Policy Brief for the EP Environment Committee
EP/IV/A/2003/09/01

Ad hoc Report on Chemicals:

Comparative Analysis of REACH and Other International Approaches

Report to the EP

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SUMMARY

Context

1 Existing EU legislation on 'new' chemicals and on 'existing' chemicals (ie on the market before 18 September 1981) sets quite extensive testing requirements on new chemicals and a procedure for carrying out risk assessments for certain existing chemicals. The scheme is widely regarded as far from sufficient for the aims of protecting human health and the environment, in particular due to weaknesses in addressing 'existing chemicals' that make up the bulk of the chemical substances on the market.

2 In response to the recognised weaknesses of existing legislation, and building on national inputs, the European Commission published, in February 2001, a White Paper entitled '*Strategy for a Future Chemicals Policy*' (EC 2001b)[1]. The White Paper presented a new regulatory system, called REACH, for the 'Registration, Evaluation and Authorisation of Chemicals'.

3 Extensive study, consultation and lobbying activities, informed the Commission in the further development of the proposed legislation, with a formal proposal launched on 29 October 2003 (COM(2003)644). This maintained the spirit and approach of REACH, though including a range of changes as regards the requirements of the scheme, aimed mainly at reducing the burden on EU's chemical industry (See Box E1) without reducing the health and environmental benefits of the scheme (see Box E2).

Box E1 Background: The EU Chemical Industry

The European chemical industry is the world's largest, and Europe's third largest manufacturing industry. In 2000 its sales exceeded €480 billion in Europe and produced a trade surplus for the region of €57 billion. World chemicals production in 2000 is estimated at €1,565 billion, with the EU accounting for 29 per cent of the total. About 1.2 million people are directly employed by the chemical industry, with many more reliant on its services for their livelihood.

Box E2 Background: The Health and Environmental Risks of Chemicals

While the full range and extent of health and environmental risks and impacts of chemical substances is not known, there is concrete evidence that a range of chemical substances causes serious health and environmental impacts, including:

- Carcinogenic substances - asbestos is known to lead to lung cancers and a link between benzene and leukaemia has been established;
- Mutagenic substances - infertility and tumours arise from exposure to PAHs, pyrene, acrylamide;
- Allergenic substances - allergies, asthma and dermatitis have been shown to be linked to exposure to chemical substances. Nickel exposure can lead to allergies as can some polymers;
- Persistent Organic Pollutants (POPs) such as DDT, PCBs - dioxins can lead to nervous system disorders, weakening of the immune system and developmental disorders;
- Endocrine disrupters - TBTs, phthalates, DDT, Lindane, Atrazine, PCBs have been linked to decreases in sperm concentrations and volumes and other reproductive disorders.

In adopting REACH the EU can avoid a large number of these health and environment 'impacts'. It has been estimated that around 45,000 DALYs (Disability Adjusted Life Years) can be avoided per year and around 4,500 cases of early mortality per year with the implementation of REACH.

[1] For Chemicals site on DGENV's web page: http://europa.eu.int/comm/environment/chemicals/whitepaper.htm and for the full text of the White Paper : http://europa.eu.int/comm/environment/chemicals/0188_en.pdf

The REACH Proposal: Key Elements

4 Registration - chemical producers will be obliged to provide basic safety data by fixed deadlines to authorities on all chemicals (existing and new) produced in quantities above one tonne per year within 11 years of legislation entering into force. Approximately 30,000 substances are believed to fall within this category. There are no requirements for chemical substances manufactured or imported in quantities under 1 tonne. Differentiated deadlines are set for different volumes of chemicals, with chemicals over 1,000 tonnes and CMRs (carcinogenic, mutagenic and reprotoxic substances) to be registered within three years of legislation coming into force. The corresponding time period is six years for chemical substances of between 100 tonnes and 1,000 tonnes, and 11 years for chemical substances of between 10 tonnes and 100 tonnes/year.

5 Testing - is required for substances put on the market in volumes greater than one tonne per year, with lower testing requirements for lower volume substances. A move towards greater contingency testing (level of testing depending on level of risk and not just volumes) is included in the REACH proposal as is a move towards greater ability to use QSARs (computational techniques to predict risk). These again reduce the burden for testing as well as reducing needs for animal testing. This includes measures for compulsory sharing of information where it concern animal tests.

6 Evaluation - for higher production volume chemicals (above 100 tonnes), and for chemicals of high concern (eg CMRs), the data from the registration phase will be evaluated. There will be approximately 5,000 substances for evaluation by competent authorities, corresponding to 15 per cent of the total. The evaluation may lead to authorisation (in the case of chemicals of 'very high concern'), risk reduction (where dangerous uses are restricted), or to no further regulatory action.

7 Authorisation - the use of chemicals considered to be of 'very high concern' would be subject to authorisation. In other words, formal permission is required before they could be marketed in the EU, and the permission would be limited to specific purposes demonstrated to be safe. The aim is for such chemicals to be phased out and substituted, unless industry can show that the use presents negligible risk or that it is acceptable, taking into account its socio-economic benefits, the lack of safer chemicals and measures to minimise exposure. The number of substances subject to authorisation is estimated at 1,400. Those chemicals of 'very high concern' include:

- Category 1 or 2 carcinogens, mutagens or reprotoxic substances (CMRs);
- persistent, bioaccumulative and toxic substances (PBTs, criteria set in Annex XII);
- very persistent and very bioaccumulative substances (vPvBs, criteria set in Annex XII); and
- on a case-by-case basis other substances which are identified as causing serious and irreversible effects to humans or the environment but which do not fulfil criteria set in Annex XII.

8. The fourth element in REACH is provisions on restrictions. Proposals for restrictions may consist of conditions for the manufacture, use and/or placing on the market of a substance or of the prohibition of these activities.

Comparing REACH to Existing Legislation

9 There is no difference under the REACH proposal in the treatment of 'existing' and 'new' chemicals, which face separate treatment under existing legislation.

10 The REACH system will significantly increase the rate at which 'existing chemicals' are addressed and move to a system where there is an explicit deadline for the bulk of chemicals to be registered – to within eleven years of the legislation passing. This therefore addresses one of the major weaknesses of the existing legislation.

11 REACH reduces some requirements on 'new' chemicals, notably moving the production/import level at which chemicals need registration from 10kg to 1 tonne. This is argued to facilitate innovation, avoid animal testing and reduce burden on industry.

12 The REACH legislation will lead to a shift in the 'burden of proof' from public authorities to industry. Currently authorities need to prove that a chemical substance is unsafe before imposing restrictions. Under REACH, industry will have to prove that the chemical can be used safely, and how. Furthermore, all actors in the supply chain will have to ensure the safety of the chemical substances that they handle.

13 In practice therefore industry will have to assess the safety of the intended uses, prior to production and marketing, rather than, as under the current system, public authorities being obliged to perform comprehensive risk assessments (that are often rather slow and cumbersome).

14 There will be increased transparency, not only for authorities and the public, but also for users. Downstream users of chemicals will get relevant information on the safe use of each substance they buy.

15 REACH will minimise, to the extent possible, animal testing. Current notification requirements for 'new substances', which start at a production/import level of 10 kg, are to have one animal test performed. At 1 tonne, a series of tests including other animal tests have to be undertaken. Under REACH the threshold moves to 1 tonne, with a series of other measures in place to minimise testing.

16 REACH should facilitate innovation, in particular encouraging the development of new safer substances. Under the present system this is discouraged by the cost of introducing new substances, and the different systems for new and existing substances, which gives incentives to use 'existing chemicals'.

Main Differences compared to the May 2003 Consultation Draft

17 The general obligation to register all chemical substances produced in quantities over 1 tonne per year remains in the October proposal. However, the information requirements (including testing requirements) for the registration of 20,000 chemicals produced between one and ten tonnes has been reduced, again reducing the burden on industry. There is no longer a requirement for complete chemical safety assessments below 10 tonnes. Furthermore, the obligation to produce an initial chemical safety assessment (CSA) of substances would no longer apply to some firms.

18 The obligations on companies to prepare chemical safety reports (CSRs) and pass them down the supply chain will be restricted. Reports will not be required for substances produced in quantities of less than 10 tonnes per year, nor from downstream users except where their use of a substance is not known to the upstream supplier.

19 REACH would no longer apply to polymers. This would remove around 30,000 to 70,000 substances from the remit of the Regulation and significantly reduce the burden on industry. In due course, registration may be required for 'certain' polymers, though at an unspecified date and following a review of the risks they pose, and taking account of the level of cost of testing, implications for competitiveness, innovation, and protection of health and the environment.

20 Chemical intermediaries – which also faced calls from industry to be excluded – remain in the proposal, though with some conditions eased. Under the final proposal around 40,000 intermediaries will need to be registered, but for most of these registration requirements will be significantly lower than for other chemical substances.

21 Companies' concerns of liability implications have been addressed by including a more clearly defined 'duty of care' provision. Firms only need to meet REACH obligations and related obligations in other legislation, addressing the fear that the original wording could lead to open-ended liability claims.

22 There are stricter rules on confidentiality.

23 Rules for applying REACH to imported articles have been softened, responding to concerns raised by the EU's main trading partners.

24 The expected costs to industry have been reduced significantly. The original cost estimate for REACH based on the draft legislation for consultation was estimated to be around €12.6bn over the 11 year period. The changes to the legislation in light of consultation are expected to lead to a reduction of costs of around €10.6bn – with major cost reductions coming from reduced requirements for chemical safety reports (€6.45bn), excluding polymers (€1.9bn), increased use of QSARS, (€0.95bn) reducing requirements for the 1 to 10 tonne bracket (€0.6bn), and lighter requirements for intermediaries (€0.6bn).

25 The estimated costs to industry of the October 2003 proposal therefore amounts to €2bn[2], covering registration (€0.5bn), testing (€1.25bn), safety data sheets (€0.25bn) and authorisations (€0.1bn). When combined with the expected €0.3bn agency fees, the total gross costs (ie excluding benefits of avoided impacts) of REACH are expected to be around €2.3bn for the 11 years.

From an environmental perspective:

26 The proposed Regulation references more prominently the 'substitution principle' which has been pushed by environmental interests to help ensure that REACH offers more adequate encouragement for the substitution of chemicals with safer alternatives. Furthermore, firms will be encouraged to present 'substitution plans', which may influence decisions on authorisations. There is therefore a reinforced authorisation system, which

[2] COM(2003)644 final

introduces a specific requirement for applicants to present a substitution plan in cases where authorisations are being granted on socio-economic grounds. It should be noted, that there is no mechanism to ensure that industry does substitute and there are no incentives for them to do so.

From an administrative perspective:

27 There will be a more streamlined administration of REACH, with the proposed chemicals agency having more responsibility in the areas of registration, evaluation and data-sharing.

From a legal perspective:

28 There will be greater legal certainty through clarifications of requirements for the duty of care, the treatment of confidential data, exemptions for research and development and sanctions. As regards 'duty of care', this will be fulfilled as long as obligations under REACH and other applicable legislation are met.

29 In summary, the ambitions of the REACH White Paper and the May 2003 proposals have been significantly weakened from the environmental perspective and expected burdens on industry significantly reduced. However, the expected health and environmental benefits are still regarded as being very significant under the new proposal. The 29 October 2003 proposals nevertheless represent a major step forward.

International Regimes and Comparison with REACH

30 There are a large number of differences between the EU's REACH proposal and existing practice in the US, Canada, New Zealand, Japan, Member States and international schemes such as the OECD's Chemical Programme, UNEP's Programme on Chemicals, and the voluntary scheme of Responsible Care that started in 1985 following the Bhopal disaster. There is also some complementarity between national and the EU scheme and international schemes, including international conventions such as the POP and PIC Conventions. An overview of differences and similarities of REACH with practice in the USA, Canada, New Zealand and Canada is given in Table E1. Details of the schemes and other international practice and given in the main report and supporting Annexes.

31 REACH goes further than most other schemes, though the final version is less ambitious than existing Dutch and Swedish schemes. Some of the differences between REACH and other schemes are points of detail as many approaches have wide parallels, and some differences have only minor costs or benefits associated. However, there are three major differences worth underlining:

32 Burden of proof – the EU's REACH in encouraging more testing, registration, and passing on of information, with specific timelines and given the quantities concerned. This will lead to a significant burden of proof for industry, one not currently in place in other countries, notably the US. REACH offers an advantage in that it directs the responsibility, and with that also possibilities, to those who should have the genuine information on chemicals, ie those who produce them. It makes sense for the burden of proof to be on industry and for the responsibility of action to be with industry, who can most effectively use their knowledge for appropriate developments and guidance for stewardship of their products.

Table E1 Comparison of REACH and Practice in the USA, Canada, New Zealand and Japan

	REACH Proposal	USA	Canada	New Zealand	Japan
Legal Base	COM(2003)644	TSCA, 1976	CEPA 1999, and NSNR	HSNO Act, 1996	CSCL 1973, am. 1986
Coverage – 'new' and 'existing' chemicals	Integrated system for 'new' and 'existing'	Split new and existing	Split new and existing	Split new and existing	Split new and existing
Thresholds	1 tonne for new and existing – pre-market	'New': 10 tonnes Pre-manufacture	'New': From 20kg for schedule one. 100kg for inclusion in domestic substances list.	No threshold – all substances have to be covered	5 tonnes up to 2003, 1 tonne from 2004
Rate of assessment	Timeline – all within 11 years of legislation passing	'Priority' programme under Toxic Release Inventory; unclear timeframe	'Virtual elimination' of toxic substances from the environment	Categorisation as to which substances 'toxic' to be done by 2006	300 per year of class 1 and class 2 – total of 1280 covered, supported by government programme
Polymers	Potential future inclusion	Listed but not included	Inclusion		
Exemptions – R&D	Yes	Yes	Yes	Yes	
Notification information requirements and classification	Include mandatory base data sets that facilitate classification/categorisation	No mandatory data sets required; no classification	Data provision leading to classification.		Include mandatory base data sets that facilitate classification/categorisation
Testing approach – use of QSARs	Some possibility Integrated	High reliance	High use, complemented by expert opinion		
Animal testing	'Minimised' but still needed	Very low use given use of QSARs et al	Very low use given use of QSARs et al	Most likely avoided by data sharing	
Testing and assessment fees – who pays & principles	Full cost recovery principle – industry to cover costs	Assessment costs covered by EPA		Assessment fees fully recouped from applicant	State testing
Burden of proof	On industry to prove chemical substances are safe.	On the EPA – EPA to prove that substances are harmful, though industry to provide data on risks			
Data sharing	Mandatory for animal testing	Not mandatory	Data sharing agreement with Australia		
Confidentiality	Respected, though disclosure the norm.	Critical driving issue. Covers intended use	Procedure for requesting confidentiality – authorities decide		
Inventories / lists	Integrated inventory building on EINECS and ELINCS	Toxic Release Inventory	The Domestic Substances List, Priority Substances List, and List of Toxic Substances	Notified Toxic Substances	ENCS
Principles	Precautionary principle, and substitution principles	Little emphasis on precautionary principle	Precautionary approach integrated		

33 Commitment to testing - REACH is the only system that moves towards a comprehensive commitment to test chemical substances, including not just 'new' chemicals, but also 'existing' ones.

34 REACH goes further than any other system in defining explicit deadlines for notification, testing, evaluation and authorisation of chemical substances. This gives a level of focus and certainty not currently existing in other systems.

35 In addition, this report notes a range of important guiding principles and examples of innovative and interesting approaches. These include: having a single scheme for both 'existing' and 'new' chemicals; extending a chemicals only scheme to include also pharmaceuticals and medicines; the use of R&D exemptions; the use of the precautionary principle, the use of the substitution principle and its application in substitution plans; the polluter pays principle; the use of contingent testing techniques and modeling techniques (notably QSARs - quantitative structure activity relationship).

Conclusion

36 A clear agreement exists that there needs to be an improvement in the legislation and systems to address chemical substances, to ensure that health and the environment can be appropriately protected while at the same time safeguarding the economic and social benefits stemming from this important industrial sector. The White Paper on REACH tried to take a big step forward and while many of the provisions have been watered down in the course of preparing the Commission proposal, the proposal still represents a major shift in the EU's approach to chemicals. Areas which still need improvement, to secure a high level of protection for human health and the environment, include the following.

37 Some chemicals, which are used below 1 tonne per year, can still be of significant danger to human health if, for example, directly exposed on humans via cosmetics, toys and textiles. **There is therefore a need to either reintroduce the general duty of care provision,** and/or to **give authorities the right to require also substances less than one tonne to be registered when there is a justified reason to believe that such substances may cause significant risk to health or the environment**. **Screening for chemicals below 1 tonne should also be reconsidered, as this is less expensive than full testing, and a procedure put in place to address them if there is a potential of causing danger.**

38 The lack of requirement for complete **chemical safety assessments and reports** (not required for chemicals under 10 tonnes) raises some concern that important chemicals would be 'missed' with this threshold. It is understood that the dropping the requirement for CSRs does not save a lot of money. Therefore the question is raised as to the cost-effectiveness of reducing the requirement.

39 While the Commission proposal notes the possibility to address polymers in due course, given the evidence that **some polymers have known health impacts (allergies)**, a date for deciding what measures are to be taken needs to be set. It is important not to lose momentum.

40 There needs to be explicit **timeframe for the authorisation** of substances of very high concern. Currently this is not made explicit.

41 At the moment REACH only ‘encourages’ company to develop ‘substitution plans’ as a part of authorisation application, but there is no control mechanism or insurance that dangerous chemicals are actually substituted when there are real alternatives, and there are insufficient measures to encourage research into substitutes. If the **substitution principle** is taken into account early on in the process and concerning also other substances than those of 'very high concern', it is possible to avoid substantial costs.

42 REACH basically states that companies that comply with REACH have fulfilled their **duty of care** requirements, giving them the sought after legal certainty. However, chemical substances under REACH only include those above 1 tonne and therefore there is a question as to what ‘duty of care’ requirements there should be for chemicals used in smaller quantities.

43 The **authorisation application** and decision will not deal with risks to the environment or human health addressed by other Community legislation (eg the IPPC Directive or Water Framework Directive). This exemption from authorisation is arguably too wide.

44 The REACH proposal is based on Article 95 of the EC Treaty (Internal Market). However, it could be questioned as to whether the proposal should be based on Article 174 (Environment), since the proposal is primarily aimed at ‘protecting human health’ and ‘preserving protecting and improving the quality of the environment’. The importance of the change in legal base is that Member States would be permitted to maintain and/or introduce stricter standards than set out in the final REACH legislation. Article 95(5) relating to the ‘environmental guarantee’ make it difficult for Member States to have stricter standards in relation to internal market. If the legal base remains Article 95, then there should at least be a clause inserted underlining that Member State initiatives to go beyond the REACH proposals would be, in principle, welcomed.

45 Questions have been raised as to what to do during the **period up to implementation**. Clarification on steps to be taken by industry and by the chemicals agency is needed.

46 At the World Summit on Sustainable Development (Johannesburg 2002) countries and the chemicals industry, committed to the Chemicals Action Plan, to minimise adverse impacts of chemicals on health and the environment by 2020. REACH promises to be a big step in achieving that objective, especially if the additional concerns noted above are addressed. However, additional complementary initiatives will be required before a truly high, and arguably needed, level of protection of human health and the environment is secured.

POLICY BRIEF FOR THE EP ENVIRONMENT COMMITTEE
EP/IV/A/2003/09/01

AD HOC REPORT ON CHEMICALS: A COMPARATIVE ANALYSIS OF REACH AND OTHER INTERNATIONAL APPROACHES

CONTENTS

1 Introduction and Aim of Report

1.1 Introduction and aim

The aim of this ad hoc report to the Environment Committee of the European Parliament is to describe the main elements of the proposed REACH legislation[3] and how REACH compares to existing EU practice, earlier ambitions for REACH, and international practice in addressing chemical substances.

The contents of the report are based on existing literature, referenced throughout the report, as well as expert input. This is the third policy brief for the EP Environment Committee under contract EP/IV/A/2003/09/01.

1.2 Context – legislative developments, the EU chemical industry and health impacts

1.2.1 Legislative developments

There is **existing EU legislation on 'new' chemicals and on 'existing' chemicals** (on the market before 18 September 1981)**.** This sets quite extensive testing requirements on new chemicals and a procedure for carrying out risk assessments for certain existing chemicals. The scheme is widely regarded as far from sufficient for the aims of protecting human health and the environment, in particular due to weaknesses in addressing 'existing chemicals' that make up the bulk of the chemical substances on the market (see Section 2 for details). Other key elements in the current legislation include the directives on the classification and labeling of dangerous substances and preparations, and restrictions on marketing and use.

In response to the recognised weaknesses of existing legislation, and building on national inputs, the European Commission published, in February 2001, a **White Paper entitled '*Strategy for a Future Chemicals Policy*'** (EC 2001b)[4]. The White Paper presented a new regulatory system, called REACH, for the 'Registration, Evaluation and Authorisation of Chemicals'. See Section 2 for details.

A Commission funded **business impact assessment** (BIA) was carried out by independent contractors[5], outlining the likely costs and impacts of the system. Member States, industry and other countries carried out their own assessments of the impacts and intense lobbying efforts from within the EU and internationally (notably the US) were launched to reduce the foreseen burden of REACH. DG Environment also launched a short benefits assessment to ensure that the benefits for human health and the environment were not overlooked in the discussions.

In **May 2003**, the Commission launched an **internet consultation on the draft legislation**. This consultation took place between 15 May and 10 July 2003 and more than 6,000

[3] Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}, COM(2003)644, 29.10.2003; Vol 1 etc. http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0644en01.pdf

[4] For Chemicals site on DGENV's web page: http://europa.eu.int/comm/environment/chemicals/whitepaper.htm and for the full text of the White Paper : http://europa.eu.int/comm/environment/chemicals/0188_en.pdf

[5] Carried out by RPA and Statistics Sweden in 2002 and updated in September 2003. See 'Assessment of the Business Impact of New Regulations in the Chemicals Sector' available at www.europa.eu.int/comm/enterprise/chmicals/bia/index.htm

responses were received. Significant pressure was seen to reduce the scope of the proposals on the grounds of the burden on industry. A wide range of studies and position papers were published from industry, governments and NGOs.

Consultation responses were taken on board by DG Environment and DG Enterprise, and REACH requirements were altered, generally weakening the proposal from an environmental perspective. In parallel, an **impact assessment**[6] was carried out to inform the proposal developments, already incorporating changes to the REACH regime. This fulfilled requirements under the Communication on Impact Assessment[7] as part of the Better Regulation Action Plan.

On **29 October 2003 a formal proposal** by the European Commission was published. While this kept to the philosophy and approach of REACH, many of the requirements were significantly weakened (see Section 2 for details). The final text now depends on the Council and Parliament.

1.2.2 Context: size and structure of the European industry

The European chemical industry is one of the EU's most international, competitive and successful industries. It is the world's largest, and Europe's third largest manufacturing industry. In 2000, its sales exceeded €480 billion in Europe and produced a trade surplus for the region of €57 billion. World chemicals production in 2000 is estimated at €1,565 billion, with the EU accounting for 29 per cent of the total.

There are around 30,000 chemical substances placed on the EU market each year at volumes of over 1 tonne/year. 10,000 have volumes greater than 10 tonnes/year, and 20,000 at 1 to 10 tonnes/year. In addition, there are around 100,000 intermediaries, of which 15 per cent are less than one tonne and a wide range of polymers (between 40,000 and 70,000).

The seven largest EU chemicals producing countries (Germany, France, UK, Italy, Belgium, Spain and Netherlands) were responsible for more than 88 per cent of EU chemical turnover in 2000 (€ 458 billions' worth). In the EU, the chemicals industry is made up of over 22,000 companies, of which SMEs account for around 96 per cent of total enterprises and 28 per cent of chemical production.

About 1.2 million people are directly employed by the chemical industry, with many more reliant on its services for their livelihood. The White Paper notes that around 3 million are dependent on this industry in the EU.

The chemical output in Europe covers a range of chemical products, such as pharmaceuticals (26%), speciality and consumer products (19.2%), plastics and polymers (15.6%), petrochemicals (14.7%) and agriculture products (4.2%).

There is no doubt that this sector is of major business, economic and employment importance. In addition to the chemical industry, the proposed REACH regulation would set

[6] Commission Staff Working Paper: 'Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} – Extended Impact Assessment. COM(2003)644 final, Brussels 29/10/2003 SEC(2003)1171/3

[7] COM(2002)276 final 5 June 2002 http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0276en01.pdf

certain requirements, and provide information on the safe use of chemicals for downstream users of chemicals. This would address virtually all sectors of industry.

1.2.3 Context: health risks, impacts

Table 1.1 presents an overview of the groups of known harmful or hazardous substances, their toxicological effects and health impacts, and examples of chemicals that are known to have these effects. This applies to humans and to animals[8]. Ecotoxicological effects and impacts on the environment are not covered in this table.

The Commission's impact assessment has underlined that by having REACH, the EU can avoid a large number of health 'impacts'. It provides an estimate of the potential scale of the benefits of REACH, stating that around 45,000 Disability Adjusted Life Years (DALYs)[9] could be avoided each year, with around 4,500 lives saved per year due to REACH. For illustrative purposes, this can be equated to health benefits of around €50 billion over the next 30 years.

Table 1.1 Examples of Health Problems Caused by Chemicals

Group of Substances	Type of Impact	Example of Chemical/substance
Carcinogenic substances	Lung cancer, leukaemia	Asbestos (lung cancer), Benzene (leukaemia), Polycyclic aromatic hydrocarbons
Mutagenic substances	Tumours, Infertility	PAHs, pyrene, Acrylamide
Allergenic substances	Allergies, asthma, dermatitis	Nickel (allergies)
Persistent Organic Pollutants (POPs)	Nervous system disorders, weakening of the immune system, developmental disorders	DDT, PCBs, Chlordane, Dioxins, Furans
Endocrine disrupters	Testicular, prostate & breast cancer, decrease in sperm concentration & semen volume, reproductive disorders	TBTs, Phthalates, DDT, Lindane, Chlordane, Atrazine, PCBs, certain organic solvents
PBT and vPvB substances	Stored in human tissue, transferred to foetus or to babies through breast milk	Flame retardants: pentabromo diphenyl ether, short chained chlorinated paraffins

1.3 Structure of report

Section 2 summarises the main elements of REACH, highlighting not only what the final proposal requirements are, but also how these relate to the earlier REACH proposals, and expectations created through the publication of the White Paper.

Section 3 presents summaries of international practice, covering, *inter alia,* current practice in the USA, Canada, New Zealand, OECD Chemicals Programme and the Responsible Care programme. Other country references are made where relevant. Section 4 compares the REACH with international practice. Section 5 presents a short conclusion as to interesting innovative practice internationally and where REACH goes beyond current practice under other regimes, national or international. These are supported by a series of annexes which contain details of the various systems.

[8] See also extended table of environmental impacts of chemicals on animals in the Commission' Impact Assessment, COM(2003) 644 final, Table 7, page 27.

[9] Based on World Bank nomenclature. This is a statistical estimates based on relationships of exposure levels of chemical substances to health impacts, eg bronchitis, cancer.

2 The REACH Proposal, Existing EU Legislation and early REACH Ambitions

This Section notes the key points of existing legislation to address chemicals, the White Paper and draft legislation for consultation, and how the final 29 October 2003 proposal compares to these.

2.1 Existing legislation

Existing EU chemicals policy comprises a number of different regulations and directives, among which the most relevant for this report include:

- Directive regulating the marketing and use of certain dangerous substances and preparations (76/769/EEC), with daughter directives regulating different substances;

- Directive on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC), with its nine amendments of which one of the most important was the seventh amendment Directive 92/32/EEC (regulating the testing of new chemicals); and

- Regulation on the evaluation and control of the risks of existing substances (793/93).

EU chemicals policy differentiates between **'existing chemicals'** and **'new chemicals'**. Existing chemicals are those that were on the market before 18 September 1981, and listed in EINECS (the European Inventory of Existing Commercial Chemical Substances). There are more than 100,000 existing substances noted in EINECS, and they account for over 99 per cent of the total volume of substances on the market. In practice, however, around 30,000 chemicals are currently in use, placed on the market in quantity over one tonne each year. However, 'existing chemicals' are currently not automatically subject to the same testing requirements as those placed on the market since 1981.

For **existing substances**[10] manufacturers or importers had to assemble information relevant for a risk assessment and submit it to the Commission. Data requirements depend on the volume. The information is to include available data on uses and on physico-chemical properties. For **lower volume** substances (production or import under 10 tonnes per year) this information does not have to be submitted. On the basis of the information, the Commission has drawn up priority lists for potentially hazardous substances that need to be examined in more detail. There are approximately 140 high volume substances on the four existing priority lists. While waiting for further assessment, the substances can be freely sold on the market. The regulation does not provide any deadlines for risk assessment. Enforcement and issuing sanctions, where the producer does not supply the necessary information, is regulated by national law in Member States.

The current assessment of the substances on the priority lists is slow and costly. Furthermore, the allocation of responsibilities is inappropriate, as Member State authorities are responsible for the assessment, and hence, one could argue, effectively subsiding industry. The obligation to provide information for the assessment lies on the producers and importers of chemicals,

[10] 'Existing substances' cover
- high volume substances: production or import more than 1000 tonnes per year
- medium volume substances: production or import between 100 and 1000 tonnes per year
- low volume substances: production or import between 10 and 100 tonnes per year

while the industrial users and distributors have no legal requirement to participate in the assessment. For that reason, it is difficult to obtain precise information as to the use of chemicals, and information on exposure arising from downstream uses is also scarce.

If the risk assessment concludes that the chemical poses a risk for the environment or human health, the Member State authority responsible for the assessment has to propose risk reduction measures. The outcome of the risk assessment and risk reduction strategy is published as a Commission recommendation. The implementation of the actual risk reduction measures is done under other pieces of legislation.

For **'new' substances**, those placed on the market since 1981 there is an obligatory notification system. The manufacturer or importer has to provide a certain amount of information - depending on the chemical's production/import quantities – on its properties relevant for risk assessment. This information has to be submitted, and the risk assessment has to be conducted by the authorities, before the chemical can be launched on the market. Testing is triggered by volumes put on the market (greater than 10 kg/yr require testing). In some cases, restrictions on the marketing and use for new substances have been introduced under Directive 76/769 following risk assessments. Around 3,000 new substances have been notified in the EU since 1981. It is broadly understood that the notification and evaluation of 'new' or post 1981 chemicals has been more or less an effective regime. However, some argue that this has stifled innovation and led to greater use of 'existing' chemicals.

The existing chemicals policy has on the whole proved unsatisfactory. The system cannot provide enough information on hazardous properties and use patterns in existing chemicals. Even for the chemicals of large quantities, where a certain risk assessment is required, there is a lack of knowledge of their use and exposure pattern. These limitations led to the February 2001 White Paper with its proposal for the new system REACH.

2.2 The White Paper and the May 2003 consultation text

In February 2001, the European Commission published a White Paper entitled '*Strategy for a Future Chemicals Policy*' (EC 2001b)[11]. The White Paper presented a new regulatory system, called REACH, for the 'Registration, Evaluation and Authorisation of Chemicals'. REACH includes three key components.

- **Registration -** chemical producers to be obliged to provide basic safety data by fixed deadlines to authorities on all chemicals (existing and new) produced in quantities **above one tonne per year**. Approximately 30,000 substances are believed to fall within this category.

- **Evaluation** - for higher production volume chemicals **(above 100 tonnes),** and for chemicals of **high concern**, data from the registration phase to be evaluated by Member State experts in association with a central co-ordinating body. There would be approximately 5,000 substances for evaluation by competent authorities, corresponding to 15 per cent of the total. The evaluation may lead to authorisation (in the case of chemicals of 'very high concern'), risk reduction (where dangerous uses are restricted), or to no further regulatory action.

[11] For Chemicals site on DGENV's web page: http://europa.eu.int/comm/environment/chemicals/whitepaper.htm and for the full text of the White Paper : http://europa.eu.int/comm/environment/chemicals/0188_en.pdf

- **Authorisation -** the use of chemicals considered to be of **'very high concern'** would be subject to authorisation – in other words, formal permission is required before they could be marketed in the EU, and permission would be limited to specific purposes demonstrated to be safe. The aim is for such chemicals to be phased out and substituted, unless industry can show that the use presents negligible risk or that it is acceptable, taking into account its socio-economic benefits, the lack of safer chemicals and measures to minimise exposure. The number of substances subject to authorisation is estimated at 1,400. Those chemicals of 'very high concern' include:

    - Category 1 or 2 carcinogens, mutagens or reprotoxic substances (CMRs), (around 850 substances and further 500 expected from future testing); and
    - particularly persistent, bioaccumulative and toxic substances, as defined in the Stockholm Convention on Persistent Organic Pollutants (POPs).

The White Paper set a target date of the end of 2005 for the registration of substances produced in quantities exceeding 1,000 tonnes per annum. Other target dates (for different volumes) range to up to 2012.

The Commission's Sustainable Development Strategy (SDS) proposal[12] to the Gothenburg European Council (15 and 16 June 2001) included the ambition that by 2020, it should be ensured that chemicals are only produced and used in ways that do not pose significant threats to human health and the environment. While this ambition was not noted specifically in the Presidency Conclusions, it was a major commitment reached at the 2002 Johannesburg World Summit on Sustainable Development. At Johannesburg, countries committed themselves to aim to 'achieve by 2020 that chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment'.

It is worth noting that under the Swedish Presidency[13], the Environmental Council adopted a series of conclusions on the future chemicals policy. It noted that the present situation is unacceptable, since there is a lack of satisfactory risk evaluation concerning many of the substances on the EU market and highlighted the so-called 'generation objective' (objective to be achieved within one generation) in the area of chemicals. The objective stipulates that within one generation, ie by 2020, chemicals will only be produced and used in a way that does not lead to significant negative impact on the environment or human health.

The Environment Council conclusions also emphasise that industry must take a greater share of the responsibility to ensure that chemicals used do not lead to adverse health effects or damage the environment. This means that industry must possess sufficient know-how on all the substances it produces or imports to ensure protection for human health and the environment. Industry must document all the necessary information and make such documentation available to the authorities when required. The Council also points out that if industry does not fulfil the requirements placed upon it to register information on a chemical within a fixed time limit, marketing that chemical will no longer be permitted.

The conclusions also strengthen the requirements for chemicals with especially hazardous properties to only be used on licence and in well-defined and well-motivated cases. The groups of chemicals covered by this system will be extended to include persistent, bio-

[12] COM (2001) 264 final. Communication from the Commission: A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development. Brussels 15.5.2001.
[13] http://www.miljo.regeringen.se/eu-internationellt/1-om_ordf-skapet/presidency-summary-eng.pdf

accumulating and toxic substances as well as those that are very persistent and very bio-accumulating, as soon as criteria for these groups have been established. The Council has also asked the Commission to look into whether there is a need to include other substances with especially hazardous properties, such as endocrine disruptors, in the licensing system.

These conclusions were a prime driver for the Commission's REACH proposals. The May 2003 consultation text built squarely on the REACH White Paper.

2.3 The Commission proposal – COM(2003)644 of 29 October 2003

The Commission Proposal was finally launched on 29 October. Environment Commissioner Margot Wallström has hailed REACH as a 'groundbreaking proposal'. Her counterpart, Enterprise Commissioner Erkki Liikanen, described it as 'the biggest reforms of this Commission' and the biggest challenge it has faced in meeting sustainable development goals. He also held up the process to date as a model example of consultation and better regulation. The consultation, which yielded over 6,500 responses to the Commission's consultation texts, ended on 10 July.

In practice, the Commission proposal is widely seen as a significantly 'watered down' version of the earlier REACH as noted in the May 2003 Consultation. This followed very extensive lobbying activity by industry and governments – within the EU and outside, notably USA.

To summarise **responses of key stakeholder groups**:

- Environmental groups welcomed the release of the proposals but have highlighted shortcomings in a proposal that is 'a shadow of its former self'. The general feeling is that too many concessions have been given to industry, and that the European Parliament and Council now need to strengthen the draft law as it proceeds through the co-decision process. Greenpeace was particularly critical of provisions allowing hazardous substances to continue to be produced under 'adequate control' conditions, and called for tougher rules on substitution.

- Industry groups cautiously welcomed the proposals and pledged their involvement in the next stages. Europe's chemical industry association, Cefic, said that the Regulation 'must strike a balance between the protection of human health and the environment, and the competitiveness of the European industry'. Criticism has been received from the American Chamber of Commerce to the EU, AMCHAM EU. In a press release issued on 29 October, it warned that the proposals still imposed an excessive burden on industry, that bureaucracy would stifle innovation, and that data sharing rules would not be workable.

The **main elements of the Commission Proposal** are:

- The Registration, Evaluation and Authorisation of Chemicals (REACH) will lead to some 30,000 chemicals registered in Europe over 11 years. All chemicals produced or imported in quantities over 1 tonne are affected; there are no requirements as regards chemicals produced in quantities under 1 tonne. Chemicals over 1000 tonnes and CMRs need to be registered within 3 years of legislation coming into force. The corresponding time

period is 6 years for chemical substances of between 100 tonnes and 1000 tonnes and 11 years for chemical substances of between 10 tonnes and 100 tonnes/year.

Information requirements are set for substances put on the market in volumes greater than 1 t/yr, with tests of substances under 10y/year done *in vitro*. A move towards greater contingency testing (level of testing depending on level of risk and not just volumes) is included as is a move towards greater ability to use QSARs (computational techniques to predict risk – see Sections 3 and 4). These again reduce the burden for testing as well as reducing needs for animal testing.

The proposal includes the possibility of using existing information to avoid unnecessary animal testing. This includes measures for compulsory sharing of information (see Box 2.1 for details).

Box 2.1 Provisions to Minimise Animal Testing

Substantial efforts have been made to minimise costs and animal testing by allowing:

- the use of existing sources of information;
- the use of information not based on testing of vertebrate animals where possible (especially below the 10 tonne threshold)
- the reading across of data from analogous substances;
- the sharing of test results;
- the grouping of similar substances; and
- dispensing with some requirements altogether where the information is not needed because of the properties or use of the chemical, or that more extensive information is already available , for example, testing can be waived in some cases on the grounds of lack of exposure during its intended use.

Companies manufacturing or importing the same substance can form consortia and share the information needed for registration. In order to facilitate this, manufacturers and importers of substances that are already on the market will have to 'pre-register' their substance (s). Companies registering the same substance will be participants in a 'substance information exchange forum' (SIEF). SIEF will be a network for exchanging information on tests involving vertebrate animals, and will result in time and cost savings and reduced need for animal testing.

The proposal includes two types of evaluation:

- Dossier evaluation aims, firstly, at preventing unnecessary animal testing and, secondly, at giving the authorities a possibility to check compliance of any registration dossier with the requirements; and
- Substance evaluation provides a mechanism for an authority to require industry to obtain and submit more information in case of suspicion of a risk to the environment or human health. Evaluation may lead to a proposal that action should be taken under the authorisation or restriction procedures in REACH, or that information should be passed to other authorities responsible for relevant legislation.

Authorisation will be required for chemical substances of 'very high concern', ie:

- Category 1 or 2 carcinogens, mutagens or reprotoxic substances (CMRs);

- persistent, bioaccumulative and toxic substances (PBTs, criteria set in Annex XII);
- very persistent and very bioaccumulative substances (vPvBs, criteria set in Annex XII); and
- on a case-by-case basis other substances which are identified as causing serious and irreversible effects to humans or the environment but which do not fulfil criteria set in Annex XII.

The fourth element in REACH is provisions on restrictions. Proposals for restrictions may consist of conditions for the manufacture, use and/or placing on the market of a substance or of the prohibition of these activities.

How these compare to existing legislation and earlier working REACH proposals is presented further below.

Expected impacts of the REACH proposal

The total cost to industry and the consumer is estimated at between €2.3 to €5.2 billion over the 11 year period (see Box 2.2 below for details). It is estimated that perhaps one to two per cent of chemicals will have to be withdrawn from the market altogether if REACH becomes law.

Around 45,000 DALYs (Disability Adjusted Life Years) can be avoided per year and around 4,500 cases of early mortality per year. For illustrative purposes this can be equated to around 50 billion EUR over the next 30 years. Benefits due to higher protection of the environment have not systematically been evaluated so far.

REACH will replace 40 existing directives and regulations.

Box 2.2 Costs of REACH

The original cost estimate for REACH based on the draft legislation for consultation was estimated to be around €12.6bn over the 11 year period. The changes to the legislation in light of consultation is expected to lead to a reduction of costs of around €10.6bn – with major cost reductions coming from reduced requirements for chemical safety reports (€6.45bn), excluding polymers (€1.9bn), increased use of QSARS, (€0.95bn) reducing requirements for 1 to 10 tonne bracket (€0.6bn), and lighter requirements for intermediaries (€0.6bn).

The estimated costs of the October 2003 proposal therefore amounts to €2bn costs to industry[14] - covering registration (€0.5bn), testing (€1.25bn), safety data sheets (€0.25bn) and authorisations (€0.1bn). When combined with the expected €0.3bn agency fees the total gross costs of REACH is expected to be around €2.3bn for the 11 years.

The expected costs to industry have therefore been reduced significantly.

[14] COM(2003) 644 final:

2.5 Comparing the proposal to the consultation draft and to existing legislation

2.5.1 Main Differences with existing legislation

There is no difference under the REACH proposal in the treatment of 'existing' and 'new' chemicals, which face separate treatment under existing legislation. However, the REACH system will significantly increase the rate at which 'existing chemicals' are addressed and move to a system where there is an explicit deadline for the bulk of chemicals to be registered – to within 11 years of the legislation passing. This therefore addresses one of the major weaknesses of the existing legislation. We can expect that many of the 'gaps' under the current system will be addressed by REACH as safety information about chemicals produced or imported in volumes higher than 1 tonne/year per manufacturer/importer will need to be provided.

REACH reduces some requirements on 'new' chemicals – notably moving production/import levels at which chemicals need registration from 10 kg to 1 tonne. This is argued to facilitate innovation and avoid animal testing, and reduce burden on industry.

The REACH legislation will lead to a shift in 'burden of proof' from public authorities to industry. Currently authorities need to prove that a chemical substance is unsafe before imposing restrictions Under REACH, industry will have to prove that the chemical can be used safely, and how. Furthermore, all actors in the supply chain will have to ensure the safety of the chemical substances that they handle. In practice, therefore, industry will have to assess the safety of the intended uses, prior to production and marketing, rather than, as under the current system, public authorities being obliged to perform comprehensive risk assessments (that are often rather slow and cumbersome).

There will be in certain cases requirements also for downstream users to assess the safety of their uses of chemicals and report information on these uses to the authorities.

There will be increased transparency, not only for authorities and public, but also for users. Downstream users of chemicals will get relevant information on the safe use of each substance they buy.

REACH will minimise, to the extent possible, animal testing. Currently notification requirements for 'new substances', which start at a production/import level of 10 kg, have to have one animal test performed. Furthermore, at 1 tonne, a series of tests including other animal tests have to be undertaken. Under REACH the threshold moves to 1 tonnes and a series of other measures are in place to minimise testing (recall Box 2.1).

REACH should facilitate innovation, in particular it should encourage the development of new safer substances. Under the present system this is discouraged by the cost of introducing new substances, and the different systems for new and existing substances which gives incentives to use 'existing chemicals'.

2.5.2 Main Differences with the May 2003 consultation draft

The general obligation to **register** all chemical substances produced in quantities over 1 tonne per year remains in the new proposal for the chemicals Regulation. However, the information requirements (including testing requirements) for registration of the 20,000

chemicals produced between **one and ten tonnes has been reduced**, again reducing the burden on industry. There is no longer a requirement for complete chemical safety assessments below 10 tonnes. Furthermore, the obligation to produce **an initial chemical safety assessment (CSA)** of substances would no longer apply to some firms.

- The obligations on companies to prepare **chemical safety reports (CSRs)** and pass them down the supply chain will be restricted. Reports will not be required for substances produced in quantities of less than 10 tonnes per year, nor from downstream users except where their use of a substance is not known to the upstream supplier.

- Reach would **no longer apply to polymers** – this would remove around 30,000 substances[15] from the Regulation and significantly reduce the burden on industry. In due course, registration may be required for 'certain' polymers, though at an unspecified date and following a review of the risks they pose, and taking account of the level of cost of testing, implications for competitiveness, innovation, and protection of health and the environment.

- **Chemical intermediaries** – which also faced calls from industry to be excluded, remain in the proposal, though with some conditions eased. Under the final proposal around 40,000 intermediaries will need to be registered, though for most of these registration requirements will be significantly lower than for other chemical substances.

- Companies' concerns of **liability** implications have been addressed by including a more clearly defined **'duty of care'** provision. Firms only need to meet REACH obligations and related obligations in other legislation, in order to fulfil their duty of care.

- There are stricter rules on **confidentiality**.

- Rules for applying Reach to **imported articles** have been softened – responding to concerns raised by the EU's main trading partners.

However, a number of items remain unchanged or strengthened:

- **The scope of the authorisation procedure itself is unchanged**. It will still apply to substances of very high concern. ie the CMRs (carcinogens, mutagens or reprotoxic substances), PBTs (persistent, bioaccumulative and toxic), vPvBs (very persistent and very bioaccumulative) and, on case by case basis, endocrine disrupters.

- The proposed Regulation references more prominently the **'substitution principle'** which has been pushed by environmental interests to help ensure that REACH offers more adequate encouragement for the substitution of chemicals with safer alternatives. Furthermore, firms will be encouraged to present 'substitution plans', which may influence decisions on authorisations. There is therefore a **reinforced authorisation system**, which introduces a specific requirement for applicants to present a substitution plan in cases in which authorisation are being granted on socio-economic grounds. It should be noted, that there is no mechanism to ensure that industry does substitute and there are no incentives for them to do so.

[15] Estimates vary on the number of polymers

- There will be a more streamlined administration of REACH, with the proposed chemicals agency having more responsibility in the areas of registration, evaluation and data-sharing.

There will be **greater legal certainty** through clarifications of requirements for the **duty of care**, the treatment of **confidential data**, **exemptions for research and development** and **sanctions,** while still protecting heath and the environment. As regards 'duty of care' - this will be fulfilled as long as obligations under REACH and other applicable legislation are met.

In summary, the ambitions of the REACH White Paper and the May 2003 proposals have been significantly weakened from the environmental perspective and expected burdens on industry significantly reduced. However, the expected health benefits are still regarded as being very significant under the new proposal. There remain, however, areas that still need improvement to secure a high level of protection for human health and the environment. These are noted in Section 5.

3 Alternative Approaches

This Section summarises the key points of alternative regimes to addressing chemicals, covering the USA, Canada, New Zealand, OECD and responsible care programmes in some detail, and making reference to other experiences (eg Japan). A comparison with the REACH proposals is made in Section 4.

3.1 USA

3.1.1 Overall Summary

The Toxic Substances Control Act (TSCA, 1976) regulates industrial chemicals. It was enacted to identify and control industrial chemical hazards that are toxic to human health and the environment. The US Environmental Protection Agency (EPA) has broad authority under TSCA to regulate new and existing chemicals. The Act also includes a provision requiring the EPA to take specific measures to control risks from PCBs. Additions have been made to address concerns about other specific toxic substances: asbestos (1986); radon (1988); and lead (1992).

For registration, there is a process of Pre-Manufacture Notification (PMN) for **new substances,** similar to the EU's pre-market approach. It requires manufacturers, importers and processors to notify the EPA at least 90 days prior to producing or otherwise introducing a new chemical product into the US. In addition to notification, any pre-existing information about the chemical should also be submitted at the same time. The EPA then has 45 days after notification (or up to 90 days if it extends the period for a good cause) to evaluate the potential risk posed by the chemical. The testing scheme includes four phases: the chemistry review phase; the hazard (toxicity) evaluation phase; the exposure evaluation phase and the risk assessment/risk management phase. The phasing is part of the contingency testing strategy to reduce the burden through staged evaluation, with greater information requirements for subsequent stages. For details see Table A2.1 in Annex 2.

On the basis of this information the US EPA either asks for more information or no further information is required and the manufacturer can proceed towards marketing the chemical. Approximately 80 percent of PMNs are dropped between the end of the chemistry review phase and the outcome of the risk phase. Some of the remaining 20 percent may also be subject to control on the basis of the EPA's categorisation approach under the new chemicals programme, which groups together chemicals with similar hazard concerns and testing requirements. These controls may include restrictions on production pending the outcomes of further testing.

Note that historically, manufacturers have withdrawn 3.2 per cent of proposed chemicals during the assessment process[16].

The EPA identified a priority-testing programme to gather information about **existing substances,** which is currently focusing on high production volume chemicals. An **inventory** - the Toxic Release Inventory (TRI) - is kept of all substances regulated under the Act.

[16] Fleischer M (2002) Regulation and Innovation: Chemicals Policies in the EU, Japan and USA. Social Sciences Research Centre Berlin. WBZ, Germany. Available on http://www.ippic.org/ippic1.pdf

The above applies to chemicals to be put on the US market. **Chemicals for export only are exempt**. Furthermore, only chemicals produced at **more than 10 tonnes per year** are included, and **polymers (see Box 3.1) and R&D chemicals are not subject** to the above requirements. Note also that the US approach is based on **pure chemical compounds (greater than 95% pure)**, rather than chemicals as put on the market.

Box 3.1 Polymer Exemption

In the mid-1980s, the US EPA established a 'Polymer Exemption Rule' on the grounds that the manufacturing, processing, distribution and use of most polymers would not represent an unreasonable risk of injury to human health and the environment. Under the terms of the Polymer Exemption Rule (as amended in 1995), the manufacture and distribution of polymers meeting the exemption criteria can take place without notification.

In addition, the 1998 Chemicals Right to Know Challenge generated the High Production Volume (HPV) program, encouraged by NGOs. This was launched against a background of EPA's analysis that demonstrated that basic screening data was incomplete for 97% of all existing HPV chemicals. The EPA initiated the HPV voluntary challenge to chemical industry to provide the basic testing data. Chemical industry agreed to provide screening data for 64% of HPV chemicals and the data, in the form of "robust summaries" will be due by 2005[17].

Strengths and weaknesses

The UK Royal Commission on Environmental Pollution (RCEP) in the development of its 24th report - *Chemicals in Products Safeguarding the Environment and Human Health*[18] heard opinions in evidence that while the US approach to chemicals management **offers advantages to industry**, it is **less precautionary**, **giving rise to doubts as to whether it offers the same degree of protection to human health and the environment as the current and proposed EU regimes**.

The US General Audit Office carried out a review of the Act in 1994 and found that it was lacking in effectiveness regarding the attainment of its protective aims, and recommended the US Congress introduce changes more in line with the European system. The review noted that the Act's requirements reflected an underlying philosophy that manufacturers and processors had the right to produce and market chemicals, and that before the EPA could take any legal action to restrict this right, it had to demonstrate that the risks outweighed both the costs to industry and the lost benefits of the unrestricted use of the chemical. The burden of proof was therefore on the EPA to demonstrate that a chemical may pose an 'unreasonable risk'. The Act does not define 'unreasonable risk' and provides little guidance on what level of risk should be considered unreasonable under the Act. It also requires producers of substances or products to report test results suggesting hazardous risks to the EPA immediately, which acts as a disincentive to carry out non-regulatory testing.

Issues of particular interest or innovative

Of particular interest is the RCEP observation that that the legal culture in the US has some role to play. In the more litigious US society a manufacturer might (in the absence of any formal regulations) be more cautious about launching a new product than in less-litigious

[17] Source: K Geiser and J Tickner, Lowell Center for Sustainable Production
[18] published 26 June 2003, see http://www.rcep.org.uk/chemicals.html

Europe. It may be that this explains the relative 'light-handedness' of formal US regulatory regimes. Liability costs in the US following marketing are much higher than those in Europe. Dow Chemicals reports figures from 1996 showing that in the US $1 was spent on litigation for every $160 of US sales; in Europe $1 was spent for every $40,000 in sales for similar products.

3.2 Canada

The Canadian Environmental Protection Act (CEPA) 1999 gives the Minister of Environment and the Minister of Health the responsibility to ensure that substances listed on the Canadian Domestic Substances List are categorised and, if necessary, screened to determine whether they are toxic or capable of becoming toxic. This **categorisation** needs to be carried out by September 14, **2006**, **or 7 years after the passage of the Act**. CEPA requires, through the **New Substances Notification Regulations (NSNR)**[19] that came into force 1 July 1994, that all new substances (both chemicals and polymers) are assessed for their potential to harm the environment, human life or health, before being imported or manufactured in Canada. Any person in Canada manufacturing or importing a new substance has to provide a notification package to Environment Canada, which will assess whether the substance is likely to harm the environment, the environment on which human life depends, or human life or health.

The Domestic Substances List (DSL) includes substances that were used in Canadian commerce for manufacturing purposes, or manufactured in or imported into Canada, in a **quantity of 100 kg or more** in any calendar year between 1984 and 1986. This list has been amended several times following assessment under the NSNR and currently contains around 23,000 substances. This list if therefore roughly equivalent in purpose to the EU's EINECS, though containing chemicals actually marketed. Note that substances as low as 20kg can be required to have a notification schedule (under schedule 1), though these do not enter into the DSL.

The categorization criteria includes scope of exposure of individuals and whether the chemical in question is persistent (P), bioaccumulative (B) or inherently toxic (iT) to humans or non-human organisms. Substances that are P or B and iT have to undergo a screening assessment.

As data for many substances on the Domestic Substances List are likely to be lacking, there is in practice a heavy reliance on the use of QSARs for the initiation categorisation, including assessment of inherent toxicity. Note that Environment Canada has produced guidance on how and when expert judgements are to be considered to categorise substances on the list (eg for when QSAR predictions are unreliable).

The screening leads to one of three outcomes:

- No further action at this time, where the assessment indicates that the substance does not pose a risk to the environment or human health;

- The substance is added to the Priority Substances List, PSL (see below) of the Canadian Environmental Protection Act to assess more comprehensively the risks; or

[19] http://laws.justice.gc.ca/en/C-15.31/SOR-94-260/text.html

- The substance is added to the List of Toxic Substances in Schedule 1 of the Canadian Environmental Protection Act – these substances can be considered for regulatory or other controls.

Substances on the PSL are of priority for assessment to determine whether environmental exposure to them poses a risk to the health of Canadians or to the environment. A Priority Substance may be a chemical, a group of chemicals, effluents or wastes.

There have been two PSLs (PSL1 and PSL2), which were established by the Ministers of Health and of the Environment, based on the recommendations of a Ministers' Expert Advisory Panel. The first PSL was published in the *Canada Gazette* in 1989, and the assessments of 44 substances on the list were completed within the legislated time frame of five years. The second PSL of 25 substances was published in 1995, and the assessments of those substances are nearing completion. Substances may be added to the PSL based upon 1) the results of a screening level risk assessment, 2) a review of a decision of another jurisdiction to specifically prohibit or substantially restrict a substance for environmental or health reasons, 3) a request made to the Minister of the Environment or 4) the results of consultations undertaken by the Minister of the Environment and the Minister of Health. If they are classified as 'toxic' then management options are identified and implemented, in consultation with stakeholders to reduce or eliminate the risks the substances pose to human health or the environment.

In addition, the Government of Canada introduced a Toxic Substances Management Policy, released in June 1995, which adopted a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. It also builds in public participation, openness and transparency in decision-making. The policy calls for the virtual elimination from the environment of toxic substances that result from human activity and that are persistent and bioaccumulative (referred to in the policy as Track 1 substances). The policy also calls for cradle-to-grave management of all other substances of concern that are released to the environment (referred to in the policy as Track 2 substances).

Strengths and Weaknesses

Extensive testing of 'new' chemicals starting as low as 20kg allows for an extensive coverage of the system. The overall ambition of the Canadian approach – of virtual elimination from the environment of toxic substances that are persistent and bioaccumulative – is noteworthy.

Issues of particular interest or innovative

The ability to use expert judgement when QSAR predictions are seen as unreliable, avoids over reliance on QSARs. The cradle to grave approach is also innovative in its extent of coverage.

3.3 New Zealand[20]

The **New Zealand Hazardous Substances and New Organisms (HSNO) Act 1996,** commenced July 2001 for Hazardous Substances[21], is to protect the environment and the

[20] Sources: Sources: Kathy Nolan, Reckitt Benckiser: The Chemical Legislation in Australia and New Zealand (ChemCon 2002) Environment Risk Management Authority (ERMA) (www.ermanz.govt.nz)

health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. It uses a risk-based approach, requiring approval to import or manufacture new hazardous substances and replaces several existing Acts.

All new substances will need to go through the **approval process** of the 'Environment Risk Management Authority' (ERMA) if they have hazardous properties that exceed the thresholds established by regulations under the Act. The only criteria are the hazardous properties of the substance, not the production volume. Applicants themselves, in the first instance, are responsible for determining whether the substance is hazardous and also for thoroughly documenting reasons for evaluating a substance as non-hazardous. Exemptions may apply in some circumstances, such as when the hazardous substance is being used in small-scale chemistry in scientific investigations or teaching being undertaken in laboratories that meet the requirements of the HSNO regulations, some foods, and some medicines. The manufacture, importation or use of a hazardous substance without an approval is an offence under Section 25(1) of the HSNO Act.

ERMA recommends that toxicity, ecotoxicity and chemistry data relevant to applications for hazardous substances under the HSNO Act is widely available on the internet, generally free of charge, and provides links to databases for applicants to assist with the preparation of applications. Thus, **animal testing** can be avoided or minimized by sharing available data. It is not clear however, how data which cannot be found on the Internet, are to be generated.

A **process to transfer existing hazardous substances,** ie approved for use under previous legislation, to the controls under the HSNO is ongoing. There are transitional arrangements allowing the continued use of existing substances under the same conditions as previously, until they are transferred to HSNO. With 210,000, the Notified Toxic Substances (NOTS - substances that have been notified by July 2001 but not assessed) are the largest group for transfer. They are grouped, progressively assessed and then transferred. The previous target dates for transfer had to be extended until 2006.

There are **two assessment categories**: the full assessment and the rapid assessment. The **full assessment** is publicly notified, and divided into subcategories in order of increasing level of hazard and risk. It requires chemical identification and composition information as well as information on toxic, ecotoxic and physical properties, intended uses, assessment and management of possible adverse effects or risks, costs and benefits, and information on possible impacts on the Maori culture. Sufficient information needs to be provided to enable all hazardous properties of the substance to be classified. The **rapid assessment** is non-publicly notified. Less information requirements apply for a new hazardous substance for which a similar substance has already been assessed and approved, or if the substance has the least degree of hazard in each of the hazard types.

Assessment **fees** are charged by ERMA on an hourly basis. All expenses are recouped from the applicant. The cost for a rapid assessment are NZD$ 400 – 3,000 (USD$ 1,300), for a full assessment NZD 5,000 - > 250,000 (USD$ 110,000). An initial fee is submitted with the application and the balance invoiced on completion. ERMA can provide a prior estimate of fees for each application.

[21] According to HSNO hazardous substances are single chemicals, mixtures or groups that exceed thresholds for explosive, oxidising, toxic, flammable, corrosive or ecotoxic properties. The criteria for each hazard category are based on a Globally Harmonised System. The hazard classification is the responsibility of the company. ERMA can be consulted but then fees will apply.

After the assessment, approved substances can be used by anyone and are listed on the Public Register on the ERMA web site. Commercially sensitive information can be protected but must be clearly identified as confidential and submitted in a separate document.

The New Zealand market is very small and there is a lack of harmonisation between NZ and the rest of the world, which influences costs and timeframes. From an industry perspective this procedure seems to present a barrier to new chemicals, new technology, research and development activities.

Strengths and weaknesses

Having both full and rapid assessments can lead to a cost effective way to assess a wide range of chemical substances.

Issues of particular interest or innovative

Assessment fees are fully recouped from the applicant. The initial responsibility for making a first evaluation as to whether a substance is hazardous or not rests with the importer, manufacturer or user of the substance. An approval process is required for all hazardous substances independently of the production volume.

3.4 OECD Chemicals Programme

Since the late 1970s, the **OECD Chemicals Programme**, embedded in the OECD Environmental Health and Safety (EHS) Programme, has aimed to assist OECD countries' efforts to protect human health and the environment, by improving chemical safety, making chemical control policies more transparent and efficient, and preventing unnecessary distortions in the trade of chemicals and chemical products. The OECD Chemicals Programme covers a variety of aspects related to chemicals of which the most relevant for this paper are co-operation in the investigation of existing chemicals, chemicals test guidelines programme, and the classification and labelling of chemicals.

Since 1988, **existing chemicals activities** in the OECD have centred primarily on the investigation of high production volume (HPV) chemicals, based on the assumption that production volume is a surrogate for data on occupational, consumer and environmental exposure. The overall objective of the **HPV Chemicals Programme** is to co-operatively undertake an initial assessment of HPV chemicals to screen them and agree on the need for further work. HPV chemicals include all chemicals reported to be produced or imported at levels **greater than 1,000 tonnes per year** in at least one Member country or in the European Union region. An OECD List compiled in 2000, contains 5,235 such substances, and is based on submissions of nine national inventories and that of the EU.

Once a chemical is selected for investigation, the first activity involves the collection of existing information on the substance and collating it in a Screening Information Data Set (SIDS) dossier. In addition to readily available data, industry is also requested to provide data and full reports of studies. When no information is available for a given data element, calculation or estimates derived from QSARs can be provided. Robust study summaries are to be prepared for the most valid and relevant study for any given SIDS endpoint.

The OECD Secretariat transfers the submitted SIDS Initial Assessment Reports (SIAR), prepared based on the information in the full SIDS Dossier and other information, to UNEP Chemicals for inclusion in their database and publication as a contribution to the Inter-organisational Programme on the Sound Management of Chemicals. They are also made available on the Internet. In this way, **all information** resulting from the OECD HPV Chemicals Programme will be **available worldwide**.

In 1998, the overall HPV Chemicals Programme was revised to increase transparency, efficiency and productivity of the Programme and to allow longer-term planning for governments and industry. It concentrates on selection, data gathering, testing and initial hazard assessment. Detailed exposure information gathering and assessment is carried out in follow-up at the national (or regional) level as appropriate, and detailed international assessment of risks to human health and/or the environment will be undertaken jointly by OECD and IPCS, for appropriate pilot cases.

Strengths and Weaknesses

Under OECD's system of **Mutual Acceptance of Data**, countries have agreed that when chemical safety tests are carried out in one country in accordance with OECD Test Guidelines[22] and Principles of Good Laboratory Practice, the other OECD countries will accept the data for assessment purposes. This saves the expense of duplicative testing and **reduces the number of animal tests**. By developing alternative testing methods and encouraging the use of other sources of information (eg QSAR) the suffering of animals is further minimised as much as possible. The test data are used within a number of national and international risk assessment programmes, including that under the existing substances Regulation.

The HPV Chemicals Programme has, especially during the last years, been successful in producing initial hazard assessment for industrial chemicals. The weakness of the programme when compared to the REACH proposal is that it does not address in any detail the exposure assessment of chemicals.

For OECD governments and industry, the results of the work done by the OECD on chemicals have reduced barriers to trade and saved time and money, estimated in 1998 at US$ 46 million per year.

Issues of particular interest or innovative

The OECD chemicals programme focuses primarily on the production, processing and use of industrial chemicals, but is also closely coordinated with other work in the OECD, particularly that on pesticides, chemical accidents and biotechnology. Thus, information arising from these areas can be used efficiently.

In 1998, the global chemical industry launched, through the International Council of Chemical Associations (ICCA), a global initiative on HPV chemicals. According to this initiative the chemical industry will, in a partnership with the OECD and its member countries, provide harmonised, internationally agreed data on intrinsic hazards of and initial

[22] The OECD Guidelines for the Testing of Chemicals are a collection of the most relevant internationally agreed testing methods used by government, industry and independent laboratories to characterise potential hazards of new and existing chemical substances and chemical preparations/mixtures.

hazard assessments for approximately 1,000 HPV substances by the end of 2004 as part of the OECD's refocused HPV programme.

3.5 Responsible Care ®

Responsible Care ® is a worldwide initiative by the chemical industry for the chemical industry. It was launched in the mid 1980s following the December 1984 Bhopal Disaster and covers over 86 per cent of the worlds chemical production[23]. The chemical industry's voluntary initiative Responsible Care was first conceived in Canada in 1985 to address public concerns about the manufacture, distribution and use of chemicals. Since 1992, when Agenda 21 was adopted at the Rio Earth Summit, the number of chemical industry associations embracing Responsible Care ® has grown from 6 to 47 countries. Responsible care ® is basically a 'voluntary'[24] code of conduct aiming at adopting a series of good practice codes, including codes of practice for transportation, distribution, manufacturing, research and development, and hazardous waste operations.

National chemical industry associations are responsible for the detailed implementation of Responsible Care in their countries and companies define their own particular plans to implement the guiding principles. Each Responsible Care programme now incorporates eight fundamental features: top level commitment; codes and checklists, use of indicators, process of communication (inside and outside industry); know-how transfer; logo; and measures to encourage member companies to sign up and systematic procedures to verify implementation. The last feature - verification - was incorporated into the programme in 1996 by the International Council of Chemical Associations (ICCA) which oversees Responsible Care.

Strengths and Weaknesses

There are quite widely divergent views as to how effective Responsible Care ® is. It is clear that it is no replacement for legislation. Responsible Care does not address the problem of lack of data for existing substances, which is one the corner stones of the REACH proposal.

Issues of particular interest or innovative

The level of industry coverage and world coverage are important.

3.6 Other countries or initiatives

3.6.1 Japan

Responsibility for chemical substance management falls under the remit of the Ministry of Economy, Trade and Industry. The Ministry of Environment is responsible for monitoring. The aim of the Japanese Chemical Substance Management Policy is to identify the characteristics of harmful effects of chemical substances, assess the risks of these through their life cycle and implement appropriate management activities through science-based risk assessments. Voluntary regulation by agreements between government and industry, operationalise this approach.

[23] Lever H (1998) *Response Care in Action*. UNEP industry and Environment Vol 21 No.102, January-June 1998. Double Issue.
[24] Some chemicals associations require their members to sign up.

In 1973, the Chemical Substances Control Law[25] was introduced to evaluate the toxicity of chemicals and regulate their manufacture. **All chemical substances, either manufactured in Japan or imported, are subject to pre-market toxicity evaluation. There are therefore mandatory base data sets that lead to classification and categorisation**. This focuses on around 300 chemicals a year and distinguishes between class 1 (persistent, high bioaccumulative and long-term toxic)[26] and class 2 chemicals (persistent or suspected of being persistent), low bioaccumulative and long term toxic)[27].

A total of 1,280 chemicals manufactured or imported up to March 2002 were evaluated. **Two government funded programmes** – one for each class of substances - have been launched to monitor systematically the fate of existing substances.

In addition there is a Law for Pollutant Release and Transfer Register and Promotion of Chemical Management that directs manufacturers of chemicals and end-products to ascertain and notify the release of chemical substances. The register covers chemical manufacturers or handled in amounts **greater than 5 tonnes per year**, and this **threshold will fall to 1 tonne per year in 2004**. 354 chemicals have been addressed so far and material safety data sheets have been requested for a further 435 chemical substances.

Strengths and weaknesses

All new chemical substances, either manufactured in Japan or imported, are subject to pre-market toxicity evaluation. There are therefore mandatory base data sets that form the basis of subsequent efforts to classify and categorise the chemical substances.

Issues of particular interest or innovative

The existence of two government-funded programs to monitor existing substances is noteworthy.

3.6.2 UNEP and its Chemicals Programme

The UNEP Programme on Chemicals has, *inter alia*, developed the International Register of Potentially Toxic Chemicals, which contains 'a wealth of information'[28].

UNEP is also the forum for the negotiation of multilateral environmental agreements. These conventions and linked protocols become legally binding on ratifying parties once they are in force. Two key conventions that directly relate to chemicals are:

- The Convention on Prior Informed Consent (PIC) – the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; and

- The Stockholm Convention on Persistent Organic Pollutants[29] (the POPs Convention).

[25] No 117, amended in 1986
[26] 11 Chemicals identified since 1973.
[27] 23 chemicals identified since 1973 that 'exhibit' persistence, and 616 chemicals that are 'suspected of being persistent'
[28] RCEP (2003) *ibid footnote 18*

The former looks to establish a procedure for obtaining and disseminating the decisions of importing countries as to whether they wish to import specific chemicals and for ensuring compliance with these decisions by exporting countries. The latter looks to phase out the production, use and emissions of chemicals that are capable of moving long distances and cause environmental effects in countries other than those where they are used.

3.6.3 Approaches in EU Member States

Particularly interesting practice on chemicals can be found in Sweden and the Netherlands[30].

Sweden has a radical forward-looking approach. It launched a Chemicals Products Act in 1980s and established a chemical products register, run by KEMI, the National Chemicals Inspectorate. The chemical products register contains information on around 65,000 chemicals - for all substances manufactured or imported in quantities greater than 100kg. Manufacturers/importers pay an annual fee to cover the cost of maintaining the register. It also developed the 'sunset chemicals' initiative to phase out the use of certain chemicals and heavy metals.

Furthermore, all Nordic Countries (including Denmark, Finland, Norway and Sweden) have a national product register which contains data on hazardous substances on the market. Producers and importers of chemicals have the obligation to submit available information to the register. The obligation applies to substances and preparations which are classified according to Directive 67/548/EEC. Production and import quantities triggering the registration obligation vary from country to country (eg in Sweden quantities greater than 100 kg).

In the Netherlands a new chemical policy was adopted in April 2001. The Strategy on Management of Substances (SOMS) is more ambitious than the Commission's October chemicals proposals. It set challenging targets for Dutch industry and business to produce data, propose 'levels of concern' for the chemicals they produce and use and take appropriate measures to reduce hazard and risk[31]. SOMS also integrates the precautionary principle and contains public access to information provisions.

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[29] Persistent Organic Pollutants (POPs) persist in the environment, bio-accumulate through the food chain and pose a risk of causing adverse effects to human health and the environment. This group of priority pollutants include pesticides (Eg DDT), industrial chemicals (eg PCBs) and unintentional by-products of industrial processes (eg dioxins).

[30] This is not an exhaustive analysis and interesting and innovative practice is also available in other countries and on more issues than noted below.

[31] Source: RCEP (2003)

4 Comparing REACH to Other Legislation and Regimes

4.1 Overview of key differences – notification and registration

The REACH proposal has the unique feature of requiring all existing substances to be treated in the same way as new substances. This is the most important difference as compared to legislation in other areas.

4.1.1 Volume thresholds

REACH requires notification and registration of all chemical substances at volumes greater than 1 tonne, with different testing requirements (see 'testing' below) for different volumes. The Canadian and Swedish systems require registration for volumes above 100kg (and the Canadian notification can be required down to 20kg). In New Zealand all hazardous substances have to undergo a process of approval independent of the production volume. Japan is committed to a 1 tonne threshold (2004), down from 5 tonnes previously, and the USA has a 10tonne/year threshold.

REACH therefore uses higher thresholds than several countries, though lower thresholds than the US.

4.1.2 Timelines / deadlines

The original REACH proposal was to register chemicals above 1,000 tonnes and CMRs by 2005. The new proposal links to the date at which legislation will be passed: for CMRs and substances produced or imported in quantities greater than 1,000 tonnes, the target date is three years after adoption of the legislation. For 100 to 1,000 tonnes, the date is six years after adoption, for 10 to 100 tonnes it is eleven years.

Canada has a deadline for categorisation of 14 September 2006. In New Zealand, the original timetable for the transfer of existing substances to the HSNO Act had to be revised, changing the target dates for example, for the largest group of substances from 2002 to 2006. The US has not stipulated any deadlines.

Recall that the WSSD sets a target of 2020 for the adverse effects on health and the environment to be 'minimised'.

4.1.3 Domestic production, use, import and export

REACH requires notification and registration for all substances manufactured in the EU or imported at quantities greater than 1 tonne. The US has no requirements for 'pure exports' and therefore there appears to be a difference as regards 'pure exports', with the EU adopting a more 'global responsibility stance'. This might disadvantage EU exports as regards third countries, but it is unclear as to whether this is a significant issue or not.

4.1.4 Products

In the US the notified chemical is most often submitted as a 'pure' compound (95% pure), while under the REACH notification of new substances regime, the notice pertains to the substance 'as marketed', which is often a mixture. This distinction has important implications

for the predictability of physical and chemical properties, biodegradation, and potential hazard concerns. In the US, the new chemical and any impurities reported by the submitter or identified by the EPA as being likely contaminants, are considered when assessments are performed.

Under REACH, the submitter is required to provide purity information for the product as marketed and any test data pertaining to this product (RCEP, 2003).

4.1.5 Polymers

Polymers were included for registration under the May 2003 Consultation document, but excluded in the 29 October 2003 proposal, though with a clause allowing future inclusion if testing costs allow and if there are valuable benefits to including polymers. Inclusion of polymers would have implied an additional 30,000 to 70,000 (some say 100,000) substances being included under REACH.

The US system excludes polymers, though there is some listing of polymers as is the case in Japan[32]. The Canadian system includes polymers. In Australia a standard notification is needed for polymers with a molecular weight less than 1000, but an import volume of 1000 kg or more. Polymers with a molecular weight of 1000 or more require only a limited notification.

4.1.6 Intermediaries

Under the final REACH proposal some of the around 40,000 intermediaries - those that are transported between 2 or more sites - will need to be registered, though for most of these registration requirements will be significantly lower than for other chemical substances. It is unclear what conditions are in other countries and how the EU would implement this in practice (eg what is a 'site'). It is understood to be a minor issue as regards health impacts.

4.1.7 Exemptions

Under the REACH proposals, marketed products less than 1 tonne per year[33] are exempt; a similar threshold applies in Japan. In the USA the threshold is 10 tonnes/year. In the EU polymers are exempt (for the moment), as is the case in the USA and Japan (for high molecular weight polymers).

REACH, the US and Japan each have schemes for exemptions of chemicals for certain research and development activities. The early REACH proposals would have led to fewer R&D exemptions in the EU than in the US, though it is understood that this point has been addressed. It is unclear exactly what the final differences are, but they are not thought to be significant.

Exemptions from the HSNO Act in New Zealand may apply in some circumstances, such as when the hazardous substance is being used in small-scale chemistry in scientific investigations or in teaching being undertaken in laboratories that meet the requirements of the HSNO regulations, some foods, and some medicines.

[32] RCEP (2003) - 24th Report
[33] Had been less than 100kg per manufacturer under existing scheme.

4.1.8 Data requirements

Under REACH for all chemical substances over 1 tonne/year registration data (and testing – see 4.2) is required, though with reduced requirements for chemical substances of volumes between 1 tonne and 10 tonnes. There is a requirement for a chemical safety assessment above 10 tonnes.

The US TSC Act does not specify a base data set, and does not lead to classification, leaving a severe burden of proof on the EPA, though with the Gore initiative giving greater responsibility to industry for very high volume chemicals. It may explain some of the US criticism of REACH, which moves even further towards requiring data from industry. **The burden or proof issue is a major difference between the REACH proposal and the US scheme.**

4.1.10 Confidentiality of data

Under the REACH proposal, data disclosure is the guiding principle, though there is a possibility to request a one-year exemption from data disclosure requirements. The US industry, on the other hand, has a fundamental right to confidentiality, ensured under legislation. **This is a major difference between the EU and US schemes.** Note that the American Chamber of Commerce has expressed concern about proposals on data sharing within REACH, and has called for the protection of confidential business information. Note also that the UK's RCEP has urged the UK to argue strongly for adherence to the EU model despite pressure to the contrary from the US.

In New Zealand commercially sensitive information can be protected but must be clearly identified as confidential and submitted to the authority in a separate document. A variety of data bases and other data sources can be used by the applicants.

4.1.11 Data sharing – test data and notifications

Under REACH, there is mandatory data sharing when it comes to the use of test results that link to animal testing, so as to avoid unnecessary animal testing. For other purposes, data sharing is not mandatory and consortia could refuse to share test information with third parties, *de facto* creating a cost barrier for new entrants. In the US there is no requirement for data sharing.

Also of interest is the existing legislation in Germany that allows that if a chemical is already registered and tested, then a second company does not need to go through the procedure all over again, but does have to pay a sum to access the previous data.

In New Zealand, an HSNO approval relates to the substance, not the product or the person applying. Once the substance is approved, it can be used by anyone. Thus no further testing is necessary. Note also that if a new hazardous substance has similar composition and similar hazardous properties to a substance that already has a HSNO approval or the hazardous properties are not above a certain threshold, then less information is needed for approval.

Under the OECD's system of Mutual Acceptance of Data, countries have agreed that when chemical safety tests are carried out in one country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice, the other OECD countries will accept

the data for assessment purposes. This can help avoid duplicative testing and the number of animal tests.

4.1.12 Data sharing with down stream users

Under REACH there are obligations on companies to prepare chemical safety reports (CSRs) and pass them down the supply chain - for substances produced in quantities greater than 10 tonnes per year.

There are some types of equivalent requirements as regards safety data sheets, but it is unclear what the final differences between the proposed EU scheme and other schemes are.

4.2 Testing and evaluation

4.2.1 Testing – coverage

Under REACH, information is required for substances put on the market in volumes greater than 1 t/yr, with tests of substances under 10t/year being less onerous. Testing can be reduced through the use of existing test results, and QSARs can be used, replacing other tests with computer simulation tests.

In Japan, all new chemical substances, either manufactured in Japan or imported, are subject to pre-market toxicity evaluation. There are therefore mandatory base data sets that lead to classification and categorisation. This focuses on around 300 chemicals a year and distinguishes between class 1 (persistent, high bioaccumulative and long-term toxic)[34] and class 2 chemicals (persistent (or suspected of being persistent), low bioaccumulative and long term toxic).

4.2.2 Testing – methods

The existing EU system is a fixed testing system and, in basic testing, solely triggered by volumes of new chemical substances, though the basic test is supplemented by different subsequent levels of testing depending on volumes of chemicals. The Japanese and the US systems are contingent testing requirement systems – where information generated during the testing procedure can be used to decide about further tests. Such a risk based approach is also now part of the proposed REACH regime, which comprises 'base' tests, 'level one' tests and 'level two' tests. This has more scope of exposure and substance driven testing requirements than the current 'volume-focused' regime.

The US approach is heavily dependent on QSARs (Quantitative Structure-Activity Relationships[35]) and other computational techniques and hence less reliant on animal testing. It uses 'pre-manufacture notice' or PMNs that contain certain information which is then screened. If no concerns are raised then there is no need for further review and chemicals are given clearance to be put on the market. Where there is insufficient evidence for the judgement (historically 14% of cases) additional test information is requested from the notifying company. Altogether this procedure is cheaper and more informative than the

[34] 11 Chemicals identified since 1973.

[35] QSARs are computer based methods that permit the prediction of physiochemical, environmental, or health effects based upon the molecular structure of a chemical, without, arguably, the need for further animal testing. It is unclear to in what proportion of cases the predictions are fully accurate.

block-testing strategy applied by the EU proposal. However, the US system leaves a considerable degree of uncertainty for about 14 per cent of the submitters of PMNs. The Canadian system also uses QSARs extensively, though does have a mechanism for using expert opinion if the reliability of the QSAR is thought insufficient. In the EU, there has historically been less use of QSARs, though there is increased scope for this under REACH. **It is important to underline that QSARs have their limitations and these need to be better understood.**

The contingent Japanese system is based on the criterion of biodegradability. If a new chemical substance is biodegradable, only a few test requirements need to be fulfilled; whereas in the case of non-biodegradability, the test requirements are much more complex, time consuming, and expensive.

The OECD Guidelines for the Testing of Chemicals are a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to characterise potential hazards of new and existing chemical substances and chemical preparations/mixtures.

4.2.2 Animal testing and data sharing

REACH – 'minimising ' requirements through, *inter alia*, the ability to use existing information, mandatory data sharing where relating to animal testing, increased use of QSARs, and reduced requirements for registering and testing chemicals at low volumes. In the USA the significant use of statistical methods rather than testing methods significantly reduces animal testing requirements.

4.3 Authorisation

Under REACH, compulsory authorisation is reserved for chemicals known to pose high risks, including carcinogens, mutagens and reproductive toxicants (CMRs), persistent, bioaccumulative and toxic substances (PBTs) and very persistent and very bioaccumulative substances (vPvBs). This applies to around 1,400 substances.

In New Zealand, all new substances will need to go through the ERMA approval process if they have hazardous properties that exceed the thresholds established by regulations under the HSNO Act. Applicants themselves, in the first instance, are responsible for determining whether the substance is hazardous.

In the USA, Canada and Japan there are also regulatory requirements, ie authorisations for chemical substances that are tested as 'hazardous', though the difference here lies in the testing regimes that help identify which chemical substances are regarded as 'hazardous'. This is not just a case of chemical properties but also exposure, which can lead to different country views.

4.4 Other issues – public access to information, burden of proof, costs, precautionary principle and sanctions

4.4.1 Public Access to information

REACH includes provision for public has access to most information, but not all. Some data has to be available, some you can obtain on the basis of a written request, some are confidential.

In New Zealand applications with full assessment need to be publicly notified so that people are able to make submissions. Public hearings for a notified application are arranged on request if considered necessary. Approved substances are listed on the Public Register which can be viewed on the ERMA web site.

All information resulting from the OECD High Production Volume Chemicals Programme will be available worldwide through the internet and publications.

4.4.2 Burden of proof

REACH shifts the burden of proof to producers and in some cases users of hazardous substances. There would therefore be a greater burden on industry than is currently the case. The Dutch Strategy on Management of Substances (SOMS) are similarly seeking to assign a greater share of chemical assessment and management to industry.

In the US, the burden of proof is with the EPA as there are no requirements for a mandatory base data set to be provided by manufacturers. This, in effect, is subsidising the US chemicals industry by using public funds to carry out any tests that are required. It is also putting a very large burden on the EPA. In Japan, there is a requirement on data to be provided by manufacturers as under REACH.

In New Zealand the manufacturer or importer making an application for approval has to submit the relevant information. For the assessment under the HSNO Act, fees are charged on an hourly basis and all expenses are recouped from the applicant. An initial fee is submitted with the application and the balance invoiced on completion.

As mentioned above, the burden of proof issue is one of the major differences between REACH and US systems.

4.4.3 Costs

A study by the Institute for Prospective Technological Studies (IPTS)[36] compared the regulatory regimes in the EU, US and Japan. It noted that the **costs of notification** were generally highest in the EU due to the list of tests to be performed, giving estimates for average notification costs ($117,000 in the EU, $80,000 in Japan and $40,000 in the USA). Note, however, that this estimate is based on current notification scheme, and the REACH proposal will considerable lower the testing costs for new substances. Note also that REACH adopts the principle of full cost recovery for testing so that there is no subsidy for industry.

In New Zealand, the **costs for** a rapid **assessment** are NZD$ 400 - 3000 (USD$ 1,300), for a full assessment NZD 5,000 - > 250,000 (USD$ 110,000). ERMA publishes a list of fees and charges. Note that all the costs are recouped from the applicant, as under REACH.

[36] Neven B and Schubert, R (1998) *Comparison of Regulatory Requirements for the Notification of New Chemical Substances in the European Union, the USA and Japan.* Institute for Prospective Technological Studies.

For OECD governments and industry, the work done by the OECD on chemicals has **reduced barriers to trade** and saved **time and money**, estimated in 1998 at US$ 46 million per year.

4.4.4 Precautionary Principle

REACH integrates the precautionary approach - the precautionary principle (Article 174.2 of the Treaty in combination with Article 6 and Article 95.3) will continue to guide the approach in the implementation of necessary measures. This is less the case under the US scheme. The precautionary approach is also a key element in the Dutch SOMS, the Swedish approach and Canadian scheme.

4.4.5 Financial sanctions

REACH sanctions have to be proportionate and dissuasive, with sanctions up to around 10% of turnover for companies that wilfully do not comply with REACH. The Japanese system also foresees sanctions for non-compliance.

4.5 Major differences

There are a large number of differences between the EU's REACH proposal and existing practice – as noted above, and summarised in Table 4.1 overleaf. Some of these are points of detail as many approaches have wide parallels, and some have only minor costs or benefits associated. However, there are three major differences worth underlining:

- **Burden of proof –** REACH, in encouraging more testing, registration, and passing on of information, with specific timelines and given the quantities concerned, will lead to a significant burden of proof being placed on the industry, one not currently in place in other countries, notably the US. REACH offers an advantage in that it directs the responsibility, and with that also possibilities, to those who should have the genuine information on chemicals – those who produce them. It makes sense for the burden of proof to be on industry and for the responsibility of action to be with industry, who can most effectively use their knowledge for appropriate developments and guidance for stewardship of their products.

- **Commitment to testing -** REACH is the only system that moves towards a comprehensive commitment to test chemical substances, including not just 'new' chemicals, but also 'existing' ones.

- **Timelines** - REACH goes further than any other system in defining explicit deadlines for notification, testing, evaluation and authorisation of chemical substances. This gives a level of focus and certainty not currently existing in other systems.

Table 4.1 Comparison of REACH and Practice in the USA, Canada, New Zealand and Japan

	REACH Proposal	USA	Canada	New Zealand	Japan
Legal Base	COM(2003)644	TSCA, 1976	CEPA 1999, and NSNR	HSNO Act, 1996	CSCL 1973, am. 1986
Coverage – 'new' and 'existing' chemicals	Integrated system for 'new' and 'existing'	Split new and existing	Split new and existing	Split new and existing	Split new and existing
Thresholds	1 tonne for new and existing – pre-market	'New': 10 tonnes Pre-manufacture	'New': From 20kg for schedule one. 100kg for inclusion in domestic substances list.	No threshold – all substances have to be covered	5 tonnes up to 2003, 1 tonne from 2004
Rate of assessment	Timeline – all within 11 years of legislation passing	'Priority' programme under Toxic Release Inventory; unclear timeframe	'Virtual elimination' of toxic substances from the environment	Categorisation as to which substances 'toxic' to be done by 2006	300 per year of class 1 and class 2 – total of 1280 covered, supported by government programme
Polymers	Potential future inclusion	Listed but not included	Inclusion		
Exemptions – R&D	Yes	Yes	Yes	Yes	
Notification information requirements and classification	Include mandatory base data sets that facilitate classification/categorisation	No mandatory data sets required; no classification	Data provision leading to classification.		Include mandatory base data sets that facilitate classification/categorisation
Testing approach – use of QSARs	Some possibility Integrated	High reliance	High use, complemented by expert opinion		
Animal testing	'Minimised' but still needed	Very low use given use of QSARs et al	Very low use given use of QSARs et al	Most likely avoided by data sharing	
Testing and assessment fees – who pays & principles	Full cost recovery principle – industry to cover costs	Assessment costs covered by EPA		Assessment fees fully recouped from applicant	State testing
Burden of proof	On industry to prove chemical substances are safe.	On the EPA – EPA to prove that substances are harmful, though industry to provide data on risks			
Data sharing	Mandatory for animal testing	Not mandatory	Data sharing agreement with Australia		
Confidentiality	Respected, though disclosure the norm.	Critical driving issue. Covers intended use	Procedure for requesting confidentiality – authorities decide		
Inventories / lists	Integrated inventory building on EINECS and ELINCS	Toxic Release Inventory	The Domestic Substances List, Priority Substances List, and List of Toxic Substances	Notified Toxic Substances	ENCS
Principles	Precautionary principle, and substitution principles	Little emphasis on precautionary principle	Precautionary approach integrated		

5 Conclusions

A clear agreement exists that there needs to be an improvement in the legislation and systems to address chemical substances to ensure that health and the environment can be appropriately protected, while at the same time safeguarding the economic and social benefits stemming from this important industrial sector. The White Paper on REACH tried to take a big step forward and while many of the provisions have been watered down in the course of preparing the Commission proposal that needed to be acceptable to both DG Environment and DG Enterprise, the final text that emerged on 29 October 2003 represents a big shift in the EU's approach to chemicals.

This report has tried to summarise what the key elements of REACH are and how they compare to existing EU legislation and initial ambitions for REACH, as well as practice internationally. In doing so, a number of interesting and innovative approaches have been identified. These are summarised in Section 5.1 below. REACH does go further - in many respects – than existing legislation and other country practice. Section 5.2 summarises how much further REACH does go and Section 5.3 asks whether REACH goes far enough, as it seems that there are some measures that could still be taken that would not compromise the *bon fide* concern of avoiding excessive business burdens.

5.1 Guiding principles, and interesting and innovative approaches

Interesting and innovative approaches identified during this study include:

- The commitment to testing, with fixed timelines, of chemical substances that have been on the market for 20 years – this is now an integral part of REACH. This should not have had to be innovative, but is.

- The approach of having a single scheme for both 'existing and new' chemical substances is new, and arguably should facilitate innovation as systems that differentiate 'existing' and 'new' have tended to be more demanding of 'new' chemicals.

- R&D exemptions is an interesting and valuable possibility, and REACH's raising the exemption threshold from 10kg to 1 tonne should support innovation.

- The precautionary principle is key to any chemicals policy – currently the limited data limits knowledge of the effects on human health and the environment. A real commitment to increased and systematic testing to assess whether chemicals are 'hazardous' and putting in place measures to reduce impacts early is a valuable and practical approach to realizing the precautionary principle. This is significantly better than addressing hazardous properties of chemicals after they have had an impact, often irreversible, on health and the environment.

- The clear and systematic approach to prioritizing and classifying chemicals, with links directly to risk management options – as required under the Dutch SOMS system - is innovative and interesting.

- The substitution principle is a key principle of REACH. Early action and development of substitution plans can avoid significant human, social and economic costs by avoiding adverse health and environment effects. Furthermore, the substitution principle is a key to

innovation and competitiveness on the market and therefore supports the EU's Lisbon objectives.

- Polluter pays principle – applying this principle, there should be no grounds for chemical companies being subsidised by authorities for testing and authorisation or subsidised through a lack of testing requirements. Furthermore, there should be no grounds for industry to continue to use substances that are hazardous when there are (cost-) effective substitutes. Industry should therefore pay for testing, authorisation (as is the case under REACH and in New Zealand) and should implement and pay for substitution programmes. Finally, industry should be liable for the costs of any impacts on health and the environment.

- Contingent testing techniques – staging testing requirements not just for volumes, but also in relation to exposure and risk, can help ensure more cost-effective testing.

- The use of QSARs - quantitative structure activity relationship - offer a valuable and low cost route for testing that can avoid animal testing. They can play an important role in chemical testing schemes, though do need to be complemented by data and non-modelling schemes, to ensure results fully reflect reality. The Canadian approach of complementing QSARs with expert input in areas where QSAR predictions are not thought reliable, is interesting.

- The Swedish and Dutch government aims to provide considerable practical help to SMEs throughout the product chain. This is a valuable approach to help address cost and capacity concerns in SMEs.

- In the Netherlands, the SOMS aims to eventually cover medicines, veterinary medicines, agricultural and non-agricultural pesticides, as well as new and existing industrial chemicals. This tries to adopt a more comprehensive approach than just a 'chemical substances' approach and arguably signposts an ideal objective for future EU chemicals policy development.

5.2 How much further does REACH go?

The 29 October 2003 REACH proposal is weaker than the May 2003 consultation draft and arguably weaker on 'new chemicals' than existing legislation, but does provide a significant step forward for 'existing chemicals'. It is generally seen as a necessary though not ideal compromise that enabled adoption by the Commission, and that stands a chance of being accepted with perhaps only minor amendments as it goes through Council and Parliament.

The proposal goes beyond the current US regime, though is less ambitious than the Dutch scheme or what some national governments and many environmental or health bodies would wish. That said, some have and will argue that the REACH proposals go too far.

5.3 Does REACH go far enough?

There are several areas where REACH could go further, without necessarily compromising the likely success of the adoption of the legislative proposal and without adding unnecessary and unacceptable burdens on industry.

Areas which still need improvement, to secure a high level of protection for human health and the environment, include:

- Some chemicals, which are used below 1 tonne per year, can still be of significant danger to human health if eg directly exposed on humans via cosmetics, toys and textiles. **There is therefore a need to either reintroduce the general duty of care provision, and/or to have authorities to have the** *right to require also substances less than one tonne to be registered when there is a justified reason to believe that such substances may cause significant risk to health or the environment. Screening for chemicals* **below 1 tonne should also be reconsidered, as this is less expensive than full testing, and a procedure be put in place to address them if they seem to have a potential of causing danger.**

- The lack of requirement for complete **chemical safety assessments and reports** (not required for chemicals under 10 tonnes) raises some concern that important chemicals would be 'missed' with this threshold. It is understood that the CSRs do not save a lot of money, and the question is therefore raised as to the cost-effectiveness of reducing the requirement.

- While the Commission proposal notes the possibility to address polymers in due course, given the evidence that **some polymers have known health impacts (allergies)**, the date for deciding what measures are to be taken needs to be set. It is important not to lose momentum.

- There needs to be explicit **timeframe for the authorisation** of substances of very high concern, as currently this is not made explicit.

- At the moment REACH only 'encourages' company to develop 'substitution plans' as a part of authorisation application, but there is no control mechanism or insurance that dangerous chemicals are actually substituted when there are real alternatives and insufficient measures to encourage research into substitutes. If the **substitution principle** is taken into account early in the process and concerning also other substances than those of 'very high concern', it is possible to avoid substantial costs.

- REACH basically states that companies that comply with REACH have fulfilled their duty of care requirements, giving them the sought after legal certainty. However, chemical substances under REACH only include those above 1 tonne and therefore there is a question as to what '**duty of care**' requirements there should be for chemicals used in smaller quantities.

- The **authorisation application** and decision will not deal with risks to the environment or human health addressed by other Community legislation (e.g. the IPPC Directive or Water Framework Directive). This exemption from the authorisation is arguably too wide.

- **Harmonisation.** The REACH proposal is based on Article 95 of the EC Treaty (Internal Market). However, it could be questioned as to whether the proposal should be based on Article 174 (Environment), since the proposal is primarily aimed at 'protecting human health' and 'preserving protecting and improving the quality of the environment'. The importance of the change in legal base is that Member States would be permitted to maintain and/or introduce stricter standards than set out in the final REACH legislation. Article 95(5) relating to the 'environmental guarantee' make it difficult for Member States to have stricter

standards in relation to internal market. If the legal base remains Article 95, then there should at least be a clause inserted underlining that Member State initiatives to go beyond the REACH proposals would be, in principle, welcomed.

- Questions have been raised as to what to do during the period up to implementation period. Clarification on steps to be taken by industry and by the chemicals agency is needed.

At the WSSD in Johannesburg the world, including high level commitment by the chemicals industry, committed to the Chemicals Action Plan - of minimising adverse impacts of chemicals on health and the environment by 2020. REACH promises to be a big step in achieving that objective, especially if additional concerns noted above are addressed. It is a significant step towards securing a high level of protection for human health and the environment, though one that will need additional complementary steps before a truly high, and arguably needed, level of protection of human health and the environment is secured.

Acronyms

BIA	Business Impact Assessment
CMR	Carcinogenic, mutagenic and reprotoxic substances
CSA	Chemical safety assessments
CSR	Chemical safety report
DALYs	Disability Adjusted Life Years
DSL	Domestic Substances List
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ERMA	Environment Risk Management Authority
HSNO	Hazardous Substances and New Organisms
HPV	High production volume
ICCA	International Council of Chemical Associations
IPTS	Institute for Prospective Technological Studies
NSNR	New Substances Notification Regulations
PBTs	Persistent, bio-accumulative and toxic substances
PIC	Prior Informed Consent
POPs	Persistent Organic Pollutants
PMN	Pre-Manufacture Notification
QSAR	Quantitative structure activity relationship
RCEP	Royal Commission on Environmental Pollution
REACH	Registration, Evaluation and Authorisation of Chemicals
SIAR	SIDS Initial Assessment Reports
SIDS	Screening Information Data Set
SOMS	Strategy on Management of Substances
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
vPvBs	Very persistent and very bio-accumulative substances
WSSD	World Summit on Sustainable Development