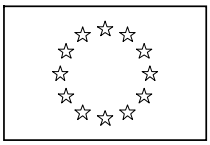

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.2.2001
COM(2001) 88 final

WHITE PAPER

Strategy for a future Chemicals Policy

(presented by the Commission)

TABLE OF CONTENTS

1. INTRODUCTION

This White Paper presents Commission proposals for a strategy on future chemicals policy in the Community with the overriding goal of *sustainable development*.

Chemicals[1] bring about benefits on which modern society is entirely dependent, for example, in food production, medicines, textiles, cars etc. They also make a vital contribution to the economic and social wellbeing of citizens in terms of trade and employment.

The global production of chemicals has increased from 1 million tonnes in 1930 to 400 million tonnes today. We have about 100,000 different substances registered in the EU market of which 10,000 are marketed in volumes of more than 10 tonnes[2], and a further 20,000 are marketed at 1-10 tonnes. The world chemical production in 1998 was estimated at € 1,244 billion, with 31% for the EU chemical industry, which generated a trade surplus of € 41 billion. In 1998, it was the world's largest chemical industry, followed by that of the US with 28% of production value and a trade surplus of € 12 billion.

The chemical industry is also Europe's third largest manufacturing industry. It employs 1.7 million people directly and up to 3 million jobs are dependent on it. As well as several leading multinationals, it also comprises around 36,000 SMEs. These SMEs represent 96% of the total number of enterprises and account for 28% of chemical production.

On the other hand, certain chemicals have caused serious damage to human health resulting in suffering and premature death and to the environment. Well-known examples amongst many are asbestos, which is known to cause lung cancer and mesothelioma or benzene which leads to leukaemia. Abundant use of DDT led to reproductive disorders in birds. Though these substances have been totally banned or subjected to other controls, measures were not taken until after the damage was done because knowledge about the adverse impacts of these chemicals was not available before they were used in large quantities.

The incidence of some diseases, e.g. testicular cancer in young men and allergies, has increased significantly over the last decades. While the underlying reasons for this have not yet been identified, there is justified concern that certain chemicals play a causative role for allergies. According to the Scientific Committee on Toxicity, Ecotoxicity and the Environment of the Commission (CSTEE), links have been reported between reproductive and developmental effects and endocrine disrupting substances in wildlife populations. The CSTEE concluded that there is a potential global problem. This concern is based on the recent findings of high levels of persistent potential endocrine disrupting chemicals in several marine mammalian species inhabiting oceanic waters[3].

The lack of knowledge about the impact of many chemicals on human health and the environment is a cause for concern. Understandably, the public is worried when hearing about the exposure of their children to certain phthalates released from toys and about increasing amounts of the flame retardant pentabromo diphenyl ether in human breast milk. Though these too are the subject of Commission proposals for bans, legislative action takes too long before yielding a result.

---

1 Substances and preparations as defined in Directive 67/548/EEC

2 Tonnage thresholds refer to volumes produced per manufacturer (or imported per importer) per annum in this White Paper unless specified.

3 Opinion of the CSTEE on Human and Wildlife Effects of endocrine disrupting chemicals (March 1999)

These examples expose the weaknesses of the current EU chemicals policy. However, the problem is not unique to the Community. Government agencies in Canada and the United States have recently launched initiatives to acquire testing data for large numbers of chemical substances currently on their markets in high volumes on which little is known about the risks. In fact, not one country has yet been successful in overcoming the huge gap in knowledge of substances.

EU chemicals policy must ensure a *high level of protection of human health and the environment* as enshrined in the Treaty both for the present generation and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the chemical industry. Fundamental to achieving these objectives is the *Precautionary Principle*[4]. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available.

It is also essential to ensure the efficient functioning of the internal market and the competitiveness of the chemical industry. EU policy for chemicals should provide incentives for technical innovation and development of safer chemicals. Recent experience has shown that innovation (e.g. in developing new and often safer chemicals) has been hindered by the burdens of the present notification system. Ecological, economic and social aspects of development have to be taken into account in an integrated and balanced manner in order to reach the goal of sustainability.

2. THE EU CHEMICALS POLICY

Increasing concern that current EU chemicals policy does not provide sufficient protection led to a debate at the informal Council of Environment Ministers in Chester in April 1998. Recognising that a review of the current policy on chemicals was necessary, the Commission made a commitment to assess the operation of four important legal instruments governing chemicals in the Community[5]. The report on the findings[6] was adopted by the Commission in November 1998 and welcomed by the Council in December 1998.

These four instruments cover a broad range of substances of different origins (e.g. industrial chemicals, substances produced from natural products, metals, minerals etc.). They regulate the testing of these substances and determine risk reduction measures. Furthermore, they establish duties regarding the safety information to be provided to users (labelling, safety data sheets). Beyond these four instruments, specific legislation exists for certain sectors

---

4 Resolution of the European Council of Nice, December 2000 on the precautionary principle which welcomes the Communication from the Commission on the precautionary principle. COM(2000)1, 2.2.2000

5 Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended [OJ 196, 16.8.1967, p. 1].
Directive 88/379/EEC relating to the classification, packaging and labelling of dangerous preparations [OJ L 187, 16.7.1988, p. 14].
Council Regulation (EEC) 793/93 on evaluation and control of risks of existing substances [OJ L 84, 5.4.1993, p.1].
Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations [OJ L 262, 27.9.1976, p. 201].

6 Commission Working Document SEC(1998) 1986 final.

and areas, for example plant protection products or cosmetics or the transport of dangerous goods.

In view of the findings, the Commission held a Brainstorming with more than 150 stakeholders in February 1999 – regulators, scientists, industry, environmental and consumer NGOs as well as representatives from applicant countries – providing the Commission with an all round view of the problems and potential solutions.

In June 1999, the Council adopted a set of conclusions for a future strategy on chemicals in the Community which provided important input to the recommendations in this White Paper, which concerns revision of the above mentioned four legal instruments.

2.1 Major problems identified by review

The present system for general industrial chemicals distinguishes between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market since that date.

There are some 2,700 new substances. Testing and assessing their risks to human health and the environment according to Directive 67/548 are required before marketing in volumes above 10 kg. For higher volumes more in-depth testing focussing on long-term and chronic effects has to be provided.

In contrast, existing substances amount to more than 99% of the total volume of all substances on the market, and are not subject to the same testing requirements. The number of existing substances reported in 1981 was 100,106, the current number of existing substances marketed in volumes above 1 tonne is estimated at 30,000. Some 140 of these substances have been identified as priority substances and are subject to comprehensive risk assessment carried out by Member State authorities.

There is a general lack of knowledge about the properties and the uses of existing substances. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively. The allocation of responsibilities is inappropriate because authorities are responsible for the assessment instead of enterprises which produce, import or use the substances. Furthermore, current legislation only requires the manufacturers and importers of substances to provide information, but not the downstream users (industrial users and formulators). Thus, information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce. Decisions on further testing of substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk. Without test results, however, it is almost impossible to provide such proof. Final risk assessments have therefore only been completed for a small number of substances.

Under Directive 76/769 on restriction of marketing and use of dangerous substances and preparations, the Commission has committed itself to carry out risk assessments and adequate analyses of the costs and the benefits prior to any proposal or adoption of a regulatory measure affecting the chemical industry. Indications of unacceptable risk (typically arising from notifications of restrictions at national level) are the subject of reports, which are peer-reviewed by the Scientific Committee on Toxicology, Ecotoxicology and Environment (CSTEE) of the Commission.

Current liability regimes are insufficient to remedy the problems found by the review. Liability is usually based on the principle that those who cause damage should pay compensation for that damage. However, in order to be held liable, it is generally required

that a causal connection be proven between the cause and the resulting damage. This is often virtually impossible for injured parties if cause and effect occur far apart in time and if adequate test data on the effects of substances are not available. Even if a causal connection can be established, compensations awarded by courts of EU Member States are generally not as high as, for example, in the US, and hence have a limited deterrent effect. In order to improve this situation and to make producers assume responsibility for their products, the Commission has announced its intention to propose Community legislation in this field[7].

2.2 Political objectives of the proposed Strategy

In order to achieve the overriding goal of sustainable development, the Commission has identified a number of objectives that must be met in order to achieve sustainable development in the chemicals industry within the framework of the Single Market.

- **Protection of human health and the environment**.
- **Maintenance and enhancement of the competitiveness of the EU chemical industry**.
- **Prevent fragmentation of the internal market.**
- **Increased transparency.** Consumers need access to information on chemicals to enable them to make informed decisions about the substances that they use and enterprises need to understand the regulatory process.
- **Integration with international efforts.** The global nature of the chemicals industry and the trans-boundary impact of certain chemical substances have made chemical safety an international issue.
- **Promotion of non-animal testing**. Protection of human health and the environment, including wildlife, should be balanced against protection of the welfare of laboratory animals. The Commission will therefore promote further development and validation of non-animal test methods.
- **Conformity with EU international obligations under the WTO.** No unnecessary barriers to trade should be created and there must not be discrimination against imported substances and products.

The strategy which is proposed must meet these objectives.

2.3 Key elements of the proposed strategy

Protection of human health and promotion of a non-toxic environment

The Commission proposes that existing and new substances should in the future, following the phasing in of existing substances until 2012, be subject to the same procedure under a **single system**. The current new substances system should be revised to become more effective and efficient and the revised obligations be extended to existing substances. The proposed system is called REACH, for the **R**egistration, **E**valuation and **A**uthorisation of **CH**emicals. The requirements, including the testing requirements, of the REACH-system depend on the proven or suspected hazardous properties, uses, exposure and volumes of chemicals produced or imported**.** All chemicals above 1 tonne should be registered in a central database. At higher tonnage special attention should be given to long-term and chronic effects.

Setting deadlines: The Commission proposes to implement a step by step process to address the 'burden of the past' and develop adequate knowledge for existing substances

[7] White Paper on Environmental Liability, COM(2000)66 final, 9.2.2000

that industry wants to continue marketing. Given the vast number of existing substances on the market, the Commission proposes that first priority is given to substances that lead to a high exposure or cause concern by their known or suspected dangerous properties - physical, chemical, toxicological or ecotoxicological. All such substances should be tested within five years and subsequently be properly assessed for their impact on human health and the environment. The other existing substances should follow in accordance with the proposals in Chapter 6.

Making industry responsible for safety: Responsibility to generate knowledge about chemicals should be placed on industry. Industry should also ensure that only chemicals that are safe for the intended uses are produced and/or placed on the market. The Commission proposes to shift responsibility to enterprises, for generating and assessing data and assessing the risks of the use of the substances. The enterprises should also provide adequate information to downstream users.

Extending the responsibility along the manufacturing chain: Downstream users, as well as manufacturers and importers, of chemicals should be responsible for all the aspects of the safety of their products and should provide information on use and exposure for the assessments of chemicals. Producers of preparations and other downstream users will be obliged to assess the safety of their products for the part of the life cycle to which they contribute, including disposal and waste management.

Authorisation of substances of very high concern: Substances with certain hazardous properties that give rise to very high concern will have to be given use-specific permission before they can be employed in particular uses. Evidence demonstrating that the specific use only presents a negligible risk or, in other cases, that the use is acceptable taking into account socio-economic benefits, lack of 'safer' chemicals for the same task and measures minimising the exposure of consumers, workers, the general public and the environment will be considered before granting an authorisation. Uses which do not give rise to concern may be subject to general exemptions from the authorisation procedure.

Substitution of hazardous chemicals: Another important objective is to encourage the *substitution* of dangerous by less dangerous substances where suitable alternatives are available. The increased accountability of downstream users and better public information will create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.

Maintenance and enhancement of the competitiveness of the EU chemical industry

Stimulating innovation: It is essential to promote the competitiveness of the chemical industry and encourage innovation, and in particular the development of safer chemicals. Regulations are a major factor in shaping the innovation behaviour of firms in the chemical industry. The Commission proposes to increase the current thresholds for notification and testing of new substances, to extend the conditions for derogation for research and development and enable test data to be used and submitted in a flexible way.

Realistic timetable for submission of data: In proposing a timescale for the submission of data, the strategy takes account of resource implications. Together with the measures to increase testing thresholds and more flexible test data, this should limit the cost for enterprises to the absolute minimum needed.

Prevent fragmentation of the internal market

Any Commission strategy on chemicals should aim at ensuring a high level of health, safety and environmental protection while at the same time ensuring the proper functioning of the

Internal Market in that sector - as in any other industrial sector within the Union. The achievement of these objectives requires that the new policy be based on full harmonisation at Community level.

Increasing transparency

Providing full information to the public: The public has a right to access to information about the chemicals to which they are exposed. This will enable them to make informed choices and to avoid products containing harmful chemicals, so creating pressure on industry to develop safer substitutes. However, commercially sensitive information will be suitably protected.

A more transparent regulatory system: The creation of a single system to be applied to all chemicals, once the existing substances have been phased in, will improve the transparency of the regulation of chemicals.

Integration with international aspects

Contributing to safe use of chemicals at a global level: A global network of industrialised and developing countries and international organisations has developed over the past decades to promote global safe use of chemicals. The Intergovernmental Forum on Chemical Safety (IFCS) was established to co-ordinate the many national and international activities, to promote chemical safety and to oversee implementation of the programme on environmentally sound management of chemicals as set out in Chapter 19 of Agenda 21, adopted by the 1992 UN Conference on Environment and Development (UNCED) at the Earth Summit in Rio. The recommendations in this White Paper will feed into the international programmes and make a major contribution to achieving safe use of chemicals at a global level.

Testing in a global market: Testing obligations will not only affect the EU chemicals industry. Importers will also be obliged to assess the safety of their chemicals, to deliver information and to share the costs of testing. This avoids distortion of the global market and ensures that the competitiveness of the EU chemical industry is not compromised.

Recognising non-EU test results: The lack of data on existing chemicals is a global concern. For example, the US have recently launched initiatives. The US initiative aims to complete testing of 2,800 high production volume chemicals by 2004 (the Gore initiative). This initiative is regarded as the first approach to systematically obtain toxicological and ecotoxicological information about the most abundant existing chemicals on the US market. Studies on the dangerous properties of chemicals performed in the US will not have to be repeated in the Community and vice versa, since testing must be carried out using globally harmonised testing methodology. Accordingly, test results of the HPV/ICCA SIDS programme of the OECD will be taken into account to reduce the number of tests to be performed in the EU.

Complying with OSPAR: The Convention for the Protection of the Marine Environment of the North East Atlantic[8] aims to prevent and eliminate pollution and to protect the maritime area of the North East Atlantic against the harmful effects of human activities (land-based sources, off-shore sources, dumping and incineration of wastes). The strategy supports this

[8] Resulting from the merger of the Oslo 1972 *Convention for the Prevention of Marine Pollution by Dumping from Ships and aircraft* and of the Paris 1974 *Convention for the Prevention of Marine Pollution from Land-Based Sources* the OSPAR Convention entered into force in March 1998. With the exception of Austria, Greece and Italy all the Member States are all Contracting parties to the Convention. The Community is also a Contracting Party to the Convention.

aim, in particular through the proposals for improved controls on downstream users of chemicals.

Persistent organic pollutants (POPs): POPs represent a special threat since they persist in the environment for a long time, they travel over long distances from their sources, accumulate in the tissues of most living organisms and poison humans and wildlife. It has been internationally recognised that there is a need for strict control of these substances. Following a mandate issued by the Governing Council of the UNEP, negotiations on an international treaty to eliminate production, use, emissions and discharges of initially 12 specified POPs - a group of highly stable organic substances – have recently been concluded. Criteria have been developed to identify further POPs among the existing substances. Furthermore, parties to the Convention will be obliged to prevent the production and use of new substances with POPs characteristics[9].

Developing countries: One of the Community's major objectives is to strengthen developing countries' capabilities and capacities for managing chemicals. Many developing countries do not have adequate legislation, administrative capacity or infrastructure to ensure the safe use of chemicals. The Rotterdam Convention on prior informed consent (PIC Convention, 1998) for certain hazardous industrial chemicals and pesticides obliged exporters of such chemicals to get the consent of the receiving country before delivery and by bilateral and multilateral programmes of training and technical assistance in respect of particular chemicals.

Developing countries are mostly importers and not exporters of chemicals. The testing requirements in the EU will ensure that imported chemicals, which constitute the large majority of chemicals used in these countries, have been evaluated. This benefit will by far outweigh the potential economic effort, such as for testing, required by chemical companies located in developing countries when manufacturing chemicals for export to the EU.

Promotion of non-animal testing

Maximising use of non-animal test methods: Testing requirements will be met as far as practicable through use of existing non-animal test methods.

Encouraging development of new non-animal test methods: Development of new non-animal test methods will be encouraged.

Minimising test programmes: Measures to increase testing thresholds and more flexible test regimes will limit the need for testing.

Conformity with EU international obligations under the WTO

Trade barriers: The new policy shall not discriminate against imported products. In that respect, the EU should conform with Article 2.1 of the WTO's Technical Barriers to Trade, which sets out that imported products shall be accorded treatment no less favourable than that accorded to like products on national origin. Without a sound scientific evaluation of the potential threats to human health and the environment, the EU will not be able to defend a measure being challenged by third countries. In accordance with Article 2.2 of the TBT, the EU shall ensure that "technical regulations will not create unnecessary obstacles to international trade".

---

9 As defined in annex D to the POPs Convention

3. KNOWLEDGE ABOUT CHEMICALS

The principal objective of assessing the risks of chemicals is to provide a reliable basis for deciding on adequate safety measures (risk management) when using them. The risk assessment provides an evaluation of whether a chemical used in a particular way could cause adverse effects. This encompasses a description of the nature of these effects and a calculation of the probability that they will occur, as well as an estimation of their extent.

Any risk assessment on chemicals is composed of two distinct elements, (1) an evaluation of the properties which are intrinsic to the chemical, called *hazard assessment*, and (2) an estimation of the *exposure* which depends on the use of the chemical. The hazard assessment identifies the *hazardous properties* (e.g. sensitising, carcinogenic, toxic for the aquatic environment) and determines the *potency* of the chemical with respect to these hazardous properties. The exposure assessment identifies the sources of the chemicals which lead to exposure and calculates the dose taken up by an exposed organism or estimates the releases of the chemical into a particular compartment of the environment.

Precise knowledge on the intrinsic properties as well as on the exposure arising as a result of a particular use and of the disposal is an indispensable prerequisite for decision making on the safe management of chemicals. Reliable knowledge on intrinsic properties is important because it also constitutes the basis for the *classification* of chemicals. A large part of the management measures laid down in sector specific legislation to protect human health or the environment are directly linked to the classification of chemicals:

- it triggers the *labelling* of the packaging of the chemicals to inform the user about the properties of the chemicals and gives advice for the safe use,
- a chemical classified as carcinogenic, mutagenic or toxic for reproduction currently initiates an examination of *restriction measures* in the consumer sector,
- it triggers *numerous safety measures* laid down in sector specific legislation in respect of occupational health, water protection, waste management, prevention of major accident hazards and air pollution.

3.1 Intrinsic Properties

The extent of testing required for detecting the intrinsic hazardous properties of a substance is often the subject of controversy. While, at first glance, it would seem reasonable to test chemicals until all hazardous properties (i.e. all adverse effects on all organisms at all potential doses) are known, theoretical and practical considerations reveal that it is neither possible nor desirable to meet this objective. First, the available testing methodology has limitations, as demonstrated by the recent discussion on the identification of endocrine disrupters. The review and the development of our testing methodology must therefore be regarded as a continual challenge. Second, ethical considerations on animal welfare as well as on the costs of testing strongly advocate for a balanced approach to the testing of chemicals so that the acquired knowledge offers proportionate benefits in terms of managing risks. This is particularly important for testing requirements for substances marketed in low volumes where extensive testing is not compensated by the income from sales.

New substances: Current EU legislation on new substances is generally considered to have been successful in testing and assessing chemicals. The testing requirements are tiered according to the volume placed on the market. The lowest volume triggering the need for testing amounts to 10 kg. More extensive testing is required when the volume reaches 100 kg, 1 t, 10 t, 100 t and 1,000 t, respectively. Generally, testing requirements at the lower volumes (10 kg to 1 t) focus on acute hazards (immediate or slightly delayed effects after short term exposure) while those at the higher tonnage levels include more expensive

studies on the effects of (sub-) chronic exposure, on reproductive toxicity and on carcinogenicity. The testing package at 1 t is termed 'base set' while those triggered by higher tonnage are called Level 1 (100 t) and Level 2 (1,000 t).

Existing substances: In contrast to new substances, existing substances have never been subjected to such a systematic testing regime. When the requirement for testing and notification of new substances was introduced in 1981, substances already on the market were exempted. A study performed by the European Chemicals Bureau on the availability of the data for high production volume existing substances[10] (substances exceeding a production volume of 1,000 t) revealed significant gaps in publicly available knowledge about these chemicals. This lack of public knowledge was identified as the major deficiency throughout the entire review process.

Action 3A: Equivalent level of information on new and existing substances

The gap in knowledge about intrinsic properties for existing substances should be closed to ensure that equivalent information to that on new substances is available. According to the timetable presented in chapter 6, existing substances will be subjected to the same procedure as for new substances. The available information should be thoroughly examined and best use made of it in order to waive testing, wherever appropriate.

Action 3B: Testing of new and existing substances

Testing and assessment of the many existing substances will require a substantial effort from industry and authorities. To meet this challenge available resources must be focussed on the most relevant chemicals. The current 10 kg threshold for mandatory testing of new substances should be increased. The following general testing regime for new and existing substances is recommended. Waiving of testing will be acceptable on due justification according to recommendations 3A and 3C. Further testing may be required by the authorities as described in chapter 4.2:

- Substances produced/imported in quantities between 1 – 10 t: data on the physico-chemical, toxicological and ecotoxicological properties of the substance; testing should generally be limited to in vitro methods,
- Substances produced/imported in quantities between 10 – 100 t: 'base set' testing according to Annex VII A of Directive 67/548/EEC. Waiving of testing will be acceptable on due justification according to Action 3A. This will in particular apply for existing substances,
- Substances produced/imported in quantities between 100 – 1000 t: 'Level 1' testing (substance-tailored testing for long-term effects). The scope of the additional testing will be based on the requirements set out in Annex VIII of Directive 67/548/EEC. Guidelines, including decision trees for the testing strategy will be developed tailoring testing according to the results of the available information, physico-chemical properties, the use and the exposure to the substance.
- Substances produced/imported in quantities above 1000 t: 'Level 2' testing (further substance-tailored testing for long-term effects). The scope of the additional testing will be based on the requirements set out in Annex VIII of Directive 67/548/EEC. Guidelines, including decision trees for the testing strategy will be developed tailoring testing according to the results of the available information, physico-chemical properties, the use and the exposure to the substance.

[10] 'Public Availability of Data on EU High Production Volume Chemicals' European Commission Joint Research Centre EUR 18996

Action 3C: Exposure-triggered testing

The current testing regime for new substances has been criticised for not taking sufficiently into account differences in the exposure to chemicals. Hence, the future system should include sufficient flexibility to waive or extend the needed testing as appropriate on the basis of particular exposure scenarios. For example, testing requirements for strictly controlled and rigorously contained intermediates should be reduced.

Action 3D: Exemptions for substances used in research and development

The volume threshold of 100 kg currently in place for research and development should be increased to 1 t. For substances undergoing process-oriented research and development, the current time period limit should be extended from one to three years. This three-year period should be extendable up to a maximum of five years.

Action 3E: Obligations for substances marketed as constituents of products

Current notification requirements cover substances placed on the market on their own or as constituents of preparations. Substances used and placed on the market as constituents of products (e.g. toys, textiles) other than preparations, however, are exempted. Nevertheless, most of the substances included in such products are covered as they are marketed either as such or as components of preparations before being included into products. However, some products, in particular products where the whole manufacturing process has been carried out outside the Community, may contain untested and unregistered substances. Where such substances may be released during use and disposal in significant amounts thus causing exposure of humans and of the environment, they cannot generally be neglected. The issue needs to be properly addressed.

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

3.2 Research and Validation

Development of alternative methods

International acceptance of results of animal tests has been a major breakthrough in minimising animal testing. This has been achieved by complying with methods developed by the OECD under its Test Guidelines Programme and obtained in accordance with the principles of Good Laboratory Practice. Once a company has carried out such a test, the results can be used for notification purposes in the Community as well as in Australia, Japan or the USA.

The Community has already taken steps to reduce duplicate testing: both Directive 67/548 and Regulation 793/93 contain provisions which avoid the need for different companies to carry out the same test. Chapter 5 describes actions to develop this approach further.

The Commission is fully committed to the legislation on the protection of animals used for experimental and other scientific purposes[11]. According to this legislation, experiments using animals must be replaced by other scientific satisfactory methods not entailing the use of animals, requiring fewer animals or causing less pain to the animals wherever possible.

---

[11] Council Directive 86/609/EEC, OJ L 358, 18.12.1986, p. 1

The following elements of the new system have been developed with a view to keep animal testing to a minimum:

- existing information on the toxicity and ecotoxicity of substances, including epidemiological studies, will be taken into account,
- the general testing requirements will be modified to incorporate exposure-driven testing where appropriate,
- tailor-made testing programmes for substances will be developed under the control of authorities for Level 1 and 2 testing,
- the development of further alternative testing methods using fewer or no animals will be fostered,
- existing substances will be grouped to minimise testing, where appropriate.

One of the major tasks of the European Centre for the Validation of Alternative Methods (ECVAM) of the Joint Research Centre of the Commission is to validate alternative methods that reduce, refine or replace animal experiments ('3 R approach'). Once these methods are established the Commission proposes their inclusion in the relevant Community legislation. Furthermore it submits them to the OECD Test Guidelines Programme, through which the Commission makes every effort to ensure that the methods are recognised internationally. Some international test methods have already been amended to reduce the number of animals required or the distress caused.

Research to minimise the use of animal tests and develop methods that do not require animal experiments is also a priority within the OECD Test Guidelines Programme, which is actively supported by the Commission.

Action 3 F: To foster research on development and validation of alternative methods both at the Community and at the level of Member States and to enhance the relevant information that can be obtained from testing without simultaneously increasing the number of animals involved.

ECVAM's central role will be maintained and the development of alternative methods should be accelerated. Further research will be carried out both at Community and national level in order to develop and validate novel testing strategies involving fewer or no animals and enhancing the relevant information that can be obtained from testing without simultaneously increasing the number of animals involved.

Other research priorities

In order to meet the goals of this White Paper, a continuous effort of research has to be made both at the Community and at the national level in order to cover the many knowledge gaps. At the community level, the Commission, through its Framework Programmes for Research, Technological Development and Demonstration, is supporting research in several other areas, like:

- Improvement and simplification of risk-assessment procedures.
- Improvement and development of new toxicological and eco-toxicological methods;
- particular research efforts need to be made for developing and validating in-vivo and in-vitro test methods as well as modelling (e.g. QSAR) and screening methods for assessing the potential adverse effects of chemicals on endocrine systems of humans and animals. Research on endocrine disrupters is also – among others - addressing the effect of low doses, long term exposure and exposure to mixtures of chemicals, and the impact of the endocrine alterations on carcinogenesis.

- Development of clean chemical production processes to reduce and to eliminate the use and generation of hazardous substances.
- Research on improved Life Cycle Assessment methodologies for chemicals.

3.3 Exposure and Use

Adequate knowledge about exposure is an absolute requirement for any reliable risk assessment. However, the process under Regulation 793/93 highlighted a general lack of knowledge on the exposure to the existing substances under review. Furthermore, in many cases, the Member State authorities responsible for the assessment were not able to establish all the relevant uses of these chemicals. This lack of knowledge and restricted access by authorities to these data hampers efficient surveillance of the chemical sector.

Action 3 G: Obligation of manufacturers, importers and downstream users to assess exposure

The general shortage of exposure data must be addressed. Exposure estimates or, if appropriate, analytical determination of the exposure should be obligatory for manufacturers and downstream users (formulators and industrial users) of chemicals. Further detail on this proposal is given in chapters 4 and 5.

Action 3 H: Information system on environmental concentrations

An information system should be established on environmental concentrations and releases. Monitoring data ascertained by the Member States or by industry should be made available in an easily accessible form.

3.4 Cost and benefit

It is estimated that base-set testing will cost about € 85,000 per substance. The cost of long-term testing is more uncertain as there is less experience. However, level 1 testing for new substances costs approximately € 250,000 per substance and level 2 testing costs approximately € 325,000 per substance. It would not only be EU industry that has to pay these costs: everyone who imports substances into the Community would make a fair contribution to these costs ensuring a global approach, see section 5.5 below. It is estimated that the testing of the approximately 30,000 existing substances would result in total costs of about € 2.1 billion, over the next 11 years until 2012.[12]

The administrative costs of the system will be recovered through a fee-based system.

As a result of the systematic testing of new substances about 70% have been identified as being dangerous. On the other hand, as little is known about the intrinsic properties of existing substances it can be assumed that the majority of these chemicals cannot be properly classified today and adequate risk management measures cannot be taken. Introducing mandatory testing for these substances would generate the necessary information to substantially improve the risk management for existing substances. If as a result the adverse impacts could be even slightly reduced, the money spent for these tests would have proven to be well spent.

The potential benefits of this policy would stem from improved risk management, in all likelihood leading to safer handling of substances, and to less exposure of consumers and

---

[12] A net increase in public resources is not expected since the REACH model refocuses the resources and removes resource intensive tasks from the authorities (general conformity check for substances below 100 t, comprehensive risk assessment on existing substances).

the environment to dangerous substances. Although it is difficult to estimate accurately and in monetary terms the potential benefits from this change some indications are possible. Indeed, if as a result of this improved risk management some human lives could be saved or the incidence and prevalence of allergic or chronic diseases could be reduced by some percent the money would have been well spent.[13] Further details are given in annex I.

4. A NEW SYSTEM OF CHEMICALS CONTROL – THE REACH SYSTEM

The current volume-triggered notification system for new substances has resulted in substantial and reliable knowledge about these chemicals. However, it involves a considerable workload for the authorities requiring a large amount of their resources even though all this effort only addresses a limited part of the chemicals on the market. Existing substances dominate the market over new substances by a factor of 15. The challenge therefore is to establish a system that can cope with the large number of existing substances. The overriding goal must be to ensure adequate information, made publicly available, and appropriate risk management of existing and new substances within the timeframe set out in chapter 6.

Action 4: To establish a single coherent system focussing public resources on those substances, where, according to experience, the involvement of authorities is indispensable and the added value in terms of the provision of safety is substantial.

The system, called REACH, will be composed of the following three elements:

(a) **Registration** of basic information for around 30,000 substances (all existing and new substances exceeding a production volume of 1 t) submitted by companies in a central database. It is estimated that around 80 % of these substances would only require registration;

(b) **Evaluation** of the registered information for all substances exceeding a production volume of 100 t (around 5,000 substances corresponding to 15 %) or, in case of concern, also for substances at lower tonnage; the evaluation will be carried out by authorities and include the development of substance-tailored testing programmes focussing on the effects of long-term exposure;

(c) **Authorisation** of substances with certain hazardous properties that give rise to very high concern (CMR substances[14] (categories 1 and 2) [15] and POPs). Authorisation requires authorities to give a specific permission before a substance can be used for particular purposes demonstrated to be safe. The number of substances subject to authorisation is estimated at 1,400 (5% of the registered substances). This estimate is based on

- 850 substances currently classified as CMR substances (categories 1 and 2)
- Substances with POPs characteristics[16]
- 500 additional CMR substances (categories 1 and 2) which may be identified through future testing.

---

13 The German 'Sachverständigenrat für Umweltfragen' (Advisory Council on the Environment) estimated in 1999 that the socio-economic costs of allergies alone for Europe were € 29 billion per year.

14 **C**arcinogenic, **m**utagenic or **r**eprotoxic substances;

15 As defined in Directive 67/548

16 As laid down in the future Stockholm convention on POPs (see chapter 2.3)

The REACH-system will be applied to new and existing substances. However, in contrast to new substances, a transitional period of 11years is required to phase in the large number of existing substances. In general, existing substances produced in higher volumes will have to be registered first. Yet the system will be flexible enough to allow for earlier registration of substances of concern produced in lower tonnage. The work programme and timetable for the transitional phase is described in detail in chapter 6.

4.1 Registration

Registration requires a manufacturer or importer to notify an authority[17] of the intention to produce or import a substance and to submit a dossier containing the information required by the legislation. The authority puts this information into an electronic database, assigns a registration number and performs spot-checks and computerised screening of the registered substances for properties raising particular concern.

Registration will be obligatory for new and existing (according to the time table set out in chapter 6) substances produced in volumes exceeding 1 t. The currently required general conformity check for new notified substances above 1 t will be replaced by spot-checks and computerised screening. The registration dossier will include the following information:

- Data/information on the identity and properties of the substance (including data on toxicological and ecotoxicological properties as set out in chapter 3),
- Intended uses, estimated human and environmental exposure,
- Production quantity envisaged,
- Proposal for the classification and labelling of the substance,
- Safety Data Sheet,
- Preliminary risk assessment covering the intended uses,
- Proposed risk management measures.

4.2 Evaluation

Evaluation requires authorities to carefully examine the data provided by industry. It also requires them to decide on substance-tailored testing programmes, following industry proposals, as set out in chapter 3 .

Substances above 100 t: When the quantity produced or imported reaches 100 t or 1,000 t (or, for existing substances, already exceeds these volume thresholds), the manufacturer or importer will be required to submit to an authority all available information and to propose a strategy for further testing based on the general information requirements defined in the legislation. The authority will evaluate the information and the testing strategy submitted by industry and will decide on the appropriate course of action.

In essence, the current approach for new substances will be maintained for substances above 100 t. The availability of a risk assessment drawn up by the manufacturer or importer will reduce the workload of the authorities. Testing programmes at Level 1 (100 t) and Level 2 (1,000 t) will be substance-tailored as set out in chapter 3.

---

[17] Chapter 8 sets out the allocation of responsibilities between the Member States authorities and the Commission

Substances below 100 t: Substances which are suspected to be persistent and liable to bioaccumulation, substances with certain hazardous properties such as mutagenicity or high toxicity, or substances with molecular structures giving rise to concern (e.g. identified by quantitative structure activity relationships, QSAR) will require an evaluation by the authorities at volume levels below 100 t. Based on this evaluation, immediate safety measures and/or further testing may be needed. Thus, the authorities' right to request additional information for low volume substances on a case by case basis, as possible under the current notification system, will be retained. Furthermore, authorities should be empowered to require additional testing, when the aggregate volume produced and/or imported by all manufacturers and/or importers exceeds the next higher tonnage threshold for a single producer or importer to a considerable degree.

4.3 Authorisation of substances of very high concern

For substances of very high concern, authorities will have to give a specific permission before such a substance can be used for a particular purpose, marketed as such or as a component of a product. The scope will be clearly defined and strict deadlines will be set for both industry and authorities.

Substances subject to authorisation: The following new and existing substances, including those produced in volumes below 100 t, which either have hazardous properties giving rise to very high concern will be progressively subjected to an authorisation regime. However, uses that do not give rise to concern will generally be exempted:

- Substances that are carcinogenic, mutagenic or toxic to reproduction (CMR substances categories 1 and 2)
- Substances with POPs characteristics[18].

Further research: Further research is needed to develop criteria for the identification of PBT and VPVB[19] substances other than POPs. The Commission will decide at a later stage how substances with these properties should be treated.

Endocrine disrupters: The majority of the endocrine disrupting chemicals would have to undergo authorisation in the REACH system. Serious human health effects which have so far been associated with endocrine disrupting chemicals are testicular cancer, breast cancer, prostate cancer, decrease in sperm concentration and semen volume, cryptorchidism, hypospadia and impaired development of the immune system and the nervous system. All these effects would qualify a substance either to be classified as carcinogenic or as toxic for reproduction and so would trigger its submission to authorisation. Furthermore, adverse effects on the endocrine system of wildlife species have been causally linked to certain POPs, which will be subject to authorisation.

Implementation of the authorisation process: A substantial number of substances qualifying for authorisation will be identified only through Level 1 and Level 2 testing when they are already used in substantial amounts. In order to allow for implementation of the authorisation procedure, transition periods to generate the required information and to draw up the dossiers for authorisation are necessary. Also, the time period needed to decide

---

[18] Fulfilling the criteria defined in annex D of the future Stockholm Convention on POPs (see chapter 2.3)

[19] substances which are persistent, bioaccumulative and toxic, substances which are very persistent and very bioaccumulative

upon the authorisation needs to be taken into account. A two-step decision-making process is therefore proposed:

- Step 1 - identification of the substances, or particular uses of substances, which will be subject to authorisation. Once identified, a precise date when all unauthorised uses of the substance will be prohibited. Furthermore, step 1 will identify, as appropriate, the scope of the uses to be exempted generally from the requirement for authorisation. Relevant substances will be fed into the system as soon as practicable, with substances of most concern being considered first.
- Step 2 - particular uses of a substance will be authorised on the basis of a risk assessment submitted by the applicant to the authorities. This assessment will cover the whole life-cycle of the substance, including disposal, with respect to the particular use. Manufacturers and importers will be permitted to submit jointly this information and/or to submit simultaneously for the use of several substances (group applications). The authorities will generally not require the applicant to carry out further testing but to establish the required exposure data to allow authorities to take a decision. An authorisation will be granted if the use presents a negligible risk. A conditioned authorisation may be granted if this is justified by the overall socio-economic benefits arising from the use. The authorities will be required to decide upon the authorisation within a reasonable time from submission of the risk assessment to avoid banning of substances by default.

Exemptions: Uses which do not give rise to concern - such as well controlled industrial uses or uses in research laboratories - may be subject to general exemptions from the authorisation procedure.

Pro-active role of industry: The current approach requires authorities to provide convincing arguments, usually in the context of a risk assessment, before restriction measures are taken. Their task is further complicated because the current system does not encourage industry to support the assessment. On the contrary, delaying the process is "rewarded" with an extended marketing period. Industry has usually provided data when such data were deemed suitable to avoid the restrictions under consideration. An apparent lack of data aggravates the situation and often leads to a risk assessment conclusion that ‘further information is required’ before an informed decision on risk management can be taken. Other delays are caused in cases where analytical methods must be developed to check compliance with a potential restriction. Authorities have to carry the main burden of the development of the analytical methodology. Such an approach is not amenable to attaining a high level of safety.

Authorisation, in contrast, requires industry to take a pro-active role in the evaluation process. If analytical tools need to be developed to control exposure, their availability should be a prerequisite for authorisation.

Increased flexibility: At the authorisation stage, a consideration of the socio-economic impact may be required. In contrast to the current system, which requires authorities to carry out cost/benefit analyses, the producer or user of the substance should be obliged to provide information substantiating any claim that the benefits from the continued use of a substance outweighs the potential adverse effects on human health and the environment. The REACH-system offers clear advantages to industry. Currently, Directive 76/769 restricts certain uses of substances without providing a mechanism to reverse such provisions on a case by case basis. In this perspective the REACH-system offers increased flexibility on condition that adequate safety measures are taken. It is more open to technological developments and will lead to a custom-tailored safety net for problematic substances.

4.4 Accelerated risk management of other substances

Specific uses of substances which do not have one of the properties listed under the authorisation system but for which restrictions are needed should be addressed in an improved and accelerated procedure.

Accelerated risk assessments: the following four elements will bring about the necessary acceleration of assessments:

(1) Due to the registration requirement of all chemicals above 1 t there will be extensive data available on the health and safety properties of all substances marketed (see chapter 5 below).

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

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

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

These four factors taken together will substantially reduce the time needed for assessment.

Accelerated legislation: two factors will contribute to an acceleration of the legislative process:

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

(2) A further acceleration is needed in order to proceed to risk management decisions for other substances in a reasonably short time frame. Thus, the Commission should be authorised to use the Committee procedure under Directive 76/769 more extensively than in the past.

This approach would take account of the full range of implications of possible restrictions; in particular, it would consider whether possible substitutes are more or less dangerous.

5. ROLE, RIGHTS AND RESPONSIBILITIES OF INDUSTRY

There is already legislation in place along the whole manufacturing chain generally allocating the responsibility for the safe use of chemicals to manufacturers and users of

chemicals. Directive 92/59/EEC on General Product Safety[20] extends the responsibility to products intended for consumer use, which should not present unacceptable risks under normal or reasonably foreseeable conditions of use. The review found that this general allocation of responsibilities has not led to a satisfactory evaluation of the safety of chemicals. Additional legal provisions stating more precisely the obligations of industry are essential. These provisions shall include ensuring that the substances they place on the market are safe for their intended use, irrespective of the tonnage produced.

5.1 Data Generation

The current system only established duties for producers and manufacturers to test chemicals, but not for downstream users. The role of downstream users in testing of chemicals needs to be further considered.

Action 5A: Obligation of downstream users to perform testing

Downstream users must assume responsibility for the safety of their products. Authorities should be empowered to require downstream users to carry out additional testing where uses differ from those originally envisaged by manufacturers or importers and the resulting exposure patterns also differ substantially from those evaluated by them. Additional testing programmes should be developed in close consultation with the authorities.

5.2 Risk/safety Assessment

Directive 67/548 and Regulation 793/93 oblige the authorities to carry out risk assessment. This imposes a considerable burden on them, particularly in assessing existing substances. As industry is responsible for safe use and disposal of chemicals and risk assessment is the preferred method to assess safety, the current work distribution between authorities and industry is inappropriate. Chemicals are used in millions of products so it is impractical for authorities to perform or be involved in these assessments. Instead, the Commission believes that, as the Council suggested, authorities should focus on areas of *major* concern.

Action 5B: Manufacturers and downstream users to perform risk assessment

Industry should have responsibility for performing risk assessments. This will require the manufacturer or importer as well as the downstream user to carry out adequate risk assessments for substances and preparations.

5.3 Information to be provided by Industry to the Authorities

Industry should provide authorities with information about all substances as set out in Chapter 4. Below the Chapter 4 thresholds, industry should generate the necessary safety data and keep the records available.

Action 5C: Obligation of downstream users to inform authorities

The Commission proposes that the authorities must be informed about any downstream use which has not been envisaged by a manufacturer or importer and which has not therefore been addressed in the preliminary risk assessment.

---

[20] OJ L 228, 11.8.1992, p.24

5.4 Information to be provided by manufacturers and importers to downstream users, other professional users and consumers

Information relevant for the safe use of chemicals must be available to all users, including consumers. Fundamentally, the safety system depends on the quality and the comprehensibility of the information passed on down the production chain. *Safety data sheets and the Labelling of the packaging* are the main carriers of this information. Shortcomings have been identified in both information systems. Safety data sheets are considered below while *classification and labelling* is addressed in chapter 7.

Action 5D: Information to industrial and professional users through safety data sheets

Safety data sheets are generally considered to be suitable communication tools to provide safety information to users, in spite of the noted shortcomings. The Commission proposes to establish a working group of Member States experts including participation of the European Chemicals Bureau to advise it on:

- ensuring better quality of safety data sheets,
- examining the current information requirements with a view to expand them in order to enable users to carry out risk assessment.

5.5 Property rights for test data

The specific provisions in Directive 67/548 and Regulation 793/93 for the sharing of test data and testing costs were designed to avoid duplicate animal testing. However, such provisions also have a benefit for industry because they reduce the overall testing costs. Furthermore, legislation for sharing of test data and the costs of testing is essential to ensure fair competition, otherwise some companies might delay testing in the hope that competitors producing the same substance would be obliged to do it before them and pick up the full costs.

The introduction of exposure-triggered testing and new obligations on downstream users to test could accentuate this problem. For example, if a downstream user carried out additional testing because of substantially different exposure patterns than those foreseen by a manufacturer of the substance, the latter might use these data to enlarge the scope of the uses of the substance. This would increase the number of potential customers and the marketed volumes, in some cases at a disadvantage to the original downstream user. Such a system would encourage the manufacturers to strictly limit the number of intended uses to a minimum, waive testing as far as possible and wait for downstream users to complete the testing. This would be a clear distortion of the market.

Action 5E: Property rights for test data

Anybody who generates testing data under the new system should be encouraged to share them and anyone who uses such data obliged to pay a fair and equitable contribution to the generator of the data.

Action 5F: Discouragement of duplicate testing

Specific provisions should be included in the legislation that duplicate tests involving vertebrate animals should be avoided. Any duplicate testing will not result in an exemption from the duty to reimburse the party who owns the property rights for the first test.

6. TIMETABLE FOR EXISTING SUBSTANCES

The testing and evaluation of the large number of existing substances on the market requires a phased approach. This chapter describes the necessary provisions and a timeframe for the testing and evaluation of existing substances. It also addresses the future role of the authorities in risk assessment.

Action 6A : Tiered approach for registration

Precise deadlines will be established for the submission of registration dossiers for existing substances. In general, substances produced in higher volumes will have to be registered first. However, the system will be flexible enough to allow for earlier registration of substances of concern (e.g. intended for consumer use or having particular proven or suspected hazardous properties) produced in lower tonnage. Under these presumptions and given rapid progress in adoption of the revised legislation, the suggested deadlines for submission of registration dossiers are basically:

- substances exceeding a production volume of 1,000 t - at the latest by end of 2005,
- substances exceeding a production volume of 100 t - at the latest by end of 2008,
- substances exceeding a production volume of 1 t - at the latest by end of 2012.

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

Action 6B: Tiered approach for testing and evaluation of high production volume existing substances

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

Action 6C: Establishment of a task force to review available data

An advisory task force composed of around 15 Member States experts, should be seconded to the European Chemicals Bureau in the interim period before the new legislation is implemented. This task force will be assigned the following responsibilities:

- evaluation of the information of the IUCLID database submitted by industry for substances exceeding 1,000 t:
  - (a) examination of the proposed classification and labelling
  - (b) assessment of IUCLID information on properties, exposure and uses
  - (c) proposal of additional testing programmes in co-operation with ECVAM
- examination of the dossiers submitted to OECD under the ICCA voluntary initiative,
- recommendation of substances which should be grouped for registration or be exempted from the general obligation of registration.

7. CLASSIFICATION AND LABELLING

Current legislation requires that dangerous substances are either classified and labelled in accordance with Annex I of Directive 67/548 (*harmonised classification*) or, if they are not

included in this Annex, in accordance with the principles laid down in Annex VI of this Directive by industry (*self-classification*). Annex I covers around 5,000 dangerous chemicals and has been established over several decades.

Systematic evaluation of new substances has revealed that around 70 % of them are classified as dangerous (e.g. carcinogenic, toxic, sensitising, irritant, dangerous for the environment). In view of the large number of existing substances and assuming that a comparable percentage of them need to be classified, the establishment of a comprehensive harmonised list of all substances is not a viable option using the current approach.

Classification according to some hazardous properties has automatic consequences for the risk management of these substances (see chapter 3). To avoid ambiguities in respect of the required management measures, the new system must retain parts of the harmonised classification .

Action 7A: Restrict harmonised classification to the most relevant properties

Authorities' resources should be focussed on the most relevant hazardous properties, such as carcinogenicity, mutagenicity and reproduction toxicity (CMR), where classification gives rise to important risk management measures.

Action 7B: Commission to seek industry list of dangerous substances

The Commission will ask Industry to provide a list containing comprehensive information about the classification and the labelling of all dangerous substances on the market. This list should be made available on the Internet and be publicly accessible free of charge.

Action 7C: To simplify the current labelling system and improving comprehensibility through Globally Harmonised System.

The current negotiations on the elaboration of a Globally Harmonised System provides an opportunity to fundamentally review the current labelling provisions, to consider simplification and to improve comprehensibility of the labels.

8. ADMINISTRATION OF THE SYSTEM

This chapter summarises the administration of the REACH system presented in chapter 4.

8.1 Decision-making in the REACH system

There are basically two different kinds of decision to be taken under the REACH-system: decisions on the information to be submitted following the evaluation of the substances and decisions on risk management in the context of the authorisation procedure.

Decision-making at the Evaluation stage: The system must provide a mechanism to ensure that, on the basis of the preliminary risk assessments provided by industry, decisions on further information or substance-tailored testing programmes can rapidly be taken for a large number of substances. The procedure under Regulation 793/93 to request additional testing for existing substances from industry has proven extremely slow and cumbersome. Under the new system, the approach taken for new substances will be followed: Member State authorities will be responsible for deciding on the additional testing and a committee procedure will only be invoked in cases where agreement cannot be reached between Member States authorities.

Decision-making

Decision making at the authorisation stage: Depending on the anticipated impact of a substance, an authorisation for actual use should either be granted by Member States or by a decision at Community level. Member States should grant authorisations for uses, which mainly need to be considered for their potential impact on workers and on the local environment. In contrast, the authorisation of the use of a substance of concern in products marketed in the Community may have a wider impact on human health or the environment as well as on the functioning of the internal market. This would imply that a Community-wide decision on the actual use of a substance is justified.

As described in chapter 4, the authorisation would encompass a two step procedure:

- Step 1 - the identification of substances or particular uses of a substance which will be subject to future authorisation, establishing a precise date when all uses which have not been authorised will be prohibited;
- Step 2 - the actual authorisation of particular uses.

Given the Community-wide internal market impact of prohibiting the use of a substance, the step 1 decision, together with identification of the uses that Member States may authorise, should be taken at Community level. Step 2, the authorisation of specific uses, would be taken at the appropriate level defined in step 1. Generally, a committee driven mechanism will be applied for all decisions taken at Community level.

Decision making in the accelerated risk management procedure:

The accelerated risk management procedure will work as follows:

- Step 1 - the identification of substances or particular uses of a substance which will be subject to future restriction, defining the scope of the restriction,
- Step 2 - the actual decision restricting or banning the use of the substance.

Given the Community-wide internal market impact of prohibiting the use of a substance, both decisions should be taken at Community level. Step 2 would imply legislation in the framework of a modernised Directive 76/769. Generally, a committee driven mechanism will be applied for all decisions taken at Community level. It would leave present working arrangements intact.

8.2 Establishment of a central entity

The Commission proposes at this stage to establish a central entity (an expanded European Chemicals Bureau) for the administration of the REACH-system and the provision of technical and scientific support. Building on its existing experience, the expanded European Chemicals Bureau should be a receiving body for the registration dossier, and forward the copies of the registration dossiers to the Member State authorities, establish and maintain a comprehensive central database on all registered chemicals, perform spot-checks and computerised screening of the registered substances for properties raising particular concern. It will also support Member States authorities in the evaluation of substances.

The central entity will provide access to non-confidential submitted information for the general public and establish an efficient and secure data exchange network with Member States for commercially sensitive information. It should support and co-ordinate the Member States with respect to the decision-making at the evaluation stage in order to ensure a coherent approach. Furthermore, the European Chemicals Bureau would provide the operational framework for the authorisation procedure and seek the views of Member State experts and of the CSTEE . Prior to the establishment of the central entity, the Commission will carry out a feasibility study and a cost/benefit analysis.

8.3 Role of Member States

Member States authorities would broadly retain their current responsibilities. They would be collectively responsible for substance registration and evaluation, similar to their current responsibilities for new substances notifications. Better consistency of decisions between Member States authorities would be achieved by the co-ordination through the European Chemicals Bureau and by developing guidelines for substances-tailored testing. The experience gained by the task force (see chapter 6) will help to prepare such guidelines.

To rectify the current unequal workload distribution between Member States authorities, the registered substances will be allocated to Member States on a proportionate basis. Current provisions concerning information exchange and the option to invoke a committee procedure in cases where agreement cannot be reached between Member States authorities should be retained.

9. INFORMATION TO THE PUBLIC

The Commission has consulted and involved all stakeholders and in particular the NGOs representing consumer interests. Full openness is essential if the public is to understand the intended benefits of the Strategy and to ensure the Commission has addressed the public interest. The Commission is therefore committed to ensuring the continued involvement of stakeholders representing the full range of interests in the implementation, management and review stages of the Strategy.

EU citizens should have access to information about chemicals to which they are exposed. Information must be presented in such a way that it enables a person to understand the risks and to develop a sense of proportion in order to make a judgement on the acceptability of those risks. Better public access to information on chemicals will increase public awareness and will lead in turn to greater accountability on the part of industry and authorities. The Commission already publishes an up-to-date multi-lingual collection of chemical substances data and this could be further developed. Furthermore, indicators on the risk of chemical use should be established.

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

The findings of the review highlighted the need of consumers for information about the health effects, environmental effects, other serious hazards and safe instructions for use of chemical products. The Commission believes that industry, including downstream users, should mainly be responsible for providing this information to consumers. This will lead to better informed purchasing decisions about such products.

There is currently no central tracking system by which the public can determine whether regulatory measures are in place or in progress for individual chemicals. There is a lack of public awareness of the requirements of current chemicals legislation. The new system should be more easily understood by the general public helping to address this lack of awareness.

Action 9A: Stakeholder access to non-confidential information in the new-system database

All stakeholders, including the general public and SMEs (small and medium sized enterprises employing less than 250 workers), should have access to the non-confidential information on the central system database (see Chapter 4). Easy to read summaries for

substances will promote use by the general public. These summaries will include a short profile of the hazardous properties, labelling requirements and relevant Community legislation, including authorised uses and risk management measures.

10. IMPLEMENTATION AND ENFORCEMENT

The Commission proposes to review the effectiveness and the efficiency of the chemicals strategy following implementation of the new legislation. The review will include an element of testing and questioning of all stakeholders.

Member States will be responsible for the enforcement of the new legislation in their territories. However, a number of enforcement projects and studies have highlighted shortcomings in compliance by industry of the current legislation on chemicals and inconsistencies in the level of enforcement activities by the Member States. Even if non-compliance can be demonstrated and damage to human health or environment has occurred, compensations awarded by courts of EU Member States often have a limited deterrent effect. The Community must address these problems by requiring Member States to establish dissuasive, effective and proportionate sanctions.

Recent studies in the Netherlands and the United Kingdom found high levels of non-compliance with the Safety Data Sheets legislation. Flaws in compliance and enforcement activities related to current legislation for new and existing substances were also noted by recent Community-wide enforcement projects (SENSE, NONS and EUREX[21]).

Action 10 A: Review of the chemicals policy

The Commission proposes to review the effectiveness and the efficiency of the chemicals policy including all the different elements that constitute its information policy, following implementation of the new legislation. The review will include an element of testing and questioning of all stakeholders.

Action 10B: Network of Enforcement Authorities

The Commission proposes to create a network of the Member States and Candidate Countries authorities responsible for enforcement of new legislation on chemicals to spread good practice and to highlight problems at Community level. This will be of increased importance when the current Candidate Countries join the Community, thus enlarging the Internal Market. One of the issues this network will be asked to consider is the need to develop minimum criteria for enforcement of the proposed legislation in the Member States. Such criteria might be set out in a Commission Recommendation in future.

---

[21] Referring to Dir. 92/32/EEC, EUREX found (of 1,400 substances at 178 companies) only a small fraction of companies directly broke the legislation but companies could not identify around 30% of substances as either ‘new’ or ‘existing’. This was similar to findings of the SENSE and NONS projects.

GLOSSARY OF TERMS AND ABBREVIATIONS

Burden of the Past: The 30,000 'existing' chemicals estimated to be on the EU market, for which little or no information is available, in particular about their long-term effects on human health or the environment.

Chemicals: General term to cover both substances and preparations (see separate entries).

Competent Authorities: A national authority or authorities designated by each Member State to implement legislation.

CMR chemicals: Chemicals classified as carcinogenic, mutagenic or toxic to reproduction under Directive 67/548 (see 'legislation').

CSTEE: Scientific Committee on the Toxicity, Ecotoxicity and the Environment of the Commission.

Downstream users: Formulators and industrial users of chemicals.

ECVAM: the JRC's European Centre for the Validation of Alternative Methods.

ELINCS: European List of Notified Chemical Substances. ELINCS, currently contains some 2,700 substances and is an ever expanding list, following notification to Competent Authorities of the placing of a 'new' substance on the market.

EINECS: European Inventory of Existing Commercial Chemical Substances, deemed to be on the EU Market between 1 January 1971 and 18 September 1981. It is a closed list of 100,106 'existing' chemicals governed by Regulation 793/93 (see 'legislation').

Existing substances: Substances in use within the EU before September 1981 and listed in EINECS. EINECS contains 100,106 entries including chemicals, substances produced from natural products by chemical modifications or purification, such as metals, minerals, cement, refined oil and gas; substances produced from animals and plants; active substances of pesticides, medicaments, fertilisers and cosmetic products; food additives; a few natural polymers; some waste and by-products. They can be mixtures of different chemicals occurring naturally or as an unintentional result of the production process.

'Existing' substances do not include: synthetic polymers (which are registered in EINECS under their building block monomers), intentional mixtures, medical preparations, cosmetic preparations and pesticide preparations as intentional mixtures; food; feedstuffs; alloys, such as stainless steel (but individual components of alloys are included); most naturally occurring raw materials, including coal and most ores.

Global Harmonisation: The Community together with its trading partners is committed to developing a global system for managing chemicals. Work is underway with the candidate countries for accession to the EU, in the framework of the OECD and at a global level in the framework of the United Nations.

Hazard assessment: Hazard identification and establishment of dose-response relationship for observed adverse effects in the specified (eco)toxicological endpoints.

Hazard identification: Identification of the adverse effects that a substance has the inherent capacity to cause.

HPV chemicals: High Production Volume chemicals. Chemicals placed on the EU market in volumes exceeding 1000 tonnes per year per manufacturer or importer.

ICCA: International Council of Chemical Associations.

IFCS: Intergovernmental Forum on Chemical Safety.

ILO: International Labour Organisation.

IUCLID: International Uniform Chemical Information Database. A Commission database used to store and distribute information collected under Regulation 793/93.

JRC: Joint Research Centre of the Commission.

Legislation: Reference in the White Paper mainly refers to four legal instruments on chemicals currently in force in the Community:

- Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended,
- Directive 88/379/EEC relating to the classification, packaging and labelling of dangerous preparations, recently replaced by 1999/45/EC,
- Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances,
- Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.

LPV chemicals: Low Production Volume chemicals. Chemicals placed on the market in volumes between 10 tonnes and 1000 tonnes per year per producer/importer.

New substances: Substances not in use in the EU before September 1981 and so not in EINECS. They must be notified before being placed on the market, after which they are registered in ELINCS. New substances are governed by Directive 67/548, as amended by Directive 92/32.

NGOs: Non-governmental organisations representing particular stakeholders' interests (e.g. consumers, environment).

Notification procedure for a new substance: Submission of a technical dossier by industry to a Competent Authority, containing information specified by Directive 67/548, as amended by Directive 92/32 (see 'legislation').

OECD: Organisation for Economic Co-operation and Development.

OSPAR: Oslo - Paris Convention for the Protection of the Marine Environment of the North East Atlantic.

PBT chemicals: Persistent, bio-accumulative and toxic chemicals.

POPs: Persistent Organic Pollutants.

Precautionary Principle: This principle is contained in Article 174 of the Treaty and the subject of a Commission Communication of 2 February 2000. It applies when there is a preliminary objective scientific evaluation indicating reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community.

Preparations: Intentional mixtures or solutions composed of two or more chemicals. They are governed by Directive 88/379/EEC, recently replaced by Directive 1999/45/EC.

QSAR: Quantitative Structure Activity Relationship. Models used to predict the properties of chemicals from the molecular structure.

REACH System: Registration, Evaluation and Authorisation of Chemicals.

Regulatory Committee: A committee composed of representatives from the EU Member States and chaired by the representative of the Commission. Its opinion is delivered by a qualified majority.

Risk Assessment: A process to determine the relationship between the predicted exposure and adverse effects in four steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation. See also 'targeted risk assessment'.

Risk characterisation: Estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance.

SIDS: Screening Information Data Set (SIDS) outlining the minimum data elements for determining whether an existing HPV chemical requires further investigation in the OECD's HPV/ICCA programme.

SMEs: Small to medium size enterprises employing less than 250 workers.

Substances: Substances are chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. While ingredients of pesticides, biocides, medicaments or cosmetics might be included in this definition, intentional mixtures or preparations of them for final use would not.

Sustainable Development: Enshrined in Articles 2 and 6 of the Treaty, it was defined by the World Commission on Environment and Development (the Brundtland Commission) as development that 'meets the needs of the present generation without compromising the ability of future generations to meet their own needs'. This objective includes the economic, social and ecological aspects of development as set out in the Final Document of the 19th Extra Session of the UN General Assembly, which was held on 23-27 June 1997. These three aspects are mutually dependent, and in order to achieve sustainable development they must be integrated and taken into account in a balanced manner. These notions are at the core of the Fifth EU Environment Action Program 'Towards Sustainability' and the Cardiff Strategy on Integration.

Targeted risk assessment: A less extensive, more specifically focused evaluation (because of a specific concern) than a comprehensive risk assessment.

Tiered Approach: Proportionate effort in relation to the volumes, intrinsic properties, exposure and/or use of chemicals; see chapter 3 for further explanation.

UN: United Nations.

UNCED: UN Conference on Environment and Development at the 1992 Earth Summit in Rio.

VPVB chemicals: Very persistent and very bio-accumulative chemicals.

WHO: World Health Organisation.

ANNEX I

Costs and Benefits of the new Chemicals Policy

Model
• Single coherent system for all chemical substances. REACH model (registration, evaluation and authorisation/rapid restriction of chemicals); • Management by Member States and European Chemicals Bureau (ECB).
Coverage
• 30,000 existing substances (= all existing substances above 1tonne/year/manufacturer); • Acute and long-term toxicity tested. Tailor-made testing for long-term effects (such as cancer, reproductive effects) for substances above 100 tonne/year/manufacturer; • Waiving of testing on due justification, all available test data used and registered; • Reduced testing for low exposure substances and R&D (research and development) substances. • Limited in vitro testing for substances between 1 and 10 t.
Costs
Cost of action. It is very difficult to give a reliable estimate of the "cost of action" implied, such as for the testing of existing substances where availability of test data generated earlier is largely unknown. However, a first estimate is given in the following. • **Testing costs for existing substances.** € 2.1 billion over *11 years* = € 0.2 billion/year, to be borne by the chemicals industry. • **Human resources for an expanded European Chemicals Bureau (ECB).** A staff of 190 people at the ECB to provide the technical and administrative framework. • **Public human resources in the Member States.** Member States will reallocate their current staff. Extra resources will be allocated to evaluation of existing substances. These resources will be freed from their current tasks by the following measures: – Computerised screening and sport checks will replace the current general conformity check for new substances below 100 t – Risk assessments will generally be carried out by industry rather than authorities – in view of the expanded ECB and the reduced efforts needed for the authorisation process instead of the current restrictions process under Directive 76/769. • **Industry human resources.** An estimate is hardly possible because an increase can be expected for processes such as the authorisation process, but a reduction can be expected because of – no notification of substances between 10 kg and 1 tonne/year/manufacturer; – less strict requirements for certain substances such as intermediates with low exposure; – less strict requirements for R&D substances (research and development). (The staff for the testing of existing substances is already covered by the above-mentioned testing costs.)

Benefits

- **Better protection of the environment and human health** through appropriate risk management based on adequate information about the dangerous properties of chemicals. This will reduce the incidence of certain diseases related to chemicals (such as cancer or allergies) and reduce the risks that chemicals can pose to the environment (such as through the accumulation of persistent chemicals in the food chains). The main difficulty is that neither the dangerous properties nor the uses of chemicals are sufficiently known. For illustrative purposes reference is made to allergies.
- **Allergy costs** are estimated at € 29 billion/year in Europe[22]. Chemical substances are considered to play a major role in inducing allergies either directly or by increasing susceptibility to natural allergens (e.g. pollen). For example a US study has shown that asthma cases have risen by 40% since the 1970s. If the new strategy makes even a small reduction in the € 29 billion of allergy costs, this will outweigh the costs of the strategy.
- Improved framework for **innovation** in the chemicals sector. This will
  - contribute to the development of novel chemicals that may **substitute** current chemicals of concern, thus decreasing the risks from chemicals;
  - strengthen the **competitiveness** of the EU chemicals industry.
- Increased **transparency** and better access of the public to information, thus enabling them to make an "informed choice" about the chemicals they want to use.

[22] The German 'Sachverständigenrat für Umweltfragen' (Advisory Council on the Environment) estimated in 1999 that the socio-economic costs of allergies alone for Europe were € 29 billion per year.