimède, 17, B - 1000 Brussels, Belgium
 Tel.+32 2 285 00 70, fax: +32 2 231 07 57
 E-mail: info@eurocoop.org
www.eurocoop.org

European Council of the Paint, Printing Ink and Artists Colours Industry (CEPE)

Av Van Nieuwenhuysse, 4, B - 1160 Brussels, Belgium
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European Environment Agency (EEA)

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 Tel: +45 3336 7100, fax: +45 3336 7199
 E-mail: eea@eea.eu.int
www.eea.eu.int/

European Environment Bureau (EEB)

34, Bd de Waterloo, B-1000 Brussels, Belgium
 Tel.: +32 2 289.10.90, fax: +32 2 289.10.99
 E-mail: info@eeb.org
www.eeb.org/activities/chemicals/main.htm

European Policy Centre

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 Tel. +32 2 231 03 40, fax: +32 2 231 07 04
 E-mail: info@theepc.be
www.theepc.net

Food and Agriculture Organisation (FAO)

Viale delle Terme di Caracalla, 00100 Rome, Italy
 Tel. +39 6 57051, fax: +39 6 570 53152
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www.fao.org

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Greenpeace International

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www.greenpeace.org

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International Chemical Secretariat

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International Council of Chemical Associations (ICCA)
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www.icca-chem.org

International Labour Organisation (ILO)
 4 route des Morillons, CH-1211 Geneva 22 Switzerland
 Tel. +41 22 799 6111, fax: +41 22 798 8685
 E-mail: ilo@ilo.org
www.ilo.org

National Food Administration, Sweden
 Box 622, SE-751 26 Uppsala, Sweden
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 E-mail: livsmedelsverket@slv.se
www.slv.se/engdefault.asp

Organisation for Economic Co-operation & Development (OECD)
 2 rue André Pascal, F-75775 Paris Cedex 16 France
 Tel. +33 1 45 24 82 00,
www.oecd.org

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 Tel. +46 8 519 411 00, fax: +46 8 735 76 98
 E-mail: kemi@kemi.se
www.kemi.se/default_eng.htm

The European Consumers Organisation (BEUC)
 Avenue de Terveuren, 36 Bte 4, B-1040 Brussels, Belgium,
 Tel. +32 2 743 15 90, fax: +32 2 740 28 03
 E-mail: consumers@beuc.org
www.beuc.org and www.chemical-cocktail.org

The European Mine, Chemical and Energy Workers Federation (EMCEF)
 E-mail: emcefbp@axelero.hu
www.emcef.org and
www.emcef.org/Committees/Chemical/Chemical.asp

The European Trade Union Confederation (ETUC)
 5, Boulevard Roi Albert II, B-1210 Brussels, Belgium
 Tel. +32 2 2240-411, fax: +32 2 2240-454/5
 E-mail: etuc@etuc.org
www.etuc.org/en/

UN Interorganisation Programme for the Sound Management of Chemicals (IOMC)
 United Nations World Health Organisation (WHO)
 Avenue Appia 20, 1211 Geneva 27, Switzerland
 Tel. + 41 22 791 21 11, fax: + 41 22 791 3111
 E-mail: infolOMC@who.int
www.who.int/iomc/en/

Union of Industrial and Employers Confederations of Europe (Unice)
 Avenue de Cortenbergh, 168, B-1000 Brussels Belgium
 Tel. +32 2 237 65 11, fax: +32 2 231 14 45
 E-mail: main@unice.be Tel.
www.unice.org

United Nations Environment Programme (UNEP)
 United Nations Avenue, Gigiri, PO Box 30552, Nairobi, Kenya
 Tel: +254 2 621 234, fax: +254 2 624 489/90
 E-mail: eisinfo@unep.org
www.unep.org/themes/chemicals
www.chem.unep.ch/default.htm
www.chem.unep.ch/saicm

United Nations World Health Organisation (WHO)
 Avenue Appia 20, 1211 Geneva 27, Switzerland
 Tel. + 41 22 791 21 11, fax: + 41 22 791 3111
 E-mail: inf@who.int
www.who.int

World Trade Organisation (WTO)
 Rue de Lausanne 154, CH-1211 Geneva 21, Switzerland
 Tel. +41-22 739 51 11, fax: +41-22 731 42 06
 E-mail: enquiries@wto.org
www.wto.org

WWF
 European Policy Office (EPO)
 36, Avenue de Tervuren - B12, 1040 Brussels Belgium
 Tel. +32 2 743 88 19, fax: +32 2 743 88 00
www.panda.org/epo/toxics