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REPORT
ON THE OPERATION OF

DIRECTIVE 67/548/EEC ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES

DIRECTIVE 88/379/EEC ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS PREPARATIONS

REGULATION (EEC) 793/93 ON THE EVALUATION AND CONTROL OF THE RISKS OF EXISTING SUBSTANCES

DIRECTIVE 76/769/EEC ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS OF THE MEMBER STATES RELATING TO RESTRICTIONS ON THE MARKETING AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS

REPORT

ON THE OPERATION OF

DIRECTIVE 67/548/EEC, DIRECTIVE 88/379/EEC, REGULATION (EEC) 793/93 AND DIRECTIVE 76/769/EEC

1. INTRODUCTION

The objective of this Commission Working Paper is to report on the evaluation of the operation of

- Council Directive 67/548/EEC[1] on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended;
- Directive 88/379/EEC[2] on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations;
- Council Regulation (EEC) 793/93[3] on the evaluation and control of the risks of existing substances;
- Directive 76/769/EEC[4] on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. These four legal instruments govern industrial chemicals in the Community.

Legislation has been in existence since 1967 when it was recognised that provisions relating to the classification, packaging and labelling of substances on the market, in particular dangerous industrial chemicals, should be harmonised throughout the Community in order to eliminate the barriers to trade that national provisions in the Member States could represent. Since then, a range of legislative instruments have been established in the Community, which seek to achieve and maintain a high level of protection of human health and the environment in the context of the Internal Market.

It was only in 1979 that the environmental protection requirement was introduced into the then existing legislation[5]. At the same time, in order to ensure a control of

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[1] OJ 196, 16.8.1967, p. 1.

[2] OJ L 187, 16.7.1988, p. 14

[3] OJ L 84, 5.4.1993, p. 1.

[4] OJ L 262, 27.9.1976, p. 201

[5] OJ L 259, 15.10.1979, p. 10.

the chemical substances to be placed on the market, it was decided to establish a notification system for "new" substances as from 1981.

Currently there is wide-spread public concern about the effects of chemicals on human health and the environment as well as the fear about new potential threats as in the case of endocrine disrupters. This concern is exacerbated by the so-called "burden of the past". Since the notification procedure has only been in place since 1981, all chemicals marketed prior to that date have never been scrutinised according to this procedure. Thus, for the majority of these chemicals few data are available. The immediate concern is therefore that man and the environment are potentially exposed to a large number of chemical substances for which the hazardous properties have not been identified and/or the risks have not been assessed.

The recent follow-up Report to the 1995 "Dobris assessment"[6] on the changes in the pan-European environment highlights the concern about toxicity and bio-accumulation aspects of chemicals, in particular pesticides, as well as the need for appropriate policy responses to the possible human and ecological impacts caused by chemicals.

2. THE EVALUATION

The evaluation of these instruments covers their effectiveness and efficiency in terms of their specific objectives, which cover the protection of human health and the environment as well as the elimination of barriers to trade. It provides an assessment of their operational weaknesses and identifies issues for further consideration in view of improvement. The findings also refer to the link-up with existing risk management measures. The detailed findings on the implementation of Directive 67/548, Directive 88/379, Regulation 793/93 and Directive 76/769 are attached as Annexes 1, 2, 3 and 4 respectively.

For the purpose of the evaluation it is essential to clarify the distinction between "new" and "existing" chemicals, since they are governed in the Community by different legal instruments.

According to Regulation 793/93 "existing" substances means chemical substances in use within the EU before September 1981 and listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). EINECS contains 100,106 entries including: industrial chemicals, substances produced from natural products by chemical modification 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; and, some waste and by-products. They can be mixtures of different chemicals occurring naturally or as a result of the production process.

"New" substances are industrial chemicals which are not listed in EINECS. They have to be notified prior to being placed on the market, after which they are registered in the European List of Notified Chemical Substances (ELINCS).

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[6] European Environment Agency (1998) Dobris +3, Report on the State of the Environment.

Directive 76/769/EEC in its introduction of restrictions on marketing and uses of certain dangerous substances is unique in that in its management of the restrictions it may target articles or products. A case in point is the ban on the use of wood treated with pentachlorophenol or creosote in children's playgrounds.

Directive 67/548/EEC

Directive 67/548 was adopted in 1967 in order to approximate the national provisions relating to dangerous substances and preparations. Since then the Directive has been amended eight times and adapted to technical progress 23 times. These modifications reflect the continuous adaptation of the Directive to the permanent increase in technical and scientific knowledge in the field of dangerous substances.

Today the Directive aims at achieving a high level of protection of human health and the environment from the hazard that dangerous industrial chemicals may cause when placed on the market and used.

The key elements are

(i) classification and labelling of chemicals according to their intrinsic dangerous properties

The placing on the market of an industrial chemical which the manufacturer, importer or distributor knows or suspects is "dangerous" requires them to examine its intrinsic properties in order to assess whether it is "dangerous" according to the Directive. If the chemical is qualified as "dangerous", it has to be placed into one or several classes of danger, such as "flammable", "toxic" or "dangerous to the environment". The Directive currently covers 15 classes of danger.

Classification of a chemical as "dangerous" requires appropriate labelling on the package. The label includes a danger symbol, standard phrases on the nature of special risks from the chemical (R-phrases) and standard safety precaution phrases (S-phrases) relating to the use.

"Harmonised" classification and labelling is undertaken by a working group of Commission and Member State experts, with the participation of industry, trade unions and EEA-EFTA representatives. The industrial chemicals for discussion are proposed by Member States and, to a lesser extent, by Industry. Chemicals for which a "harmonised" classification and labelling has been agreed by the Commission services and Member States as dangerous are listed in Annex I to the Directive.

Classification according to the Directive 67/548 may have repercussions on the marketing and use of a chemical. Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[7] may, after an assessment including economic and social implications, ban the marketing to and use by the general public of chemicals which are in

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[7] OJ L 262, 27.9.1976, p. 201.

category 1 or 2 of the danger classes "carcinogenic", "mutagenic" or "toxic to reproduction", and Directive 90/394/EEC controls the presence of carcinogens at the workplace when they fulfil the criteria for "carcinogenic" category 1 or 2.

(ii) notification of "new" chemicals prior to marketing

Since 19 September 1981 any manufacturer wishing to place a chemical on the market has to notify this to the national Competent Authority (CA), provided the chemical has not been on the market before that date.

The notification of a "new" chemical requires detailed information about its production, use and its intrinsic properties to be submitted to the CA, including a proposal for classification and labelling. On acceptance of the dossier by the CA the chemical may be marketed throughout the European Union. Subject to increasing tonnage limits the manufacturer has to provide additional data to the CA. These additional data may require a modification of classification and labelling or of the risk assessment.

(iii) risk assessment of "new" chemicals

Since 1993[8] the notification of a "new" substance requires a risk assessment which evaluates the danger to human health and the environment upon exposure. The conclusions of the risk assessment may have an impact on the production, handling, classification, labelling, marketing or use of the substance, or induce other protective measures.

Directive 88/379/EEC

Directive 88/379, known as the "Preparations Directive" sets out harmonised rules for the classification, packaging and labelling of dangerous preparations (mixtures) so as to

- optimise the functioning of the Internal Market by reducing the obstacles to trade arising from different classification and labelling of preparations in Member States;
- give at the same time a high level of protection to persons coming into contact with preparations, either at work or in private by providing a label giving essential information on the hazards involved and precautions to be taken and adequate packaging requirements and by introducing a safety data sheet for industrial users.

A dangerous preparation is a mixture of substances (of which at least one substance is classified as dangerous) which in accordance with the provisions of the Directive is classified as dangerous. It is estimated that there may be one million preparations on the EU market. Once a preparation has been classified, packaged and labelled by the producer or importer according to the rules of Directive 88/379 it can be marketed throughout the EU without any obligation to supply prior information to national authorities.

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[8] Council Directive 92/32/EEC (7th Amendment of Council Directive 67/548/EEC), OJ L 154, 5.6.1992, p. 1.

It was decided from the beginning that classification of preparations would not be routinely done on the basis of laboratory tests, as is the case with dangerous substances. The sheer number of dangerous preparations on the market would make such a procedure impractical but tests were also considered generally unsuitable because of the costs to industry, especially SMEs and because the number of test animals needed would not be compatible with animal welfare. Instead of routine use of tests a calculation method of classification called the "Conventional Method" was developed. According to the "Conventional Method" the classification of a preparation can be calculated from knowledge of the classifications of the component substances and their concentrations on the basis of the formulae provided in the Directive.

Clearly there is a very close link between the Dangerous Preparations Directive and the Dangerous Substances Directive. Not only does Directive 88/379 use the substance classifications of Directive 67/548, it also uses the same categories of danger, the same criteria for labelling, the same labelling scheme, the same test methods (where needed) and the same packaging rules. A consequence of this close link is that modifications to Directive 67/548 inevitably have consequences for the classification of Preparations.

The Preparations Directive has been continuously developed over the past ten years. In addition to changes arising from the Substances Directive, rules have been introduced for gaseous preparations Regulation (EEC) 793/93. Safety Data Sheets, additional safety information for industrial users (e.g. first aid measures in case of fire, handling precautions etc.) for Child Resistant Fastenings (to protect children against using dangerous preparations) have also been introduced.

Regulation (EEC) 793/93

Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances was adopted on 23 March 1993 and entered into force on 4 June 1993. This Regulation is based on Article 100A of the Treaty and is generally known as the "Existing Substances Regulation". The Regulation was developed in response to the Fourth Community Action Programme on the Environment (1987-1992), which underlined the need for a legislative instrument, which would provide a comprehensive structure for the evaluation of the risks posed by "existing" industrial chemicals.

In order to make the Regulation fully applicable, a number of steps had to be completed, including the adoption of Commission Regulation (EC) No 1488/94 of 28 June 1994, which lays down the principles for the assessment of risks, and the production of the Technical Guidance Documents on Risk Assessment and Risk Reduction Strategies, which were published in 1996 and 1998 respectively.

Regulation 793/93 aims to identify and reduce the risks related to the production and distribution of "existing" industrial chemicals. In principle, the Regulation seeks to protect man and the environment from exposure to dangerous industrial chemicals via all possible routes. "Man" comprises in this context "worker, consumer and man via the environment". The basic principle of the Regulation is that controls on hazardous chemicals should be based on an assessment of the actual risk to human

health and the environment, rather than the hazardous properties of the substance only. This approach, based on sound science, is strongly supported by Industry.

One of the purposes of the Regulation was to ensure that each chemical is assessed on the basis of the same criteria. The Regulation was also designed to ensure that a Member State would not notify its intention to restrict the marketing and use of a chemical without carrying out a risk assessment according to principles agreed by all Member States. Thus, the Regulation introduced a coherent and consistent system for evaluating the risks related to "existing" industrial chemicals, which is applicable throughout the Community and at the same time avoids fragmentation of the Internal Market.

Manufacturers or importers were required to provide specific information on EINECS-listed chemicals produced or imported into the Community in volumes in excess of 10 tonnes per year. The most recent data provided by industry shows that of the 100,106 chemicals listed on EINECS, on the market there are approximately

- 2,500 High Production Volume chemicals (1,000 tonnes or more per year); and,
- between 15,000 to 20,000 Low Production Volume chemicals (10 to 1000 tonnes per year).

The remaining 80,000 or so chemicals are produced or imported in quantities of less than 10 tonnes per year or are not traded at all.

Of the 100,106 EINECS chemicals, approximately 3,000 have been classified as dangerous in Annex I of Directive 67/548.

Some EINECS chemicals which meet the volume criteria of Regulation 793/93 may have undergone an equivalent assessment under other EC legislation. They will therefore not be assessed again under Regulation 793/93. These chemicals are essentially of occupational concern or used mainly as pesticides.

For practical reasons, a priority setting approach for Regulation 793/93 was introduced to determine which chemicals should be assessed first. Three priority lists, totalling 110 chemicals, were adopted by a regulatory committee of national representatives and set out in three Commission Regulations between 1994 and 1997.

In these Regulations, each substance is formally assigned to a Member State "Rapporteur" on a voluntary basis, for evaluation and presentation of a risk assessment report for consideration by the Member States. This procedure places the burden of proof with the Public Authorities. If the conclusion of the risk assessment is that the risks are not adequately managed, the Regulation requires the determination of a strategy to reduce those risks.

Risk reduction measures may subsequently be considered within the framework of other relevant legislative instruments, such as Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations, or worker and consumer protection legislation. Such measures can also include the use of voluntary (environmental) agreements.

Overall, the Regulation

- provides a comprehensive system to determine possible risks to human health and the environment from "existing" chemicals and related measures for reducing those risks;
- is not intended to rapidly manage urgent or emerging new problems for those "existing" chemicals which are not already on the priority lists;
- is not intended to cover the risk assessment and the corresponding risk reduction measures of harmful "existing" chemicals which are not industrial chemicals and are controlled by other legislative instruments.

DIRECTIVE 76/769/EEC

Directive 76/769/EEC, known as the "Limitations Directive" establishes harmonized rules to remove obstacles to intra-EU trade arising from restrictions in Member States applying to dangerous substances, preparations and articles associated within these. It also establishes harmonized rules where there is a consensus that these are needed to protect human health, the environment and the interests of consumers. In all cases, the Directive sets out to assure a high level of protection of public health and the environment.

Initiatives to harmonize may arise from many sources. The main source so far is the notification by Member States under Directive 83/189 of new technical rules. However, this could change in the future as an increasing number of risk reduction measures may arise from Regulation 793/93.

Where initiatives entail restrictions for a substance not yet included in Annex I of the Directive 76/769, these must be introduced through Council and Parliament by Co-Decision Procedure. However, a modification of restrictions of a substance already included can be introduced more quickly through the Technical Progress Committee. In all instances time is of the essence as there is an immediate threat to human health and/or the environment and to the Internal Market. The risks posed by the substance in question must be quickly evaluated as must all the economic and social implications of restricting the substance in order to manage the risks. Targeted risk assessments, concentrating on the dangerous effect(s) of concern and using available data, are performed and are followed by an analysis of the advantages and drawbacks of possible control measures.

Restrictions under Directive 76/769 generally take the form of controlled use i.e. they restrict the substance for particular uses only. In a minority of cases they take the form of a ban with exemptions or even a total ban on marketing as in the case of PCBs. Up to date, the Directive has been amended 18 times providing for restrictions on 42 substances or groups of substances, covering about 900 individual substances in total, of which the majority are cancer causing substances banned for consumer use. These restrictions for the most part seek to protect human health, although a good many also protect the environment and some are specifically intended to protect consumer interests.

3. FINDINGS

In general the findings highlight the need to use the current instruments more efficiently and implement as well as enforce them more rigorously and consistently, the need to streamline the instruments and develop them in order to take account of new emerging problems. They also recognise the role of sound science and highlight the need to meet more fully the concerns of the outside world by giving full consideration to the precautionary principle. They point at the need to give emphasis to the co-operation in the frame of international organisations such as the OECD and the UN, with a view to achieve internationally agreed harmonised rules and to benefit fully from the worldwide available scientific expertise.

More specifically the findings highlight the importance of

- hazard identification as the initial key step in protecting both human health and the environment from the potential harmful effects of industrial chemicals;
- the distinction between hazard identification, risk assessment and risk management;
- the concept of the "burden of proof" in relation to the different instruments of hazard identification, risk assessment and risk management;
- ascertaining the number of "existing" industrial chemicals which constitute the "burden of the past" and of drawing up a clear strategy for assessing these for their harmful effects in order to address the public concern.

Directive 67/548/EEC

In general the provisions of Directive 67/548 have proven satisfactory, although certain criticisms have been made of the system for notifying new substances. The classification and labelling of some 4,500 dangerous industrial chemical substances has been agreed Community-wide. 2,100 "new" industrial chemicals have been notified and registered in ELINCS. Since 1993 400 "new" chemicals have been subject of a risk assessment in accordance with Directive 92/32.

The review has highlighted a number of findings concerning the practical operation of the Directive, which need to be addressed. A number of weaknesses in the practical operation are due to a lack of resources.

(i) classification and labelling

- the time period of one to two years to agree on a harmonised classification and labelling and its publication is too long;
- the system of R-phrases and S-phrases has become too complex;
- classification and labelling provisions are not sufficiently applied and enforced in the Member States;
- it is difficult to trace the chemicals which have not been classified as "dangerous" under the Directive;

- there is no adequate follow-up for substances classified in Annex 1 as carcinogenic, mutagenic or toxic to reproduction (category 1 or 2), even though the effects of such substances are of major concern.

(ii) notification of "new" chemicals and risk assessment

- industry claims that innovation and competitiveness of the chemicals industry are hampered by the existing provisions for polymers, intermediates and exemptions for research and development;
- "new" industrial chemical substances are known to be marketed without prior notification;
- circulation of the confidential notification dossiers among Competent Authorities is too long (50 % of the dossiers take 4 months, 10 % take longer than one year);
- despite the requirement for annual publication[9], due to delays in data processing ELINCS has not been published since 1994;
- risk assessment requires inordinate effort in terms of staff resources and time.

(iii) structure of the Directive

- eight amendments and twenty-three Adaptations to Technical Progress have dispersed the provisions of the Directive among different pieces of legislation. In addition the text of the Directive has become confusing, and important provisions such as the principles of risk assessment are contained in other directives.

Directive 88/379/EEC

Directive 88/379 has generally proven effective in eliminating technical barriers to the free circulation of dangerous preparations and, as a result of constant adaptation, has provided a high level of health protection.

There have, however, been a number of problems related to implementation and enforcement. Some preparations on the market have not been classified and some are classified differently by different manufacturers. This occurs because of lack of understanding or lack of expertise, especially in smaller companies and because of different interpretations of certain rules. There is also evidence that the requirement in the Directive of having the same labels for all users may not be ideal in terms of costs for the manufacturer and comprehensibility for the user. The Directive is also deficient in the sense that it does not cover pesticide preparations, does not deal with the dangers that dangerous preparations present to the environment nor does it deal systematically with non-classified preparations which may nevertheless present a danger for users.

It thus became urgent to find solutions to these problems in order to safeguard the cohesion of the Internal Market and to preserve a high level of protection for human

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[9] Commission Decision of 21 December 1984 concerning the list of chemical substances notified pursuant to Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 30, 2.2.1985, p. 33.

health and the environment. The solutions to these problems are also important for Austria, Finland and Sweden in the framework of the Accession Treaties. To that effect on 18 July 1996 the Commission presented a Proposal to Council and Parliament for a new Directive on Dangerous Preparations. This Proposal seeks to bring together in one legal instrument all the legislation to date on preparations and to remedy the above-mentioned deficiencies with regard to pesticides, dangers to the environment and the dangers from non-classified preparations.

The proposed new Preparations Directive includes in its scope the classification, packaging and labelling of pesticides. This should eliminate barriers to trade associated with different systems in Member States for classifying and labelling of pesticides, for safety data sheets and for packaging of pesticides. It should also improve the level of protection of human health and the environment as it includes stricter rules than those applicable to pesticides at present under Directive 78/631/EEC.

The proposed new Preparations Directive also covers dangers to the environment posed by dangerous preparations. The new harmonised approach should remove the trade barriers linked to national systems and provide new protection to the environment.

Also included in the proposed new Directive are rules for preparations not classified but which may nevertheless be dangerous. Those marketing such preparations will be required to compile a special Safety Data Sheet and make it available on request.

The proposed new Directive, for which a Common Position was adopted in the Council in September 1998, will thus solve many problems related to 'Dangerous Preparations'. However, one of the remaining key problems lies with enforcement where Member States should identify possible ways to improve their monitoring and control mechanisms.

Practical problems relate to

- the operation of the Directive (technical issues which need to be addressed in order to guarantee the functioning of the Internal Market and to solve any legal uncertainty which may derive from their implementation);

- the comprehensibility of labels which needs to be analysed in-depth in order to find whether the information on the label reaches all users (consumers, professional users, manufacturers, authorities and medical staff);

- the improvement, if necessary, of the current situation in terms of the international harmonisation of rules on Dangerous Preparations which should be given high priority in view of its potential trade implications and safety benefits.

Regulation (EEC) 793/93

So far 110 "existing" industrial chemical substances have been selected as "substances requiring immediate attention because of their potential effect on man on the environment" in the 3 priority lists published in 1994, 1995 and 1997. However, the complexity of the risk assessment process necessitated a lengthy lead-in time

before technical work on individual chemicals could commence because of the need for technical guidance.

Out of the total of 110 priority chemicals, 38 have been or are being discussed. 19 risk assessment reports have been completed. For 14 chemicals risk reduction measures are recommended; for 3 chemicals further testing is required and for 2 chemicals there is no need for risk reduction measures.

To date, the time necessary from the publication of a priority list to the circulation of the first draft of the risk assessment report at the Technical Meeting appears to average between 18 and 29 months. In general, a further 9 to 25 months are needed from the circulation of the first draft until an agreement is reached on the risk assessment report. During 1998 the pace of completion has increased. It is currently taking 9 months to finalise the assessment discussions. This improvement comes as a result of the increased technical competence of those national experts working on the risk assessment process.

A Commission Recommendation concerning the results of the risk evaluation for 4 chemicals and strategies for reducing the risks for 3 of them should in principle be published before the end of 1998. This means that, since 1994, only 4 chemicals have gone through the whole process foreseen in the Regulation.

The operational experience gained so far highlights the following issues:

- there is a lack of commitment from both Member States and Industry;
- there is a lack of resources in Member States and the Commission to carry out the necessary activities;
- the priority setting approach was not applied successfully for the first three priority lists in identifying the chemicals of greatest concern;
- the nature, scope and amount of data to be assessed for the in-depth risk assessment necessitate a lengthy process;
- the burden of proof is placed on Public Authorities rather than on Industry.

DIRECTIVE 76/769/EEC

In general Directive 76/769 has been successful in preserving the Internal Market and in protecting human health and the environment.

- Over the past 20 or so years, the Directive has been amended 18 times providing for restrictions on 42 substances/groups of substances covering about 900 individual substances. Furthermore, the provisions on substances included in Annex I have been adapted to technical progress on four occasions.

- In all cases, except asbestos, it has been possible to introduce Community-wide restrictions when Member States have planned to, unilaterally, introduce national restrictions and in most cases Member States, have refrained from derogating from the harmonized rules. There are nevertheless derogations on the grounds of Article 100A(4) from the harmonized rules for pentachlorophenol, cadmium and creosote. The situation would seem to have improved, however, in recent times as derogations have not been requested since the creosote Directive of 1994.

Another sign of improvement is that no Member State has voted against any amendment or adaptation of Directive 76/769 since that time.

- However, whilst in most cases agreement on harmonized restrictions has been found and sustained, there have been delays in implementing some of these. For example, the amendment on nickel in jewellery under Directive 94/27 is not yet operational as CEN has not yet adopted the test methods needed for entry into force. Delays are also experienced in introducing bans on substances classified as carcinogenic, mutagenic and toxic for reproduction (categories 1 and 2) as it may happen under certain circumstances the quicker Committee Procedure is relinquished for reasons of political sensitivity in favour of the full co-decision procedure involving the European Parliament. In addition, in the case of asbestos, ongoing discussions on the safety of the substitutes and on the economic consequences of a ban, have contributed to further delays. The Directive in its present form, after 20 years of operation, has become rather complex and not always easy to interpret and use. It has also become somewhat outdated in its legislative approach. For example, it lacks a well-defined scope, precise definitions and a safeguard clause.

4. ISSUES

The assessment and evaluation of the operation of the legal instruments concerned need to be further developed in the light of comments to this Report from the Member States and interested parties. A number of issues to be considered are presented below.

Directive 67/548/EEC and Regulation 793/93

The findings of the evaluation of the operation of the two legal instruments highlight a number of issues which will need to be addressed in the future. These issues concern the need to

- address operational weaknesses in the implementation of and compliance with both Regulation 793/93 and Directive 67/548, in particular the review should focus on the risk assessment and risk reduction strategy procedures under Regulation 793/93;

- restructure and rationalise Directive 67/548 to give it the necessary clarity and transparency in order to make it more user friendly and streamline its provisions to ensure that Industry is not unnecessarily hampered in terms of innovation and competitiveness;

- clarify the commitment of Member States in order to ensure effective implementation of Regulation 793/93; this should be determined in terms of political support for completing work on "existing" chemicals in future and in terms of actual resources;

- ascertain the number of "existing" chemicals which constitute the "burden of the past" and review them to see if their hazardous properties have been

identified since this will make it possible to develop guidelines and criteria for the appropriate assessment and management of any risks;

- address the "burden of proof" in relation to hazard identification and risk assessment of "existing" chemicals;
- consider the appropriate consultation of the Scientific Committee for Toxicity, Eco-toxicity and Environment in line with the general approach of the Commission[10] to scientific advice;
- ensure that Member States consider liability as well as withdrawal of substances as a means to improve compliance;
- achieve better co-ordination in order to improve efficiency, effectiveness and consistency of approach in both the processing of hazard identification and risk assessments and the definition of risk reduction strategies for chemicals;
- address international co-operation and co-ordination in order to make optimal use of existing expertise and resources;
- ensure that the instruments keep up with new scientific developments, such as the potential threat of endocrine disrupters.

Directive 88/379/EEC

The findings of the evaluation of the operation of this instrument have identified the need to

- assess the comprehension of the information on the label of dangerous preparations by all target groups;
- identify the causes of delays and non-compliance by Member States and where necessary ensure that Member States take the appropriate measures to remedy the situation and consider withdrawal of preparations as a means to improve compliance;
- address those technical issues which are important for the practical operation of the Directive;
- develop a system for the compilation of safety data sheets for preparations not classified as dangerous;
- address the issue of international classification and labelling of preparations.

Directive 76/769/EEC

The findings have highlighted the need to

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[10] COM(97) 183 fin. of 30 April 1997

- resolve the outstanding cases of Article 100A (4) for PCP, Cadmium and Creosote in such a way as to respect internal market principles as well as a high level of protection for human health and environment;

- accelerate the adoption of new restrictions under the Directive by giving preference to the Committee Procedure wherever possible;

- accelerate the adoption of restrictions characterised by scientific uncertainty or high economic costs as in the current case of asbestos, by further improving risk assessment procedures;

- address the delays in the practical implementation of new restrictions introduced under the Directive as those caused by difficulty in adopting test methods;

- ensure the appropriate consultation of the Scientific Committee for Toxicity, Eco-toxicity and Environment in order to ensure the sound scientific basis and independence of the risk assessments under Directive 76/769;

- update and rationalise Directive 76/769/EEC by means of a recast;

- ensure that the precautionary principle is given full consideration in the introduction of marketing and use restrictions of dangerous substances and preparations.

Findings

on the Operation

of

Directive 67/548/EEC
on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

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1. BACKGROUND

Directive 67/548/EEC[1] was adopted in 1967 to approximate the national provisions relating to dangerous substances and preparations. The then existing national provisions of the six Member States differed widely and thus hindered the Community trade of chemicals. In addition to the trade aspects, it was recognised that there was a need to ensure the protection of public health, in particular the health of workers handling dangerous substances.

This resulted in the introduction of common provisions on the

- classification of dangerous substances, since placing a substance into one or several defined classes of danger characterises the type and severity of the adverse effects that the substance can cause;
- packaging of dangerous substances, since adequate packaging protects from the known danger(s) of a substance;
- labelling of dangerous substances, since the label on the packaging informs about the nature of the danger(s) of the substance inside and about the safety measures to apply during handling and use.

The combined standardised provisions should ensure the establishment of a common market in the field of dangerous chemical substances and a high level of protection of human health. Protecting the environment from the dangerous effects of substances was not considered in 1967.

1.1. Classification, packaging and labelling of dangerous substances

The Directive initially included eight classes of danger, such as "explosive" or "toxic", a list of substances classified as dangerous in Annex I, danger symbols such as a scull with crossed bones underneath in Annex II, standard phrases on the nature of special risks (R-phrases) in Annex III and the wording of safety precautions (S-phrases) relating to the handling and use of dangerous substances in Annex IV. This initial structure developed over time to take account of the continuous increase in scientific and technical knowledge.

Annex V now contains testing methods to determine the potentially dangerous properties of substances, Annex VI provides detailed criteria on the proper choice of the class of danger and on how to assign the danger symbols, R- and S-phrases to a tested substance. Annexes VII and VIII do not relate to the classification or labelling of substances, but to the notification of "new" substances. Annex IX includes provisions on child-proof fastenings and tactile warning devices as special packaging and labelling elements.

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[1] OJ 196, 16.8.1967, p. 1.

Currently there are fifteen classes of danger which, in addition to the initial classes, include extremely strong effects, such as "extremely flammable" or "very toxic", and less immediate effects, which only become apparent in the long run, such as "carcinogenic", "mutagenic" or "toxic to reproduction" effects (CMR effects). Also "dangerous for the environment" is an integral part of the system.

It is important to note that all the categories of danger refer to both substances and preparations. Preparations are mixtures of two or several substances. Details on preparations are, however, included in Directive 88/379/EEC[2] on the classification, packaging and labelling of dangerous preparations. A proposal for a replacement Directive is at present under consideration in the European Parliament and Council.

In order to classify a substance it is necessary to determine its intrinsic physico-chemical and toxicological properties according to the testing methods in Annex V of the Directive (or equivalent if deemed acceptable by expert advice), to place the substance into one or several classes of danger according to the provisions of Annex VI and to assign proper R-phrases or combinations of R-phrases to it, also in accordance with Annex VI.

The outcome of the classification determines the labelling which has to be placed on the package containing the substance. The danger symbol(s) for the label are taken from Annex II and the R-phrases are the ones assigned during classification. In addition, S-phrases have to be selected according to Annex VI.

The obligation to label a dangerous substance according to the provisions of the Directive rests with the manufacturer, distributor or importer of such a substance, in short with the person responsible for placing the substance on the market. This is laid down in Article 6 of the Directive with reference to "existing" substances, which are the substances that were on the market on or before 18 September 1981. However, "existing" substances only need to be classified and labelled when they are known or suspected to be dangerous.

For "new" substances - substances marketed only after the target-date of 18 September 1981 - the manufacturer or anyone else placing it on the market has to include information about possible dangerous properties of the substance, accompanied by the appropriate classification and labelling, in a so-called notification dossier to be submitted to the Competent Authority for acceptance. Thus "new" substances have to be examined whether they are potentially dangerous.

For some 4500 "existing" and "new" dangerous substances classification and labelling have been harmonised in the Community and published in Annex I to the Directive according to Article 4 (3). To agree on classification and labelling of "existing" substances the Commission regularly convenes a number of Working Groups. They are composed of experts from the Member States and normally consider

– the effects on human health, in particular CMR effects, in the CMR Working Group. Where more in-depth, scientific advice is required in order to reach

[2] OJ L 187, 16.7.1988, p. 14.

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agreement on classification and labelling, the additional "Specialized Experts Group" has to provide information;

- the effects on the environment in the Environment Working Group;
- the effects as active ingredients of pesticides in the Pesticide Working Group. Also "new" substances are considered if they exclusively serve as active ingredients of pesticides.

The meetings of these four Working Groups are hosted by the European Chemicals Bureau (ECB) of the Joint Research Centre, totalling about ten meetings per year.

For "new" substances, except those serving exclusively as pesticides, Competent Authorities in charge of the notification system agree on the classification and labelling. Their meetings are equally convened by the ECB, about two times per year.

A further obligation of the Directive concerns the safety data sheet (SDS) according to Directive 91/155/EEC[3], adopted in 1991 and modified by Directive 93/112/EEC[4]. Any person responsible for placing a dangerous substance on the market has to supply the industrial user with a sheet containing information relating to the safe handling of the substance during storage, transport and disposal, such as information about hazards, first-aid, fire-fighting and accidental release measures, and toxicological and eco-toxicological properties.

1.2. Notification of "new" substances

The distinction between "existing" and "new" substances was introduced by the 6th amendment of the Directive[5], adopted in 1979 and in force in the Member States since 1981. Since then, any substance to be placed on the market, whether dangerous or not, but not on the market on or before the target-date of 18 September 1981, has to be notified by the manufacturer, distributor or importer to the national Competent Authority (CA). "Notification" includes the submission of detailed data about the production, use and intrinsic properties of the substance, including a proposal for classification, packaging and labelling. Only on approval of the notification dossier by the CA may the substance be marketed.

Notification of a substance requires a considerable effort on the part of the notifier. The quantity of information to be submitted depends on the amount of substance which is placed on the market. If the yearly amount is 1 ton to less than 10 tons, a "base set" of notification data have to be submitted to the CA, as laid down in Annex VII A to the Directive. The base set includes data on the identity of the substance, such as the molecular formula, production figures, proposed uses including exposure estimates, safety measures concerning handling, storage and transport, emergency measures, data about the physico-chemical properties, the

[3] OJ L 76, 22.3.1991, p. 35.

[4] OJ L 314, 16.12.1993, p. 38.

[5] OJ L 259, 15.10.1979, p. 10.

toxicology and eco-toxicology of the substance, information about the possibility to render it harmless and about packaging. In addition, the notifier has to submit a proposal for classification and labelling.

For smaller amounts, fewer data have to be submitted, in accordance with Annexes VII B and C of the Directive, but for higher tonnages more in-depth data are required, as laid down in Annex VIII (level 1 and level 2). Limits for data requirements are at 10 kg, 100 kg, 1 ton ("base set" notification), 10 tons, 100 tons, and 1000 tons per year and manufacturer. In addition, the data pertaining to the next higher tonnage level have to be provided if the total amount on the market exceeds 5 times the yearly amount.

To allow for exceptions in special cases the introductory clause of Articles VII A, B, C and VIII state that "If it is not technically possible or if it does not appear scientifically necessary to give information," the CA may agree that fewer data are sufficient for the notification at a certain tonnage level. The "reasons shall be clearly stated and be subject to acceptance by the competent authority."

In conclusion, the effort prior to placing a "new" substance on the market is considerable. The invaluable benefit of the notification system is, however, that the approval by the CA of one Member State makes the notification valid in all Member States. The notified substance may be marketed throughout the Community, without any further marketing hurdles.

It is important to note that any placing of a "new" substance on the market has to be notified, whether or not it has been notified earlier by another manufacturer, importer or distributor. In this way control is kept of

- the slight difference in composition or impurities that the same substance may have when synthesised by different manufacturers following different chemical pathways;

- all importers who place the same substance from the same third country manufacturer on the market.

Furthermore, a manufacturer outside the European Union wishing to export to a series of European Union importers may designate a "sole representative" according to Article 2 (1) (d) of the Directive. This person must be established in the Community and acts as the notifier for either all or some of the importers of the specific substance. This procedure eliminates or reduces unnecessary multiple notifications and reduces the administration costs both for CAs and industry.

1.3. EINECS and ELINCS

In order to distinguish between the large number of "existing" substances which were already on the market at the time of the entry into force of the 6th amendment to the Directive, on 18 September 1981, and the "new" substances which would be placed on the market for the first time after this date, the 6th amendment required the Commission to compile the list of "existing" substances, called European Inventory

of Existing Commercial Chemical Substances (EINECS)[6]. This inventory was published in 1990 and collected over 100,000 entries.

"New" substances have to be listed in the European List of Notified Chemical Substances (ELINCS), according to a Commission Decision of 1984[7]. This list shall be updated before 31 December of each year by publishing the "new" substances notified before 1 July of the same year. It currently comprises over 2,100 entries.

1.4. Risk assessment

The 7th amendment[8] to Directive 67/548/EEC, adopted in 1992 and in force since 1993, added the risk assessment for "new" substances to the notification scheme. The principles of risk assessment are laid down in Commission Directive 93/67/EEC[9] of 1993, in force since that year. Risk assessment evaluates and weighs the danger that human health and environment face when exposed to the substance of concern. If exposure is high, protective measures will have to be taken or the substance may even have to be banned. On the other hand, if the environment or parts of the environment are not at all exposed to the dangerous substance, there is no risk. In this sense risk assessment completes the information necessary for a high level of protection for human health and the environment.

The risk assessment of a "new" substance is prepared in three steps:

- assessment of the toxic effects and of the dose-response relation, where appropriate;
- assessment of the exposure to workers, consumers and man indirectly exposed via the environment;
- description of the risk for human health and for the environment.

The description of the risk ends up in one of four conclusions to be drawn according to Directive 93/67/EEC. They reach from "no concern" to "immediate recommendations for risk reduction". Risk management puts these recommendations into practice.

According to Article 7 (1) of Directive 67/548/EEC the notifier of a "new" substance may provide a preliminary risk assessment when submitting the notification dossier to the CA, but the definitive assessment is prepared by the CA.

It is important to note that for "existing" substances the risk assessment principles are contained in Commission Regulation (EC) 1488/94 of 1994[10], as a consequence

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[6] OJ C 146 A, 15.6.1990, p. 1.

[7] OJ L 30, 2.2.1985, p. 33.

[8] OJ L 154, 5.6.1992, p. 1.

[9] OJ L 227, 8.9.1993, p. 9.

[10] OJ L 161, 29.6.1994, p. 3.

of Council Regulation (EEC) 793/93[11] on the evaluation and control of the risks of "existing" substances. However, the principles on how to prepare the risk assessment are virtually the same as for "new" substances.

To support the preparation of risk assessments a four part Technical Guidance Document of over 700 pages has been published by the Commission[12] in 1996. It provides scientific and technical details concerning the risk assessment preparation, such as algorithms to assess consumer eposure, guidance on the use of structure activity relationships and the description of the risk assessment report format. It takes due account of the differences between "new" and "existing" substances.

1.5. Risk management

Risk management issues are covered by Directive 67/548/EEC only marginally. If the risk assessment of a "new" substance leads to the conclusion that "The substance is of concern and the competent authority shall immediately make recommendations for risk reduction" such recommendations may entail

- modifications to the classification, packaging or labelling;
- modifications to the Safety Data Sheet prepared according to Directive 91/155/EEC;
- modifications to the recommended methods and precautions or emergency measures, as delivered in the notification dossier;
- advice to the relevant control authorities that they should consider appropriate measures for the protection of man or the environment.

True restrictions on the marketing and use of dangerous substances, however, are included in Directive 76/769/EEC[13] adopted in 1976 and in force since 1978. The 14th amendment[14] of this Directive, adopted end of 1994 and applicable as from mid 1995, stipulates that all substances of Annex I to Directive 67/548/EEC classified in category 1 or 2 of the classes "carcinogenic", "mutagenic" or "toxic for reproduction" have to be assessed for their risks and advantages in order to propose restrictions where necessary. Since then over 850 such substances have been restricted and may therefore not be used as such or in preparations for the general public. They are listed in the annex to that Directive.

Exemption is only made if such a substance is present at a very low concentration. This concentration limit is laid down in Annex I to Directive 67/548/EEC, and is

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[11] OJ L 84, 5.4.1993, p. 1.

[12] Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessments for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances. Parts 1 – 4. Office for Official Publications of the European Communities, Luxemburg, 1996.

[13] OJ L 262, 27.9.1976, p. 201.

[14] OJ L 365, 31.12.1994, p. 1.

agreed on the occasion of the classification of the substance for that Annex. If no such concentration limit appears there, the "general" concentration limits in Directive 88/379/EEC[15] on dangerous preparations apply.

Risk management aspects also govern Directive 90/394/EEC[16], adopted in 1990 and in force as from the end of 1992, on the protection of workers from carcinogens. Its 1st amendment[17] lays down that any substance which meets the classification criteria of Annex VI to Directive 67/548/EEC for a carcinogen of category 1 or 2 has to be considered a carcinogen. This definition not only covers substances which are intentionally placed on the market, as Directive 67/548/EEC on dangerous substances or Directive 88/379/EEC on dangerous preparations, but any substance which may incidentally appear at the workplace, for instance during a production process. A list of such substances including their occupational exposure limits is in the annex to the Directive. It is interesting to note that the proposal for the second amendment[18] of Directive 90/394/EEC also includes substances which fulfil the criteria of Annex VI to Directive 67/548/EEC for a mutagen of category 1 or 2, since mutagens can be expected to show carcinogenic effects in the human body.

A further example for the management of risk is Directive 98/24/EC[19] of April 1998, to be set in force in 2001 at the latest, on the protection of workers from chemical agents in general. This Directive considers substances as "dangerous" when they fulfil any of the criteria for "dangerous" laid down in Annex VI to Directive 67/548/EEC, whether or not the substance has obtained a harmonised classification and labelling under that Directive. Also dangerous preparations fall under the Directive. However, substances and preparations which are only "dangerous for the environment" are excluded, since the Directive is restricted to worker protection issues.

1.6. Amendments and Adaptations to Technical Progress

Amendments to the Directive

At the time of adoption of Directive 67/548/EEC in 1967 the date for implementation of its provisions was fixed at 1 January 1970. The 1st amendment to the Directive[20] related to the classification of certain dangerous substances and was also due to enter into force at the beginning of 1970. However, due to unexpected difficulties in connection with the implementation, the 2nd amendment[21] set the

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[15] OJ L 187, 16.7.1988 p. 14.

[16] OJ L 196, 26.7.1990, p. 1.

[17] OJ L 179, 8.7.1997, p. 4

[18] OJ C 123, 22.4.1998, p. 21.

[19] OJ L 131, 5.5.1998, p. 11.

[20] OJ L 68, 19.3.1969, p. 1.

[21] OJ L 59, 14.3.1970, p. 33.

implementation date forward to 1 January 1971, and, as this time limit proved to be insufficient, the 3rd amendment[22] prolonged the delay by a further year. The final date of entry into force was therefore 1 January 1972.

The 4th amendment[23] was adopted in 1973 and introduced the possibility to modify the Annexes of the Directive by an "Adaptation to Technical Progress" (ATP). Technical progress requires a rapid adaptation of the technical requirements of the Directive and the time-consuming preparation of an amendment was not considered suitable for this purpose.

Whereas the 5th amendment[24] laid down certain details of labelling, a major step forward was the 6th amendment, adopted in 1979, because it introduced the notification system for "new" substances. It also provided for the establishment of EINECS, the list of "existing" substances. Furthermore, several new classes of danger were added, including "dangerous for the environment".

The 7th amendment, of 1992, essentially required that the principles of risk assessment be laid down. It introduced the "sole representative" in the notification system, and added the Safety Data Sheet as a hazard communication facility for the professional user. Finally the 8th amendment[25] replaced the term "European Economic Community" by "European Comunity" in the Directive, to take account of the modification of the Treaty.

Since the Directive is based on Article 100a of the Treaty, an amendment requires the co-decision procedure between European Parliament and Council. Such a procedure may take two years under normal circumstances or half a year at least if quick agreement can be found.

Adaptations of the Annexes to technical progress

Since the introduction of the "Adaptation to Technical Progress" (ATP) technique by the 4th amendment to the Directive in 1973 twenty-three technical adaptations have been introduced. Annex I was adapted 18 times, whereas Annexes III, IV and VI were modified only 6 to 7 times. The other Annexes, namely II, V, VII, VIII and IX, were adapted less often.

In principle the scientific and technical aspects of the provisions in the Directive are discussed by Commission expert groups, of which the above-mentioned CMR Working Group is the most prominent. The issues of agreement are usually included in a Draft for a Commission Directive adapting Directive 67/548/EEC to technical progress. This Draft is submitted to the Regulatory Committee procedure according to Article 29 of the Directive, where distinction is made between the ATPs of Annexes I (list of dangerous substances with harmonised classification and

[22] OJ L 74, 29.3.1971, p. 15.

[23] OJ L 167, 25.6.1973, p. 1.

[24] OJ L 183, 14.7.1975, p. 22.

[25] OJ L 236, 18.9.1996, p. 35.

labelling), III (list of R-phrases), IV (list of S-phrases), V (test methods) and IX (provisions for child-proof fastenings and tactile warning devices), which follow the IIIa Comitology Procedure[26], and the ATPs of Annexes II (danger symbols), VI (classification and labelling criteria), VII (information required for notification) and VIII (additional information required for notification) which follow the IIIb Procedure.

2. PRACTICAL OPERATION

After 30 years of practical operation the Directive has generally proven effective in protecting human health and the environment against the hazards of chemical substances placed on the market. The three yearly report prepared in accordance with Article 32 of the Directive confirms this assessment, even if there is room for improvement.

Classification and labelling, but also the notification of "new" substances provide informative illustrations of the effective practical operation of the Directive. Points requiring improvement shall be emphasised wherever necessary.

2.1. Classification and labelling

Facts and figures

"Moderately harmful" effects

The fifteen classes of danger that the Directive defines in Article 2 cover a wide range of physico-chemical and toxicological effects. Substances which damage human health, in the short, middle or long term, fall into one of three classes: "very toxic", "toxic" or "harmful". The divide between these classes and their boundaries are determined by the criteria in Annex VI to the Directive. Therefore substances which cause effects less than "harmful" are outside the scope.

However, during the review of the Directive concerning the exemptions in the Accession Treaty of Austria, Finland and Sweden[27], evidence was provided that certain weak effects should be taken on board. If exposure to a substance causes "dryness or cracking of the skin" or "drowsiness or dizziness after inhalation", this should be signalled on the label.

Thus, two new R-phrases will have to be included by an Adaptation to Technical Progress by the end of 1998 in Annex III, and their criteria for application and use in Annex VI. No additional category of danger is necessary, because these weak effects only need to be taken into account in addition to other more severe dangers of certain substances.

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[26] OJ L 197, 18.7.1987, p. 33.

[27] OJ C 241, 29.8.1994, p. 9.

New "effects"

Certain new effects are causing concern but are not yet covered by the Directive. Immunological, neuro-developmental/neuro-behavioural and reproductive/endocrine disrupting effects were observed in connection with a number of pesticides, contaminants and other chemical substances. Traces of these substances can be detected in the environment, from where they enter the food chain and subsequently may affect human health. Therefore they should be covered by the provisions of the Directive. Inclusion of these new effects would require one or several new classes of danger.

Proper testing methods to detect these effects, which are observed as a "by-product" during other investigations are not yet available. However, first efforts are under way in Europe and in the United States. Once available for use, these methods can be included in Annex V to the Directive. Subsequently, classification criteria for these effects will need to be developed for Annex VI and the necessary labelling elements introduced in Annexes II, III and IV.

International harmonisation of classification and labelling

Acute toxic effects, well covered by the Directive, are at present under discussion at the Organisation for Economic Co-operation and Development (OECD). According to the present status of discussions oral effects will be divided into five classes, which also cover acute oral effects weaker than "harmful" according to the meaning of Directive 67/548/EEC. If the outcome of the OECD discussions is binding an amendment of the body of the Directive and the adaptation of Annexes II, III, IV and VI would be necessary. This would enlarge the number of substances covered by the Directive and enhance the protection of human health.

Link with OECD testing methods

OECD also establishes testing methods for dangerous effects for use in their member countries once such methods are sufficiently developed and approved. Development and approval of the testing methods are actively supported by the EU Member States, who are members of the OECD, and the Commission. After approval the Commission normally proposes the OECD method to Member States for inclusion in Annex V of Directive 67/548/EEC. This is done through an Adaptation to Technical Progress and does not pose significant problems since Member States have already agreed on substance in the OECD.

This ensures a high level of harmonisation between OECD testing methods and the methods in Annex V and eliminates the need for separate developments in the Community, thus avoiding a duplication of effort. Nevertheless the Community may also establish testing methods irrespective of OECD developments.

Activities in the Community may also feed back on OECD activities. Thus, the Commission recently announced to OECD the intention to delete a specific testing method for acute toxicity from Annex V because this method requires a comparably large number of test animals. In addition, two further methods for acute toxicity are available in the Annex. To keep the largest possible extent of harmonisation the

Commission has requested OECD to first delete the corresponding OECD testing method. As a consequence OECD discussions are now under way.

Classification of "new" substances

It is generally assumed that any chemical substance is hazardous. Environmentalists claim that the goal for the future should be zero hazardous substances and that the notification scheme for "new" substances fails to give incentives to develop non-hazardous alternatives[28].

Yet an overview in the three yearly report of the 740 "new" substances notified between 1994 and 1996 shows that on average only 70 % were classified as "dangerous". At the lower end of the scale were "new" substances for use in the paints industry, the lacquers and varnishes industry[29], where only 43 % of the substances were classified as "dangerous". This is less than half of the total number of notified "new" substances.

The highest percentage of hazardous substances was found among the chemicals for synthesis, which were "dangerous" in 88 % of the cases. This is not surprising since substances have to be reactive, even "aggressive", if they are to function as building blocks for other substances.

Areas for possible improvement

The practical operation of the Directive over the last few years has revealed a number of weaknesses, which mainly concern the structure and procedures of the classification system and the compliance with the labelling provisions.

Self-responsibility of the manufacturer for classification and labelling

According to Article 6 of the Directive "existing" dangerous substances not listed in Annex I have to be classified and labelled by the manufacturer, distributor or importer themselves. The self-responsibility only applies if an "existing" substance is known to be dangerous or at the least is suspected to be dangerous. Where the manufacturer does not consider the marketed substance to be dangerous no classification or labelling are necessary.

Even if this should ensure the protection of health and environment from the hazards of "existing" dangerous substances the experience of Competent Authorities is that in certain cases

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[28] Letter of Greenpeace international, European Unit, of 17 April 1998 to Commissioner Bjerregaard, in connection with the Informal Environment Council in Chester on 24 – 26 April 1998.

[29] Notification of New Chemical Substances in accordance with Directive 67/548/EEC on the Classification, Packging and Labelling of Dangerous Substances – Technical Guidance for the Completion of a Summary Notification Dossier for a New Chemical Substance utilising the Structured Notification Interchange Format (SNIF), Base-set and Levels 1 and 2. Office for Official Publications of the European Communities, Luxemburg, 1997.

- "existing" substances are not classified at all by the manufacturer, even if it can be reasonably expected that they are potentially dangerous;

- "existing" substances not listed in Annex I are self-classified by different manufacturers in a number of different ways.

The self-responsibility for classification and labelling of "existing" substances should therefore be reconsidered as well as measures to improve compliance with the provisions. This may include increased enforcement activities at Member State level.

Harmonised classification and labelling

Annex I of the Directive contains all substances where classification and labelling have been agreed for the Community, whether "new" or "existing".

To reach agreement

- classification and labelling of every recently notified "new" substance is circulated by the ECB to the national CAs with a minimum six month deadline for confirmation or modification. Under this procedure classification and labelling of a range of notified substances is agreed before presenting them to an Adaptation to Technical Progress (ATP) to update Annex I. Since the procedures for an ATP require approximately further six months a total of one to two years is required on average from acceptance by a national CA of the classification and labelling proposal in the notification dossier until the entry into Annex I.

- the CMR Working Group discusses the available toxicological data of an "existing" substance during three meetings on average. The Group also takes into account special data and views that industry may provide. As this discussion process takes nearly a year and a certain number of agreed substances are collected before presentation to an ATP, the total time necessary adds up to between one and two years.

The time period of one to two years to update Annex I for both "new" and "existing" substances is unsatisfactory since potential users of the substance are not officially informed during this period. The delay may even be longer depending upon the available resources. Questions should be raised on how to accelerate the updating of Annex I.

System of R- and S-phrases

Annex III of the Directive currently contains over 120 R-phrases and R-phrase combinations. Annex IV provides almost 80 S-phrases and combinations. The assignment of these phrases and their combinations to dangerous substances, following the criteria in Annex VI, is subject to detailed conditions including detailed exemptions. In particular S-phrase assignment can be "obligatory", "recommended", "normally limited to special cases", and so on. National experts in the CMR Working Group, where classification and labelling of "existing" substances is dealt with, have indicated that the system has become extremely

complicated and that a fundamental revision of its practical arrangements should be considered to simplify the provisions.

In addition, the comprehension of the phrases by users should be assessed in order to ensure that the intended message is clearly understood.

Enforcement

During the inspection of 100 companies[30] manufacturing "new" dangerous substances in the field of photochemicals, paints, intermediates, dyestuffs and paper industry chemicals the classification of over 500 of substances was examined. Since all substances were registered in Annex I of the Directive, selecting the appropriate classification and labelling should have been an easy task.

However, the classification was not correct for 25 % of the examined substances and over 40 % were not correctly labelled. These figures should be considered rather high, since classification and labelling merely had to be copied from Annex I. It is therefore essential to reflect on how to lower this error rate.

Since the responsibility for enforcement of classification and labelling provisions rests with the Member States, it is necessary to examine whether national legislation should make manufacturers or anyone else placing a substance on the market, liable for any damage resulting from the "uninformed use" of dangerous substances which are not classified and labelled according to the Directive. This would have to apply to

- all substances in Annex I and
- all substances classified and labelled under the self-responsibility of the manufacturer according to Article 6 of the Directive.

It should further be considered whether a substance not classified and labelled according to the Directive should immediately be withdrawn from the market, either by the responsible entity having placed it on the market, or by national authorities.

"New" substances not classified as "dangerous"

Whereas information on the classification and labelling of substances which are "dangerous" are publicly available in Annex I to Directive 67/548/EEC, no information is systematically compiled about substances which are not classified. Since this concerns 30 % of the notified "new" substances, it is not satisfactory that this information is not centrally stored except in the archives of CAs or the ECB. Ideas should be developed to assure that this information, generated under considerable efforts, remains available to stakeholders.

[30] European inspection project Solid Enforcement of Substances in Europe (SENSE), Final report January 1998.

2.2. Notification of "new" substances

Facts and figures

Number and countries of notifications

Shortly after 1981 when the notification scheme entered into force a dozen "new" substances were notified per year. In 1996[32] over 350 "new" substances were notified in the Community, which represents an average of 1.5 substances per working day. The steady increase of the yearly number of notified substances dropped from 260 "new" substances in 1993 to 180 in 1994. This may be explained by the necessary adaptation of notifiers to the entry into force of the 7th amendment of the Directive in the autumn of 1993. But numbers rapidly recovered and reached a high point in 1996.

Overall some 2100 "new" substances were notified up to date. Since the placing on the market of a "new" substance has to be notified even if it is already marketed by a different manufacturer, the total number of notifications is 3800.

By country the largest number of notifications was processed in the United Kingdom and in Germany with some 25 % each, followed by France, the Netherlands and Italy, each with about 10 %.

By origin of manufacturer, non-EU manufacturers accounted for ±60 % of all notifications and ±55 % of all notified "new" substances and were almost exclusively situated in Switzerland, Japan and the United States. This exemplifies that industry in other parts of the world is capable of coping with the provisions of the Directive.

Areas for possible improvement

The notification requirements of the Directive are deemed too restrictive by industry, yet hostile to innovation. A further matter of concern is the omission of the notification for "new" substances.

Innovation and competitiveness

Industry continuously complains that the notification provisions of the Directive are too strict and stifle innovation. They voice this opinion especially in three areas: polymers, intermediates, research and development.

– Polymers.

[32] 7th Progress Report of the European Chemicals Bureau of Directorate General "Joint Research Centre", 1997, p. 10.

Article 14 (2) of the Directive stipulates that every polymer which contains more than 2 % (by weight) of a "new" substance must be notified. The requirements for the notifications of such polymers are laid down in Annex VII D of the Directive, including special provisions to alleviate the testing burden. Thus,

(1) the "family approach" places polymers with similar physico-chemical properties into a group and toxicity testing is only necessary for one member.

(2) for polymers with certain physico-chemical properties a reduced toxicity testing is acceptable.

In addition, a Guidance Document on the polymer provisions was finalised by Commission, CAs and industry in 1997[33]. This Guidance interpretes the provisions of the Directive in the largest possible sense and will be in use until the year 2000, when it will be revised in the light of the acquired experience.

Industry claims that, due to the strictness of provisions for the notification, opportunities to develop innovative polymers were lost, but are unable to substantiate these claims. It may be that industry prefers to variate the composition of "existing" polymers, in order to make further use of their production machinery and to avoid the risk of failing in a costly notification.

Notification data show about a dozen notifications of "new" polymers per year since 1993, when Annex VII D entered into force[34]. This represents approximately 3 % of all notified "new" substances.

– Intermediates.

Substances which appear temporarily during the numerous steps of a synthesis are called intermediates. If such an intermediate is processed in a factory other than the original one, it is "placed on the market" since it is made available to another manufacturer. This requires the usual set of tests to be carried out, as for any other substance placed on the market for final use by the public at large.

Since an intermediate is only handled by professional staff and on a controlled number of sites, the exposure of man and the environment is limited. Therefore, industry claims that a reduced test set would be sufficient for intermediates, without lowering the level of protection of human health and the environment.

Proposals on how to reduce testing for intermediates are being discussed by the national CAs and with industry. In principle the testing requirements of the next lower tonnage level would appear to be sufficient for intermediates placed on the market at a certain level. However, it is not yet entirely clear how "limited exposure" shall be assured. Discussions with the CAs are likely to be finalised by

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[33] NOTIF/20/97, approved by the 54th Meeting of the Competent Authorities for New Substances on 15 December 1997 in Brussels.

[34] Notification database of the European Chemicals Bureau (ECB).

the end of 1998 and result in the proposal for an amendment of Directive 67/548/EEC.

- Research and development.

  According to Article 13 (2) of the Directive "new" substances may be placed on the market in a quantity of up to 100 kg per year for scientific research and development (scientific R&D), without any testing. For process-oriented research and development (PORD), the marketed quantity is unlimited, provided that the manufacturer respects certain conditions including a limited testing, but restricted to one year. Exceptionally this year may be extended for a further year by the CA.

  Industry claims that these exemptions from the notification scheme are still too restrictive, in particular the one year limitation under PORD, to develop innovative substances. The CAs, however, feel that insufficient use has been made of the exemptions. Discussions with the CAs and with industry have not led to a modification of the Directive, but industry keeps putting the issue on the table.

In conclusion polymers, intermediates and R&D exemptions are the three main topics where industry claims that alleviation of the current requirements of the Directive is necessary, because they are stifling innovation. On an international scale the chemical industry is voicing these concerns in the framework of the Trans-Atlantic Business Dialogue (TABD), which is an industry driven event with participation of the chemical industry and the administration from both the United States and Europe.

A recent "Study on the impact of EU environmental regulation on selected indicators of the competitiveness of the EU chemical industry"[35], however, concludes on the basis of empirical evidence, that the strictness of environmental regulation is not a significant explanatory factor for the competitiveness of the EU chemical industry. The study asserts that environmental improvements can go hand in hand with an improvement of the company's competitiveness.

Circumvention of the notification

The inspection of ±100 companies producing dyestuffs[36] revealed that almost 40 % of the 140 "new" substances examined had not been notified at all and were thus illegally marketed. A further, similar project showed, however, that only 5 % of the 233 "new" substances inspected were not notified. Especially the result of the first inspection project underlines the importance to enforce the provisions laid down in the Directive.

Since the responsibility for enforcement rests with the Member States, it should be examined whether liability for any damage resulting from the use of "new" substances which are not notified may not be included in national legislation. In

[35] Sofres Conseil, Report for the European Commission, 1998.

[36] European inspection project on the Notification of New Substances (NONS), Final report July 1996.

addition non-notified "new" substances should immediately be withdrawn from the market by the manufacturer or anyone else who placed them on the market or by national authorities.

Circulation of notification dossiers

After the notification of a "new" substance the dossier has to be circulated among national CAs in order to maintain the information on notified substances at the same level. Since data must be kept confidential the dossier is transmitted through the Permanent Representation of the notifying CA's Member State in Brussels to the ECB by diplomatic pouch, multiplied there and transmitted back, via the receiving Member States' representations, to the other CAs.

This form of circulation takes 4 months for 50 % of the notification dossiers, and 10 % of the dossiers take longer than one year. This is too long for a number of CAs. Suggestions for improvement include

- direct electronic transmission between CAs and the ECB;
- immediate circulation of the summary information of a notification in order to quickly identify repeat notifications;
- circulation of notifications by ECB within 30 days.

These suggestions need consideration by Commission and CAs in the near future in order to accelerate the necessary flow of information.

Tonnage limits triggering data requirements

According to the Directive data requirements for the notification of a "new" substance depend on the tonnage placed on the market. According to Competent Authorities, however, certain substances such as ingredients for cosmetics may require more data than provided according to their marketed volume. Consequently the link between tonnage limits and data requirements should be reviewed.

Publication of ELINCS

The list of notified "new" substances ELINCS has last been published in 1994 and a new publication is being prepared for late 1998. This is not in accordance with the commitment to update ELINCS before the end of every year as provided in the above-mentioned Commission Decision establishing this list. It might be necessary to reconsider the frequency and the format of publication.

2.3. Risk assessment

Facts and figures

Number and countries of risk assessments

During 1994 – 1996 almost 380 risk assessments for the "new" notified substances were prepared by the CAs in the fifteen Member States. "No concern" was concluded by over 50 % of the assessments, ±20 % requested that the assessment be revised in the light of the additional data on the substance that the manufacturer

would have to provide when reaching the next higher tonnage limit. A further 20 % of the risk assessments required immediate collection of further information on the substance, less than 10 % made immediate "recommendations for risk reduction". Thus, a comfortable majority of 70 % of all risk assesments expressed no concern or only slight concern on the notified "new" substances, only 30 % required immediate action.

By Member State, the CA of the United Kingdom prepared 40 % of all risk assessments, Germany 30 %, France 15 % and the Netherlands 10 %. Only 5 % of the risk assessments came from the remaining Member States.

Coherence of risk assessments

In order to ensure a coherent outcome of risk assessments in all Member States the principles are laid down in Directive 93/67/EEC and detailed instructions are given in the Technical Guidance Document. Even so, CAs from different Member States appear to differ in the interpretation of the guidelines, also the reporting format is not unique. However, these differences are at present under discussion within the CAs and can be expected to be solved rapidly through the commitment of CAs to a uniform application of the guidelines.

Risk assessment and notification

An example for the role of risk assessment in the notification process is the notification of a substance for use as a toner in laser printer cartridges. During the notification process it became clear in the dialogue between the CA and the notifier that the risk assessment would immediately conclude the substance be withdrawn from the market. The intrinsic danger was much too high to tolerate the leaching of the substance from printed paper into the water during paper recycling. As a consequence the notifier withdrew the notification.

Areas for possible improvement

A number of CAs stressed that preparation of a risk assessment was resource intensive and consumed too much time. Between one and two years are sometimes needed to complete the work. In order to alleviate the burden some CAs suggested that no risk assessment be prepared for

- substances not classified as "dangerous";
- "new" substances notified with a reduced data set as laid down in Anexes VII B (100 – 1000 kg/year or 5000 kg cumulative) and C (10 – 100 kg/year or 500 kg cumulative) of the Directive;
- substances placed on the market in quantities of less than 10 tons;
- substances that would not be marketed within 1 to 3 years;
- site limited intermediates;
- substances intended for certain use categories.

The underlying tendency is that the results of the classification and labelling exercise may be sufficient to appraise whether an extensive risk assessment, as required by Directive 93/67/EEC, is neccessary. This approach will have to be discussed among Commission and Member States in the near future.

2.4. Risk management

Directive 67/548/EEC includes an only rudimentary approach to risk management. The most severe conclusion from the risk assessment of a "new" dangerous substance according to Directive 93/67/EEC requires the notifier to take action to lessen the risks to human health and the environment.

An extreme case would be the non-acceptance of the notification dossier by the Competent Authority because of the foreseeable unacceptable risk that the "new" substance presents. Suggestions were made by Competent Authorities that such "new" substances could be compiled in a list in order to avoid that subsequent manufacturers submit notification dossiers for the same substance.

The main impact that Directive 67/548/EEC has on risk management lays in the link to Directive 76/769/EEC on the restrictions of marketing and use. Half a year after publication of carcinogenic, mutagenic or toxic to reproduction substances (CMR substances) of category 1 or 2 in Annex I to Directive 67/548/EEC, The Commission has to submit a proposal to the European Parliament and the Council in order to possibly restrict such substances under Directive 76/769/EEC. This proposal has to take account of the risks and advantages of the substances. Experience has shown that it is not always possible to meet this deadline, the preparation of the proposal to update Directive 76/769/EEC requires more time.

Where dangerous substances requiring restriction measures, such as the above-mentioned CMR substances, are not yet covered by Directive 76/769/EEC they must be included by an amendment of this Directive by a European Parliament and Council Directive. The necessary co-decision procedure usually requires eighteen to twenty-four months. It may be questioned whether such a procedure can be considered efficient to maintain a high level of protection for human health and the environment.

2.5. Structure of the Directive

Directive 67/548/EEC has been amended eight times after the adoption in 1967 and its nine Annexes have been adapted to scientific and technical progress twenty-three times. The dispersion among 32 pieces of legislation has made the Directive very complex and makes the understanding of the complicated matter a difficult exercise. In addition the permanent adaptation of the Annexes requires a close follow-up by any user.

To remedy the situation the Directive was informally consolidated by the Commission and made available in English, French, German, Italian, Portuguese and Spanish in order to cover the most important languages in Europe and world wide. The consolidated version has made the daily work with the Directive

considerably easier, nevertheless the original texts are the ones that remain legally binding.

The formal codification, which would officially assemble the multiple parts of the Directive and make it legally binding, has been severely hampered by translation problems for Finnish and Swedish. In addition codification, by its official character, requires more efforts than the informal consolidation. This is especially important with regard to the permanent adaptations to technical progress.

Some provisions of the Directive are almost incomprehensible because they are based on implicit expert knowledge, or need a clearer drafting, such as the definition of polymers in Article 2 (1) (c) or the 10-year-rule in Article 9.

Another aspect that complicates the understanding of the provisions is the sometimes confusing structure of the Directive. Missing clarity makes it difficult for the beginner to overview the manifold rules which are laid down, and the trained user may overlook provisions which could be important for an actual problem.

A clear structure of Directive 67/548/EEC is even more important because the Directive is embedded in a well-developed network of provisions on chemical substances. Provisions of the Directive

- are "used" by other Directives, such as Directive 88/379/EEC on dangerous preparations or Directive 76/769/EEC on the restrictions on the marketing and use, or
- point to other Directives, such as Directive 93/67/EEC on risk assessment principles or Directive 91/155/EEC on the Safety Data Sheet, which are vital for the practical operation of Directive 67/548/EEC.

This begs the question whether the structure of Directive 67/548/EEC, when revised, would not benefit from the inclusion of the provisions of some of the other instruments dealing with chemical substances.

3. CONCLUSIONS AND RECOMMENDATIONS

In general the provisions laid down in Directive 67/548/EEC have proven satisfactory. The requirement to classify dangerous substances according to their intrinsic physico-chemical and toxicological properties is undisputed. The detailed classification system allows to take a large range of effects into account, whereby effective protection from the multiple potential dangers of chemical substances is possible.

The link with Directive 76/769/EEC relating to restrictions on the marketing and use has allowed to ban from use by the general public over 850 carcinogens, mutagens and substances toxic to reproduction of category 1 and 2, which cause special concern. The connection with Directive 90/394/EEC on the protection of workers from carcinogens controls the presence of carcinogens at the workplace when they are covered by the criteria of Directive 67/548/EEC.

Also the notification of "new" substances is accepted by all stakeholders. This provides control over the substances prior to placing them on the market and identifies the persons in charge. Acceptance also exists for the necessity to provide increasing details about the properties of the notified substance with increasing amount of substance placed on the market.

However, criticisms have been raised over a number of points, and weaknesses detected. These concern

Classification and labelling

- the obligation of manufacturers to self-classify and label "existing" dangerous substances;
- the length of procedures necessary to reach harmonised agreement on the classification and labelling of dangerous substances and to publish them in Annex I to the Directive;
- the complex system of R- and S-phrases;
- the insufficient enforcement of the provisions for classification and labelling;
- the difficulty to trace the chemicals which have not been classified as dangerous under the Directive.

Notification of "new" substances

- the hampering of innovation and competitiveness of the chemicals industry, especially in the fields of polymers and intermediates and concerning exemptions for research and development;
- the circumvention of the obligation to notifiy "new" substances;
- the length of procedures for the circulation of notification dossiers and other information among the national Competent Authorities;
- the irregular publication of the list of notified "new" substances ELINCS.

Risk assessment

- the outstanding efforts in personnel and time necessary to carry out a proper risk assessment. Risk assessment always "lags behind".

Risk management

- there is no adequate follow-up for substances classified in Annex I as carcinogenic, mutagenic or toxic to reproduction (category 1 or 2), even though the effects of such substances are of major concern;

Structure of the Directive

- the complicated structure of the Directive which has grown over more than thirty years through 8 amendments and 23 adaptations to technical progress;

- the non-availability of an officially consolidated version.

To improve the practical operation of the Directive the following recommendations should be considered.

Classification and labelling

- Review of the obligation of manufacturers, distributors and importers to self-classify and label "existing" dangerous substances.

- Acceleration of harmonised classification and labelling. Updating of Annex I on a twice-yearly basis. Review of Annex I adaptation procedure.

- Provision of adequate expertise and resources in the relevant instances.

- Fundamental expert review of the R- and S-phrase system.

- Member States to ensure the enforcement of provisions.

- Member States to consider liability as a means to improve compliance, and to consider withdrawal of substances from the market in case of non-compliance.

- Commission to propose the establishment of a list of substances which have not been classified as dangerous under the Directive.

Notification of "new" substances

- Polymers: A guidance document to ease up the notification of polymers has been agreed by Commission, Member States and industry. Revision foreseen, as appropriate, in about two years.

- Intermediates: Improved notification scheme currently under discussion between Commission and Member States. Input of industry forthcoming.

- Exemptions for research and development: Industry to make better use of the existing possibilities for exemptions.

- Member States to ensure the enforcement of notification provisions.

- Member States to consider liability and withdrawal of non-notified "new" substances from the market as means to improve compliance.

- Accelerated circulation of notification dossiers, possibly using encrypted e-mail.

- Review of tonnage limits triggering data requirements for notification and possible inclusion of further criteria for special cases.

- Publication of the list of notified "new" substances ELINCS more regularly, possibly under a revised format.

Risk assessment

- Risk assessments only for substances classified as dangerous.

- Risk assessments to be modulated according to volumes marketed, with a minimum level of 1000 kg/year/manufacturer or a total of 5000 kg on the market.Severity of hazard is to be taken as the main qualifier, however.

- Special risk assessment conditions for site limited intermediates.

- List of "new" substances presenting an "unacceptable" risk.

Risk management

- Acceleration of follow-up for substances classified in Annex I as carcinogenic, mutagenic or toxic to reproduction (category 1 or 2).

Structure of the Directive

- Restructuring of Directive to give it the necessary clarity and transparency, including provisions currently in other legal instruments, such as the principles of risk assessment or the provisions on the Safety Data Sheet.

Findings
on the Operation
of
Directive 88/379/EEC
on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations

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1. BACKGROUND

1.1. INTRODUCTION

European chemical industries manufacture and use a large number of chemical products. 90 to 95% of all chemicals on the European market are preparations. The range of uses includes industrial chemicals, such as solvents and coatings; petrochemicals, including fuels and lubricants; agricultural chemicals, including pesticides and fertilisers; consumer products, such as detergents and disinfectants; and many others. A majority of these chemicals are of low concern for human health or the environment but a significant proportion have properties which are hazardous either to human health and/or to the environment.

Initially most legislation on chemicals existed at national level but considerable disparities between the national legislation of the Member States increased the need to introduce harmonised legislation on chemicals at European Union level.

In 1967 the first Directive[1] concerning the classification, packaging and labelling of dangerous substances was adopted.

Since 1969, in the context of a general programme dealing with the elimination of technical barriers to trade, particular concern was given to the classification, packaging and labelling of mixtures of chemicals (preparations).

Up to 1988 the Council had adopted the following Directives concerning dangerous preparations: in 1973 on solvents[2-3], in 1977 on prints, varnishes, glues inks and related products[4-5], and in 1978 on pesticides[6-7].

However, already since 1979 several Member States had envisaged methodologies for an overall evaluation of preparations independent of their area of application.

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1 OJ L 196 of 16.8.1967 p.1

2 OJ L 189 of 11.7.1973, p.7

3 OJ L 229 of 30.8.1980, p.57

4 OJ L 303 of 28.11.1977, p.23

5 OJ L 147 of 6.6.1983, p.11

6 OJ L 203 of 29.7.1978, p.13

7 OJ L 88 of 2.4.1981, p.29

1.2. WHY A DIRECTIVE ON DANGEROUS PREPARATIONS?

Towards the end of 1980 the Council of Ministers of the EEC recognised the advantage of having one single Directive on preparations to replace the other existing Directives. As a consequence it invited the services of the Commission to prepare an appropriate proposal.

Directive 88/379/EEC[8] was adopted on 7 June 1988 and came into effect on 16 July 1991.

Objectives

In 1988, the Directive had two legislative objective:

- to simplify Community legislation on the classification and labelling of dangerous preparations by reducing the number of existing directives on individual groups of chemical preparations;

- to meet formal requests from the Member States, to have an harmonised system applicable to all preparations which the Commission has acknowledged to be justified.

The aim was therefore to classify and label all preparations according to a simple procedure by taking into account the degree of hazards they might present, irrespectively of their uses.

The objectives of the Directive are:

- to provide a high level of protection to persons who come into contact with such preparations , either at work or in private (e.g. at home), by providing a label giving essential information on the hazards involved and the precautions to be taken;

- to improve the functioning of the Internal Market by reducing the obstacles to trade of chemical preparations that arise from different classification and labelling.

1.3. FACTORS CONSIDERED WHEN DRAWING-UP THE DIRECTIVE ON DANGEROUS PREPARATIONS

8 OJ L 187 of 16.7.1988, p.14

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The development of a directive on "general industrial " preparations did, however not mean that totally new legislation had to be set-up . Indeed, the progress made by Community legislation on dangerous substances could be used as a basis for this development. Just as chemical substances form the ingredients of chemical preparations, the dangerous substances Directive would logically serve as a basis for the dangerous preparation Directive.

It is for that reason, that the legislation on dangerous substances and dangerous preparations is so linked. Nevertheless, some fundamental differences exist also and need to be reminded.

1.3.1. Essential common points between the Directives on dangerous substances and dangerous preparations

The Directive on the classification, packaging and labelling of dangerous preparations is closely linked to Directive 67/548/EEC on dangerous substances and in particular on the following provisions:

- the use of the same categories of dangers as defined in Article two of Directive 67/548/EEC. Dangerous preparations are classified and labelled on the basis of the same categories of danger as those applicable to dangerous substances. (e.g. flammable, irritant, toxic etc.)
- the use of the classification and labelling of dangerous substances listed in Annex I as well as their concentration limits, when specified.
- the use of the symbols and indication of dangers described in Annex II. Therefore, the symbols and the indications of danger described in Annex II to Directive 67/548/EEC apply also to preparations.
- the use of the nature of special risks (R phrases) listed in Annex III and of safety advice (S phrases) listed in Annex IV to Directive 67/548/EEC is also applicable to dangerous preparations.
- the use of the test methods described in Annex V to Directive 67/548/EEC when laboratory tests are performed on the preparations
- the use of the criteria to classify and label dangerous substances and dangerous preparations contained in Annex VI (Labelling guide), except when the classification of the preparation is carried out on the basis of the "conventional method". In this case solely the provisions of the Directive on dangerous preparations applies.

Because of the close link between dangerous substances and preparations it must be underlined that any modification to the legal framework of dangerous substances may have consequences for the classification of preparations and in particular modifications to the labelling guide. (see chapter on developments).

1.3.2. *Key differences between the provisions of the directives on dangerous substances and on dangerous preparations*

♦The dangerous substances Directive uses a single system, based on test methods, to determine the properties of the substances for their classification and labelling under different categories of danger.

The dangerous preparations Directive allows the use of 2 systems for the evaluation of health effects:

- either the same as for substances (except for C, M ,T properties) or
- the use of a conventional calculation method

The reasons for this difference are:

The proposal for a directive elaborated in 1983 provided for derogation to replace the determination of the properties of preparations on the basis of laboratory tests by a theoretical assessment of the hazards.

The approach pursued at the time anticipated the situation of today relating to the trade of chemical substances. The number of chemical substances placed on the European market until September 1981 (closing date for the European Inventory of Existing Chemical Substances EINECS) was 100,106. An estimation that several hundreds new chemicals would be added each year to the number of substances already on the market indicated that the total number of chemical substances was bound to inflate with time. On the basis of this assumption, it was estimated that the number of chemical preparations on the European market would at least be ten-times the total number of chemical substances.

If all preparations placed on the market were to be dealt with in the same way as substances, under the provisions of Directive 67/548/EEC, an enormous number of laboratory tests would have needed to be carried out to determine the hazardous properties of the preparations. This was not acceptable for the following reasons:

- First from the financial burden point of view which would have had to be born entierly by industry.

- Secondly, from an economical operators point of view; this approach would have resulted in sacrificing the potential of SMEs' which play an important role in this area of products of the chemical industry.

- And finally also, from an animal welfare point of view; this approach would have necessitated the use of to many animals for experimental purposes.

The above important issues advocated an alternative system for the determination of the health effects of preparations which is necessary for their classification and subsequent labelling. Therefore, the establishment of a "conventional method " was well justified.

♦The second important difference to the existing legislation on dangerous substances is the fact that no notification is required under the provisions of the Directive prior to placing a preparation on the market.

The reason for this difference is that:

The concept of new and existing preparations does not apply to preparations. All substances both included in ELINCS and in EINECS are taken into account for the evaluation of the hazards of the preparations. However, if a preparation contains a new substance, the person responsible for placing the preparation on the market should prior to its placing on the market, notify this substance according the provisions of Directive 67/548/EEC.

Given the large number of preparations placed on the market and the possibility for industry to use a conventional method for the determination of hazardous properties of preparations as an alternative to testing, it was not deemed crucial by authorities to establish a notification/authorisation procedure which would have required considerable resources.

2. DESCRIPTION OF DIRECTIVE 88/379/EEC

2.1. SCOPE

The provisions of Directive 88/379/EEC apply to preparations which contain at least one substances classified as dangerous and which are considered to be dangerous within the meaning of the Directive. The exempted groups are :

- a) medicinal or veterinary products as defined by Directive 65/65/EEC[9]
- b) cosmetic products as defined by Directive 76/768/EEC[10]
- c) mixtures of substances which, in the form of waste, are covered by Directive 75/442/EEC [11]
- d) pesticides covered by Directive 78/631/EEC[12]
- e) munitions and explosives placed on the market with a view of obtaining a practical effect by explosion or a pyrotechnic effect
- f) foodstuffs in a finished stage intended for final consumer
- g) animal feedingstuffs in a finished stage intended for final consumer
- h) the carriage of dangerous substances by rail, road, inland waterway, sea or air
- i) preparations in transit which are under customs supervision provided they do not undergo any treatment or processing

Normally, all the exempted groups of preparations are covered by other specific Directives for the protection of health, safety and the environment when they are placed on the market. However, the dangerous preparations Directive is regarded as a safety net for all preparations which are not more tightly regulated.

It must be underlined that the Directive on dangerous preparations includes preparations intended for both industrial uses and the domestic market.

For the latter category of users the Directive on dangerous preparations also provides for special labelling requirements for preparations which are not classified as dangerous but which owing to their properties may present certain hazards to the

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[9] OJL No 22, of 9.2.1965 p.369/65

[10] OJL No 262, of 27.9.1976 p.169

[11] OJL No194, of 25.7.1975 p.39

[12] OJL No 206, of 29.7.1978 p.13

users. Examples of such preparations are cyanoacrylate glues (instant glues) or paints containing lead derivatives.

2.2. PURPOSE

The purpose of Directive 88/379/EEC is to provide a legal instrument allowing to harmonise the classification, packaging and labelling of dangerous preparations placed on the E.U. market.

The aim is to protect both the professional users and general consumers as well as the environment from the hazardous properties of dangerous preparations.

2.3. DETERMINATION OF THE HAZARDS OF PREPARATIONS

As has already been mentioned, the dangerous preparation Directive is a legal instrument that requires to any person responsible for placing a dangerous preparation on the market to classify, package and label it in accordance with its provisions.

Providing that the manufacturer, the importer or the distributor, complies with the requirements of the Directive, he may place any dangerous preparation on the market without prior information to the national authorities.

For the purpose of classification with respect to the different hazard categories described in Article 2 of the Directive, the intrinsic properties relating to physico-chemical and health hazards of the preparation must be evaluated. The way this evaluation has to be carried out depends on the properties examined:

- For physico-chemical hazards deriving from explosivity, flammability or oxidising properties, the evaluation must be carried out by using the test methods of Annex V to Directive 67/548/EEC.

- Regarding health effects, two options are available:

  • by using the test methods of Annex V to Directive 67/548/EEC

  • by the conventional method

All health effects shall be assessed either by tests or by the conventional method. If the preparation has already been tested for some of its properties, the results of these tests are used for the classification of the preparation for those properties. All other properties have to be assessed by applying the conventional method. However, properties as carcinogenicity, mutagenicity and toxicity for reproduction should always be determined by the conventional method.

It is important to underline that when the Directive was adopted, the criteria for classifying a substance as dangerous for the environment were not existing. Therefore, the evaluation of environmental effects was not required for preparations.

However, since that time, a new category of danger for the environment and criteria for the classification and labelling as dangerous for the environment have adopted for substances. Because of the existing link between the Directives this important change would also need to be to be reflected in the preparations Directive. (see evaluation 4.2.)

2.4. CLASSIFICATION AND LABELLING

The classification of preparations, deriving from the determination of the intrinsic properties of preparations, is performed by applying the criteria of the Labelling Guide, Annex VI to Directive 67/548/EEC, and in addition by applying the rules set out in the dangerous preparation Directive in the case where the conventional method is applied.

The conventional method is based on concentration limits applied to individual, classified substances. These concentration limits are:

either those specified in Annex I to Directive 67/548/EEC for the substances included in this Annex, or

these specified in Annex I to the Directive on dangerous preparations where the substance or substances do not appear in Annex I to Directive 67/548/EEC or they appear in without concentration limits.

The conventional method also takes into account the principle of additivity of some toxicological properties. In this case, the mathematical formulas described in the Directive can be used.

The information deriving from the classification is used to determine the labelling by applying the rules of Article 7 of the Directive of dangerous preparations. Article 7 provides for the appropriate information to be put on the label, such as the identification of the person responsible for placing the preparation on the market, the symbols and the indication of danger accompanied by the relevant risk phrases (R phrases) and the safety advice (S phrases) intended for safe handling and use of the preparation.

In addition, the labelling must also take into account special requirements for preparations described in Annex II to this Directive. These additional requirements are mainly intended to protect the general public from the hazards of these preparations.

In spite of the fact that the classification and labelling of dangerous preparations is carried out on the basis of rules of the Directive on dangerous preparations, it is important to stress that the provisions of the Directive are intimately linked to the Community legislation on dangerous substances.

2.5. PACKAGING OF DANGEROUS PREPARATIONS

The provisions for the packaging of dangerous preparations have been essentially taken from the Directive on dangerous substances. These provisions can be regarded as good management practices and are not specific to preparations. During the development of this Directive, specific problems of packaging relating to preparations have been identified such as child resistant fastenings and tactile warnings, which will be commented further down in this Annex.

2.6. SYSTEM FOR SPECIFIC INFORMATION (SAFETY DATA SHEETS)

.When the Directive was adopted the authorities and the Commission were aware of the fact that the first information provided to the users, by a harmonised system of classification and labelling of preparations, was of course of vital importance but insufficient in terms of safety with respect to their life cycle, especially regarding their manipulation, their use, their transport and their disposal.

Therefore, in addition to the information provided to users on the label, the dangerous preparation Directive requires more detailed specific information for industrial users such as for example, first measures in case of fire or accidents, or storage and handling, in the form of safety data sheets. The details for such information are set-up in a separate implementing Directive.

2.7. COMPLIANCE WITH THE PROVISIONS OF THE DIRECTIVE

The Directive places on the person responsible (manufacturer/importer/supplier) for the placing the preparation on the market the obligation to classify, label and package this preparations as well as to compile and submit a safety data sheet in accordance with the provisions of this Directive. However, the Directive is addressed to the Member States who are responsible to take all necessary measures to ensure its correct implementation and enforcement.

3. EVOLUTION

The evolution of the Directive on dangerous preparations took place very quickly after its adoption for two essential reasons. The first one related to requirements included in declarations made by the Council at the moment of its adoption , such as the development of a conventional method intended for gaseous preparations. The second one related to technical progress such as particular labelling requirements for certain groups of preparations (i.e. elastomers) or specific packaging requirements

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intended to protect special target groups, i.e. children and blind or partially sighted people. All these developments have been made either in the form of amendments (implementing directives) or as adaptations to technical progress of the Directive.

It is necessary to stress at this point that the above mentioned adaptations to technical progress were undertaken quickly and efficiently following a simple comitology procedure set out in Article 15 of the Directive.

3.1. IMPLEMENTING DIRECTIVES

3.1.1. Safety data sheets for dangerous preparations

It has been explained earlier that a directive implementing safety data sheets was needed pursuant the provisions of Article 10 of Directive 88/379/EEC. Directive 91/155/EEC[13] was adopted only three years after the dangerous preparations' Directive. This technical directive specifies the conditions for which safety data sheets must be supplied for dangerous preparations to industrial users and their technical content.

According to the Directive, safety data sheets have to be supplied to professional users for any preparation dangerous within the meaning of Directive 88/379/EEC. The safety data sheets are aiming to warrant a high level of protection by providing all the information required for safe handling and use of the preparations at the work places.

3.1.2. Child resistant fastenings – Tactile warnings

The statistics from the poison centres of the Member States have shown over the past decades that young children remained a particularly exposed target group to dangerous chemicals and especially so for household products which fall under the provisions of the dangerous preparation Directive. It was felt appropriate by the authorities and the Commission that this problem should be addressed in the Directive by including special provisions for child resistant fastenings. Given that blind or partially sighted people is also a target group with special needs it was also appropriate to introduce specific provisions for this case.

These provisions called for an amendment to Directive 88/379/EEC in a first step by Directive 90/35/EEC[14] and an adaptation to

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[13] OJL No 76, of 22.3.1991 p.35

[14] OJL No 19, of 24.1.1990 p.14

technical progress in a second step by Directive 91/442/EEC [15]. Again it is important to stress the efficacy and the rapidity of these changes.

3.2. ADAPTATIONS TO TECHNICAL PROGRESS

3.2.1. Classification and labelling of gaseous preparations

Owing to their physical state and their conventional units of measurement differing from those adopted for solid and liquid preparations , gases have to be treated as a separate case under the provisions of Directive 88/379/EEC. After consultation with the relevant industrial sector and discussions at Community level, Directive 90/492/EEC[16] containing additional tables with concentration limits for the classification of gases was adopted. This adaptation to technical progress contains also provisions for the evaluation of hazards deriving from physico-chemical properties.

3.2.2. Other adaptations to technical progress

In order to maintain consistency with the technical developments of the Directive on dangerous substances and , in particular with the Labelling Guide several adaptations to technical progress were needed to the Directive on dangerous preparations.

Directives 93/18/EEC[17] and 96/65/EEC[18] were adopted in order to introduce criteria for the classification of the preparations containing substances affected by specific R-phrases (R 33, R 64, R65).

4. EVALUATION

4.1. INTRODUCTION

After almost ten years of practical application and enforcement by the Member States, the existing legislative framework on dangerous preparations has generally proven effective in gradually eliminating the different technical trade barriers for the

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15 OJL No 238, of 27.8.1991 p.25

16 OJL No 275, of 5.10.1990 p.35

17 OJL No 104, of 29.4.1993 p.46

18 OJL No 265, of 18.10.1996 p.15

free circulation of chemical preparations in the Community that arose from different classification and labelling requirements.

Harmonised rules for the classification; packaging and labelling of dangerous preparations together with existing rules on dangerous substances have contributed to the creation of a comprehensive framework for chemicals, which is of paramount importance for the competitiveness of the chemical industry.

Directive 88/379/EEC on dangerous preparations pursued a high level of health standards through permanent adaptations to scientific progress and by taking into consideration newly emerging effects related to the protection of human health such as Directive 96/65/EEC which introduces the classification of the preparations on the basis of their aspiration hazard.

However, the Directive on dangerous preparations has shown to have a number of weak aspects and its implementation has given rise to a number of problems. These problems mainly relate to the function of the Internal Market, the protection of the environment and to the practical application of the Directive.

4.2. INTERNAL MARKET

4.2.1. Pesticides (Plant protection products covered by Directive 91/414/EEC[19]) and biocides covered by Directive 98/8/EC[20]).

4.2.1.1. Analysis of the current situation

The new harmonised authorisation process of pesticides which also includes provisions on classification, packaging and labelling laid down in the above mentioned Directives has brought to light the need for updating the legislation on classification, packaging and labelling of pesticides.

A study on the labelling of plant protection products, carried out by the Commission services clearly demonstrated that different requirements in relation to classification, packaging and labelling of pesticides exist between Member States.

In relation to the classification and labelling of pesticides for health effects, some Member States use the provisions of Directive 78/631/EEC and others apply the criteria of Directive 88/379/EEC. In some cases, Member States have their own system to classify pesticides for other effects.

Furthermore, depending on the Member States, the transfer of the information on the label derives either directly from the classification

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[19] OJL No 230, of 19.8.1991 p.1

[20] OJL No 123, of 24.4.1998 p.1

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of the pesticides on the basis of their hazardous properties or results from the risk assessment made by the competent authorities of the Member States on the basis of the intended use of the product.

This complexity becomes more apparent in the way that Member States classify and label pesticides for environmental effects. In this case, both classification and labelling are essentially based on national criteria. Whilst for some Member States the evaluation of the effects of the active ingredients on the aquatic environment is carried out on the basis of the criteria of Annex VI to Directive 67/548/EEC, the evaluation of the effects of pesticides to other compartments of the environment is solely carried out on the basis of national legislation.

The packaging requirements for pesticides vary also between Member States. In general, the authorities of the Member States require that packaging is made according to the provisions of Directive 78/631/EEC. However, some Member States have introduced particular national packaging requirements (i.e. requirement for child-resistant fastenings depending on the degree of hazards and the volume of the package).

For safety data sheets, some Member States apply the provisions of Directive 91/155/EEC(-) for dangerous and even for some pesticides which are not classified as dangerous according to Directive 88/379/EEC on dangerous preparations. Regarding submission of the SDS there are also differences between the Member States. In some cases the safety data sheet is provided along with the registration dossier and in other cases there are no specific requirements.

4.2.1.2.Conclusions

On the basis of this analysis it is obvious that differences do exist between the Member States in relation to the classification, labelling, packaging and submission of a safety data sheet of pesticides. This non-harmonised situation causes operational difficulties to the EU industry (e.g. same pesticide already authorised in one Member State have to be labelled in a different way to be placed on the market of another Member State) and in the long term have the effect of fragmenting the Internal Market by introducing obstacles to the free circulation of these specific preparations throughout the European Union.

In addition, these differences may also lead to different levels of protection for both human health and the environment.

4.2.2. Preparations not classified as dangerous under the scope of the existing legislative framework on dangerous preparations.

4.2.2.1. Analysis of the current situation

Some Member States have introduced into their legislation some of the provisions of the existing legal framework – notably those concerning packaging, labelling and the submission of a safety data sheet for some preparations that are not classified as dangerous in order to improve the existing level of health and environmental standards.

It must be stressed that this issue concerns a lot more preparations than dangerous preparations.

4.2.2.2. Conclusions

Such national legislative provisions may have the effect of jeopardising in the long run the achievement of the internal market for chemical preparations and raise the issue of a possible conflict between national measures to protect human health and the environment and the free movement of goods. Also these concerns have been reinforced by the exemptions granted to Sweden and Austria under the Accession Treaty.

This situation which was also re-enforced by the fact that non-classified preparations may have a potential risk to health and the environment led the Commission to act at EU level. This point will be developed in the following chapter.

4.3. ENVIRONMENT

Classification criteria for preparations "dangerous for the environment"

4.3.1. Analysis of the current situation

Directive 88/349/EEC classifies preparations as dangerous on the basis of their physico-chemical properties and of their health effects.

During 1992-1993 two Directives (Directive 92/32/EEC[21] and Directive 93/21/EEC[22] were adopted. The first one introduced, among other elements, a new category of hazard: dangerous for the environment. The second introduced criteria for environmental hazard

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21 OJL No 265, of 18.10.1996 p.15

22 OJL No 265, of 18.10.1996 p.15

classification as well as risk and safety phrases for the labelling of chemical substances.

As a result of these two Directives, efforts were made by the Commission and the Member States with the aim of finding appropriate approaches to develop rules on environmental hazard classification and labelling of preparations.

These efforts have, to a great extent, been fostered by the need to establish a system of criteria for environmental classification of preparations that is uniform, i.e. that identical criteria be used for all categories of preparations, irrespective of their function or their practical uses and to guarantee a high level of protection for the environment.

In a general sense, it was obvious that information on the environmental effects of preparations is of fundamental importance, if the users are to take account of the hazards to the environment in their choice of products. It was also essential to guide the users to handle the preparations in a correct way and to dispose of them in an environmentally acceptable manner.

This information is most readily provided by labelling the preparations and by compiling safety data sheets for preparations intended for industrial uses.

4.3.2. Conclusions

The Commission was required, therefore to propose Union-wide criteria for classification and labelling of chemical preparations as dangerous for the environment which deal with the hazards to the environment while assuring the free circulation of chemical preparations within the Internal Market.

4.4. PRACTICAL APPLICATION OF THE DIRECTIVE

4.4.1. Introduction

Until the adoption of Directive 88/379/EEC on dangerous preparations major differences between Member States' national measures concerning labelling of dangerous preparations existed.

The objectives of the Directive were therefore to achieve a harmonised level of protection for human health by giving the same information through the label to all users across the European Union and to ensure equal competitive conditions for the chemical industry throughout the Internal Market.

4.4.2. Analysis of the current situation

Responsibilities for operating and enforcing the Directive

Obligation of the person responsible for placing a preparation on the market

According to the existing provisions of the current legislative framework, in particular articles 3 and 7 of the Directive 88/379/EEC, the principle of the so-called self-responsibility applies. This means that the obligation to classify and label a preparation is placed on the person responsible for placing it on the market whether they are the manufacturer, distributor or importer. In addition, it is the obligation of the manufacturer/importer/distributor to communicate the information on the dangerous properties of the preparation to the professional users through the compilation of safety data sheets.

Obligation of the Member States

According to this Directive, it is the obligation of the authorities of the Member States to assume overall responsibility for the implementation of this legislation and to provide the necessary controls and penalties to ensure that the legislation is being complied with fully and properly by the person responsible for placing the preparation on the market (enforcement).

Furthermore, Directive 88/379/EEC provides to the Member States the possibility to take actions, which they consider appropriate and feasible within their legal, economic and political national framework, against preparations which constitute a hazard to human health and the environment although satisfying the requirements of the Directive (safeguard clause).

Problems identified in this area

It can be reasonably expected that some preparations, although having dangerous properties, are not classified at all by the manufacturers or that they are classified and labelled by different manufacturers in different ways. This occurs because of lack of understanding or lack of expertise, especially in smaller companies and because of different interpretations of some rules.

Another problem may be that the enforcement of this legislation is given different emphasis in different Member States. For example, some Member States may enforce passively (i.e. by investigating only complaints) whereas others may be more proactive in their surveillance of products on their market. The penalties for non-compliance may also be different. Problems of compliance resulting in different labels for the same preparation occur in all Member States.

Comprehensibility of the label

One of the fundamental objectives of the Directive is to provide all users with the same information through the label. The main benefits of uniform labels are that all users are afforded the same level of protection and that industry has to meet with the same labelling requirements across the European Union.

However, it is critical that the information contained in the label actually penetrates all target groups (consumers, professional users, manufacturers, authorities and medical staff). A preliminary study carried out by the Confederation of Family Organisations in the European Community) COFACE indicated that current labelling provisions may not achieve this objective. Although this study was limited in scope it clearly highlighted the need for further investigation.

A better understanding of the comprehensibility of this information among EU Member States is a pre-condition for cost effective labelling requirements. Seen in the broader perspective of ensuring the protection of the general public, it is closely linked to the following questions :

- do users read the labels ?
- do they understand the information on the label ?
- does the information make them behave in a way which reduces personal risks?
- do they get the information they need ?
- do they want more information or another kind of information ?
- should the same information be presented in a different way ?

Other practical issues

There are a number of technical issues to be addressed which the implementation of Directive 88/379/EEC has revealed:

1. Metals/alloys

There is no definition on the alloys. The question therefore on whether an alloy should be considered as a substance or a preparation is still open. This situation creates uncertainty to the industry who does not know if Directive on dangerous substances applies or the one on dangerous preparations.

2. Poison Centres

The role of the poison centres needs to be clarified. The Member States implement the provisions of article 12 of the Directive in different ways. The kind of information required to be submitted by the person responsible for placing on the market a preparation to these centres varies between the Member States.

3. Preparation/article

There is no definition allowing to distinguish between preparation from article. Member States apply different rules and thus the free circulation of certain products is not guaranteed.

4.4.3. Conclusions

There is a need to review all the areas covered under this chapter. Problems relating to the practical application of the Directive should be solved in order to create a transparent and precise legal framework for both the Member States and industry to operate. Correct implementation of the Directive will safeguard a high level of protection for human health and the environment. In relation to the information contained in the labels there is a need for an in-depth analysis of the relation between the national background and the comprehensibility of this information.

4.5 International Harmonisation

The summit in Rio in 1992 adopted a programme of action for sustainable development which includes a section on the international harmonisation of classification and labelling systems for chemicals. An Intergovernmental Forum on chemical safety (IFCS) has been established under the UN to supervise this programme.

The programme has first started with the exercise on the harmonisation of classification criteria for dangerous substances. This exercise, of paramount importance for the trade of chemicals throughout the world, is aiming to provide and internationally agreed system for the classification and labelling of substances.

However this process is slow. For example discussions on the harmonisation of the end-points on acute toxicity in the Organisation for Economic Co-operation and Development (OECD) started in 1993 and are still on going. The reasons for this include complexity of the technical issues involved and the fundamental differences between Member countries approaches.

Recently a similar exercise for dangerous preparations was launched at the OECD.

5. IMPROVEMENTS

5.1. PROPOSAL FOR A NEW DIRECTIVE ON DANGEROUS PREPARATIONS

5.1.1. State of play

- The proposal (COM(96)347 final) [23] for a European Parliament and Council Directive on classification, packaging and labelling of dangerous preparations was adopted by the Commission and subsequently submitted to the European Parliament and the Council on 18th July 1996

- The Common Position following the first reading at the European Parliament was adopted on 24 September 1998

5.1.2. Purpose of the proposal for a new Directive

In general the purpose of the new Directive is to harmonise the legislation on classification, packaging and labelling of dangerous preparations and at the same time to ensure a high level of protection for both human health and the environment.

Following the analysis carried out in the forgoing chapter 4: "Evaluation" the new proposal was basically introduced in order to provide Union-wide solutions to the problems related to the Internal Market and the environment.

Furthermore, this proposal will recast existing rules of Directive 88/379/EEC on classification, packaging and labelling of dangerous preparations, its adaptations to technical progress as well as its implementation Directives. In this way the Commission puts into practice the principle to simplify existing Community legislation and thus make this legislation more easily understandable by all interested parties involved (authorities, industry and finally the general public).

5.1.3. Pesticides

Provisions for classification, packaging and labelling of pesticides are introduced into the scope of the new Directive. The present Directive 78/631/EEC on classification, packaging and labelling of pesticides has raised criticisms on a number of points and its weaknesses has been proven as it covers only dangerous physico-chemical properties and acutely toxic properties.

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[23] OJC No 283, of 26.9.1996 p.1

The new Directive takes into consideration all the dangerous properties for the classification and labelling of pesticides similar to all other chemicals covered by the Directive.

The proposal for the classification and labelling of pesticides will be the responsibility of the manufacturer; however, the final decision will be taken in the context of the authorisation procedure of these preparations by the competent authorities for the Member States applying the rules of the new Directive. The new Directive will not affect specific Community legislation in relation to the authorisation procedure of pesticides (plant protection products and biocides). The proposal also includes provisions in relation to safety data sheets for pesticides. It places the obligation on the manufacturer to compile a safety data sheet which will have to be submitted with all the other information to the competent authorities for the authorisation of these chemicals. Lastly, a practical consequence of the inclusion of the pesticides in the new Directive will be that Directive 78/631/EEC will be repealed.

Therefore, the objective to ensure equal competition rules among firms producing pesticides, to establish a real Internal Market for these chemicals and to introduce a high level of environmental and health protection will be guaranteed.

5.1.4. Preparations not classified as dangerous

The new Directive extends the application of certain provisions to preparations which although not classified dangerous within the meaning of the Directive, may present a danger to the user.

According to the new Directive the person responsible for marketing preparations not classified as dangerous for professional users will have to compile and submit on request a safety data sheet to the recipient of the preparations.

Safety data sheets giving detailed information about the chemical composition and the dangerous properties of the preparations, as well as precautionary measures for use, shall be submitted on request also for preparations not classified as dangerous but which contain 1 % or more of substances dangerous for health or the environment, or substances for which there are Community exposure limits at the workplace. This information is needed by the employers and the economic operators to take the necessary measures to protect the employees at the workplace.

It should be mentioned that this provision would not affect the legislation of the Member States concerning worker protection at the work place. It defines the obligations of the person responsible for the marketing of such preparations. There is a link, however, between the proposed Directive and the Community legislation for worker

protection. The information provided according to the new proposal, by the person responsible for marketing a preparation will be used by the employer in accordance with the existing and specific legislation issued for the protection of workers.

5.1.5. *Preparations dangerous for the environment*

The new proposal for a directive introduces a transparent and easy-to-use methodology for the classification of preparations dangerous for the environment. A similar approach to the one used for the classification of preparations dangerous for human health is used for the classification of preparations dangerous for the environment.

The classification of a preparation as dangerous for the environment is, normally carried out by applying the conventional method. However, under certain conditions the acute toxicity for aquatic organisms can also be determined by applying the test methods of Annex V to 67/548/EEC.

In that respect, the provisions of the new directive are consistent with the rules developed earlier in the case of health effects of preparations.

The conventional method is based on the classification of the substances and their concentration limits in the preparation.

The proposed approach is considered as theoretically logical and scientifically justified. In addition, the total fraction of preparations being classified as dangerous for the environment on the basis of this proposal and on the basis of the assessment carried out using national product register does not seem to be significantly higher than the total fraction classified as dangerous for human health. In other words, the criteria introduced for the classification of the preparations as dangerous for the environment guarantee a high level of protection of the environment as the criteria for human health ensure a high level of protection for health.

Furthermore, the label of a preparation will inform users about the dangerous properties of a preparation and give advise for the safe use of the preparation. The warning symbol for substances dangerous for the environment will also be used for preparations dangerous for the environment.

5.2. OTHER AREAS FOR POSSIBLE IMPROVEMENTS

The Commission is convinced that the new proposal for a Directive on classification, packaging and labelling of dangerous preparations is a rather satisfactory basis and an important step to improve EC legislation on chemicals.

However, there may be other ways of further improving the legislation pertaining to the area of hazard assessment of chemical preparations. Proposals which have been put forward, and which the Commission believes merit further discussion, include :

- reinforcing enforcement mechanisms at national level
- studying comprehensibility of the labelling requirements
- developing a system for the compilation of safety data sheets for preparations not classified as dangerous
- introducing a harmonised system for the classification of dangerous preparations at United Nation level.
- reviewing some technical issues to improve practical application of the Directive

5.2.1. Non- compliance and Enforcement

The Directive 88/379/EEC as well as the future proposal for a directive requires manufacturers, importers and suppliers of chemical preparations to carry out a hazard assessment, to package, to label and to compile a safety data sheet for their products. This basic hazard information obtained by the original manufacturer is made available either to subsequent users to enable them to take appropriate measures to reduce the risks at the workplace or it is addressed directly to the general public.

This requirement should be considered by industry as a real challenge and should increase the self-responsibility of manufacturers, importers or suppliers of chemical preparations. Already, examples such as the establishment of an environmental management system (based on the international standard ISO) at companies level, are emerging where companies have re-evaluated the requirements of their customers and made changes which resulted in an improved service, increased competitiveness and lower impact of chemical preparations on the human health and the environment.

However self-responsibility of industry needs to be coupled with a mechanism for auditing and controlling companies. Enforcement, therefore, becomes a growing focus of attention in this context.

When the proposed directive is adopted Member States will also be responsible for enforcing the new provisions concerning

classification and labelling for the environment. It is therefore essential that Member States should take all necessary measures to improve their monitoring and control mechanisms, for example by strengthening their inspection systems and by taking administrative and judicial measures, in order to ensure that this legislation is properly implemented and eventually enforced.

It is important for the Commission to identify the causes of delays and non-compliance by Member States and where necessary ensure that the Member States take the appropriate measures to remedy the situation.

Another possible option to improve compliance is to increase the legal liability for industry so that they are responsible for accidents to occur as a result of not applying correctly the Directive (i.e. not labelling or wrong labelling). However this system of self-enforcement could result in disproportionate legal or insurance costs for SMEs, and needs to be examined thoroughly.

5.2.2. *Comprehensibility of labels*

The issue of how to improve understanding of the information on the label of dangerous preparations by the receiver is crucial. In this context, the following are some of the questions which need to be addressed such as :

- What will be the benefit or risks of simpler information ?
- What will be the added value of more common and easily recognised names of chemical compounds?
- Will more information lead to decreased comprehensibility?
- How can general education, specific training and increased awareness (environmental, consumer, health) be an effective method to improve comprehensibility?

The answers to these questions should be analysed in order to find concrete ways to improve the existing situation, if necessary.

In view of the central importance of this issue, the Commission initiated a major study on the comprehensibility of labelling in 1998 and has given its commitment to report to Council on the findings within two years after adoption of the proposed directive on dangerous preparations. The findings would also have implications for the labelling provisions for the dangerous substances directive.

5.2.3. *Safety Data sheets for preparations not classified as dangerous.*

The new proposal for a directive on dangerous preparations introduces the obligation for the manufacturer, importer or supplier of a "non-dangerous" preparation to provide a safety data sheet to the professional users. (This issue was explained under point 5.1.4)

However there are many such preparations on the European market. Establishing and updating full data sheets may be costly, may entail a disproportionate burden to the producers which also includes a lot of SMEs and a great load of follow-up work for the enforcement authorities. Among the producers, SMEs may have particular difficulties because often they do not have the necessary technical or human resources.

There is, therefore, a need for the Commission to examine this issue and to amend the "Safety Data Sheets" Directives to take into account the principle of proportional information before the implementation date for the new proposal of the directive on dangerous preparations.

5.2.4. *International harmonisation of classification and labelling of chemicals*.

A world-wide system of classification and labelling of preparations, both for safe transport and safe use it is highly desirable and it would at the same time improve safety and facilitate international trade.

Because of the magnitude of the task, its potential trade implications and safety benefits and the fact that it can only be accomplished through international efforts, this exercise should be given the highest priority and necessary resources. The Commission and the Member States should reflect on how the on-going process which is rather slow at this moment could be further improved and accelerated.

5.2.5. *Technical issues*

The Commission and the Member States should discuss all technical issues such as alloys, articles and the role of the poison centres which create practical problems with the application of the Directive with view of finding acceptable and operational solutions to these problems. An option is to establish a Guide to Dangerous Preparations Directive which will address all these issues and their respective solutions. This guide will be of outmost importance in particular for the SMEs.

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Findings

on the Operation of

Council Regulation (EEC) No 793/93 on the Evaluation and Control of the Risks of Existing Substances

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APPENDICES:

1. INTRODUCTION

The Council of the European Communities, in approving the Fourth Community Action Programme on the Environment (1987-1992), stated that one of the priority areas was the evaluation of the risks to the environment and human health posed by chemical substances. This Action Programme underlined the need for a legislative instrument, which would provide a comprehensive structure for the evaluation of the risks posed by "existing" chemicals. In particular, the Action Programme stated that such a legislative instrument "will establish a procedure for treating priority lists of chemicals for immediate attention, as well as setting out the means for gathering information, requiring testing and evaluating the risks to people and the environment".

As a result the Commission considered there was an urgent need to introduce regulatory measures in this area, since a harmonised approach to risk evaluation and control of "existing" chemicals would provide the basis for a high and consistent level of protection for man and the environment throughout the Community and would in addition prevent the fragmentation of the Community market for chemicals.

In 1989, during the negociations of the 8th amendment to Directive 76/769 on the restrictions on the marketing and use of certain dangerous substances and preparations, the Council recognised that the control of chemical substances should be based on the evaluation of their risks to man and the environment.

In the Organisation for Economic Co-operation and Development (OECD), the importance of the work carried out on "existing" chemicals had already been recognised with the 1987 Decision-Recommendation of the OECD Council on the Systematic Investigation of Existing Chemicals. This OECD Act stated that "Member Countries should establish or strengthen national programmes to systematically investigate existing chemicals". In 1988 the OECD launched an extensive programme on "existing" chemicals, in which some EC Member States were already active.

At the end of 80s, a general overview of the Community situation showed considerable disparities in the national legislation concerning chemicals in the Member States. It therefore became necessary to introduce uniformity in the internal market as well as to guarantee a co-ordinated approach towards a high level of protection to man and the environment.

2. OBJECTIVES OF THE REGULATION

Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances was adopted on 23 March 1993 and entered into force 60 days after its publication in the Official Journal of the EC, on 4 June 1993. It is based on Article 100A of the Treaty and is generally known as the "Existing Substances Regulation".

Regulation 793/93 aims at the protection both of man from exposure to dangerous substances via all possible routes and of all the compartments of the environment. "Man" comprises in this context "worker, consumer and man via the environment". The basic principle of the Regulation is that controls on hazardous chemicals should be based on an assessment of the actual risks to human health and the environment, rather than the hazardous properties of the substance only. This approach, based on sound science, was supported by Industry and the other stakeholders.

The choice of legal instrument was determined by the need for quick and uniform action on "existing" chemicals in the Community.

It was important to have a centralised system for data reporting and collection and a single, consistent picture for each chemical. This required Industry to organise itself and to provide consistent and joint data for each specific chemical.

Thus, the Regulation introduces procedures for

- the collection of data on "existing" substances produced in or imported into the Community;
- the preparation of lists of priority substances for which the need for assessment is greatest;
- the assessment of risks; and,
- the identification of any measures needed to control those risks.

In order to make the Regulation fully applicable a number of steps had to be completed, the most important of which was the adoption of Commission Regulation (EC) No 1488/94 of 28 June 1994, which lays down the principles for the assessment of risks. This Regulation entered into force 60 days after its publication in the Official Journal of the EC.

One of the purposes of the Regulation was to ensure that each substance is assessed on the basis of the same criteria. The Regulation was also designed to encourage that a Member State would not notify its intention to restrict the marketing and use of a chemical without carrying out a risk assessment according to principles agreed by all Member States. Thus, the Regulation introduced a coherent and consistent system for evaluating the risks related to chemical substances, which is applicable throughout the Community and at the same time avoids fragmentation of the Internal Market.

The EU work conducted under Regulation 793/93 is co-ordinated with "existing" substances work done in the Organisation for Economic Co-operation and Development, which contributes to Chapter 19 of Agenda 21.

Overall, the Regulation:

- provides a comprehensive system to determine possible risks from "existing" chemicals and related measures for reducing those risks;
- is not intended to rapidly manage urgent or emerging new problems for those "existing" substances which are not already on the priority lists;
- is not intended to cover the risk assessment and the corresponding risk reduction measures of harmful "existing" substances which are not industrial chemicals and are controlled by other legislative instruments.

Substances covered by the Regulation

Regulation 793/93 sets up a programme designed to identify and control the risks posed by some of the 100,106 chemical substances in the European Inventory of Existing Commercial Chemical Substances (EINECS). EINECS is a closed inventory and it serves, in the first instance, Community-wide as a legal tool for distinguishing "existing" from "new" chemicals.

EINECS was drawn up by the European Commission in application of Article 13 of Directive 67/548, as amended by Directive 79/831, and in accordance with the detailed provisions of Commission Decision 81/437. It lists and defines those chemical substances which were on the European Community market between 1 January 1971 and 18 September 1981. In terms of Article 1(4) of amended Directive 67/548, these are substances to which the pre-marketing notification provisions of the Directive do not apply.

EINECS includes

- industrial chemicals;
- substances produced from natural products by chemical modification or purification, such as metals, minerals, cement, refined oil and gas and their products including pitch;
- substances produced from animals and plants, such as lanolin, turpentine, rosin oil and resin acids, except where they are used solely in foodstuffs;
- food additives;
- ingredients or active substances of pesticides, fertilisers, medicaments, such as aspirin and paracetamol, and cosmetic products;
- monomers;
- natural polymers, including natural rubber and starch ;
- some waste and by-products, including some by-products of processed coal, such as coke and coal tar pitch.

EINECS does not include

- synthetic polymers (these are registered in EINECS under their building blocks, monomers);
- intentional mixtures;
- medical preparations, cosmetic preparations and pesticide preparations as intentional mixtures;
- food, feedstuffs;
- alloys, such as stainless steel, but includes most individual components of alloys;
- most naturally occurring raw materials, including coal and most ores.

It is important to note that EINECS represents approximately 0,006% of the 16 million substances which have been attributed a Chemical Abstracts Service Registry Number (CAS RN) by the Chemical Abstracts Service, which identifies the substances referred to at least once in the scientific literature. On the other hand, EINECS probably overstates the number of substances commercially significant by at least a factor 4.

For "new" substances, those chemicals marketed after 18 September 1981, a notification procedure was established under Directive 79/831, which is the 6th amendment to Council Directive 67/548 on the approximation of laws on classification, packaging and labelling of dangerous substances. This requires notification of "new" substances to Governments before they are marketed. Council Directive 92/32, the 7th amendment to Directive 67/548, introduces the requirement to carry out risk assessments for every "new" substance notified under this Directive.

Reporting and collection of information

Since it would not be possible to try to collect the information and to evaluate the risks for all "existing" substances, the Regulation makes a distinction in approach in terms of the quantities produced or imported of the substance.

Thus, the Regulation provides for a systematic approach for "existing" substances produced or imported in quantities in excess of 10 tonnes/year; for the substances of smaller production or import volumes, the collection of information and the risk evaluation are carried out on a case-by-case basis.

Approximately 70 "existing" substances - ranging from Vitamin A and castor oil to limestone, nitrogen and carbon dioxide - do not require reporting because it is generally supposed that there are no risks associated with them. They are listed in Annex II to the Regulation. The Community may decide, at a future date, to request information to be reported on any of these substances, but this would only be done if there were valid reasons to believe that the substance presents a serious risk to people or the environment.

The systematic approach for the collection of information provides for a step-by-step procedure that includes as:

- PHASE I

  the collection of information to be submitted by Industry, for those substances of a relevant production or import volume - in excess of 1000 tonnes/year - which are included in Annex I, as a pragmatic list of High Production Volume (HPV) substances. For these substances, a complete data set had to be submitted by manufacturers or importers over a 12-month period, ending in June 1994. This pragmatic step was chosen, since it could be implemented more quickly and it took into account the work already done in some Member States and would therefore avoid duplication of work and waste of resources;

- PHASE II

  the systematic collection of information for all other substances of a production or import volume in excess of 1000 tonnes/year, which do not appear in Annex I. For these substances a complete data set had to be submitted by manufacturers or importers over a 24-month period, ending in June 1995;

- PHASE III

  the systematic collection of information for substances of a production or import volume between 10 and 1000 tonnes/year (Low Production Volume (LPV) chemicals). For these substances a limited declaration form had to be submitted by manufacturers or importers within a period of 24 months, starting from June 1996 and ending in June 1998.

Data on some 1500 substances were delivered during the first of these phases. Data on some 1000 substances were delivered during the second phase. The processing of the information for phase III is ongoing. It is expected, though, that between 15,000 to 20,000 substances will be notified in this phase.

The data reporting from manufacturers and importers represents an important and necessary step as it gives to the authorities a complete picture of the Community market in HPV and LPV "existing" substances.

Data includes

- the name of the substance;
- produced and/or imported quantities;
- classification and labelling information under Directive 67/548;
- reasonably foreseeable uses;
- physico-chemical properties;
- toxicological and ecotoxicological properties.

In this phase of data reporting, chemical companies are allowed, when appropriate, to present jointly substance-related data, in order to avoid any duplication of work.

A preliminary analysis of the data submitted, shows that there are substantial data gaps in the knowledge of the effects of these HPV chemicals. The Commission services are currently carrying out a detailed study to confirm the initial findings.

For substances of lower volume - exceeding 10 tonnes/year but not greater than 1000 tonnes/year - a smaller information package is acceptable. The data to be submitted includes

- the name of the substance,
- produced and/or imported quantities,
- classification and labelling information under Directive 67/548,
- reasonably foreseeable uses.

The information about the properties of the substance, behaviour and effects do not require reporting. In a subsequent stage on the basis of the experience gained with the HPV substances, it will be decided what other data are necessary for the priority setting.

Potential number of substances for assessment under the Regulation

The data provided by Industry under Regulation 793/93 shows that of the 100,106 substances listed on EINECS, on the market there are approximately:

- 2,500 HPV chemicals (1,000 tonnes/year or more); and,
- between 15,000 to 20,000 LPV chemicals (10 to 1000 tonnes/year).

The remaining 80,000 or so substances are produced or imported in quantities of less than 10 tonnes per year or are not traded at all.

According to Industry there are

- 1,000 HPV substances; and,
- 200 LPV substances,

which are potential candidates for a risk assessment under Regulation 793/93, but these figures need to be verified. This of course excludes substances primarily used as active ingredients of pesticides and medicaments, for example.

Therefore, when the concept of "the burden of the past" is referred to, in terms of the actual number of "existing" substances on the market covered by Regulation 793/93, Industry's estimated figure is 1,200.

Until now, of the 100,106 EINECS substances, approximately 3,000 (2,150 if generic entries excluded) have already been classified as dangerous and labelled accordingly.The classification is based on physico-chemical and toxicological properties, on specific effects on human health and environmental effects. These substances are listed in Annex I of Directive 67/548 and others are continuously examined and added to Annex I. The total number of substances listed in Annex I, "new" and "existing", is currently approximately 4500.

Form and content of information

The Community decided that information should to be submitted in computerised form, since this enables large volumes of data on thousands of substances to be handled quickly and consistently.

All these data are collected by means of diskettes, using a special software package, called HEDSET (Harmonised Electronic Data Set), and stored in the IUCLID (International Uniform Chemicals Information Database), former EUCLID, managed by the Commission. The diskettes, together with guidance notes and the address for reporting information, are available free of charge from the Commission Offices.

The data set represents an important tool since it facilitates the selection of priority lists of substances that require priority attention because of their possible effects on man and the environment.

Confidential information

IUCLID is publicly available with the exception of confidential information. Some of the reported information may be commercially sensitive and should therefore not be accessible to competitors. Companies are required to inform the Commission about the data that should be treated as confidential and the reasons why its disclosure would harm them industrially or commercially.

Additional information on reported substances

Once a company has reported information on a substance, the report is to be updated

- when new uses of substance lead to substantial changes in human or environmental exposure to it;
- when new information on its properties or effects could influence the Community's view on its potential risk;
- every three years, if the amount produced or imported is no longer in the volume range that the company reported.

If there are reasons to believe that the substance may pose a serious risk, Industry can be asked to report further information, including additional testing. This requires a formal decision of the Regulatory Committee under Article 15 of the Regulation.

If a company is aware that an EINECS substance, produced or imported in any quantity by it, may present a serious risk to human health or the environment, it must inform the Commission services, even if it has not previously reported on the substance.

Priority lists

Due to the large number of substances covered by the Regulation, a priority setting approach was adopted.

The Regulation, however, does not define the system to be used in drawing up the lists of priority substances, since the Commission considered that, given the changing scientific nature of this area, it was more appropriate to remain flexible and to leave this task to the Commission services and the Member States by means of the Regulatory Committee procedure. Work being carried out in other fora or under other Community legislation as well as previous work under such programs or legislation are to be taken into consideration.

It should be noted that, given the deadlines imposed by the Regulation, the first list had to be published before June 1994 and no reporting was required until then. The first list was then prepared in an empirical fashion, by considering national proposals in the light of work carried out under other programs. The same approach was used for the second and third priority lists. From 1999, the lists will be drawn up agreed by the Regulatory Committee using the priority-setting scheme foreseen by the Regulation (see below).

The Regulation sets out the factors to be taken into account in drawing up priority lists. The information provided by companies will be given a set of scores by computer.

A substance may obtain high scores if, for example,

- it is produced in large volumes;
- it is used in a dispersive way rather than, say, in a few sealed systems;
- it stays in the environment for a long time without breaking down into harmless substances;
- it is highly toxic to humans, animals or plants;
- it has chronic effects;
- it is carcinogenic, toxic to reproduction or mutagenic;
- little is known about its properties, uses or effects.

Substances will be ranked for assessment on the basis of these and other factors, such as assessments already carried out for OECD or other international bodies. However, such an automated system is only a crude indicator. The process will therefore require an evaluation by experts. The Commission and Member States will thus ensure that substances do not appear on a priority list unless they are of significant concern.

Some substances may have undergone an equivalent assessment under other EC legislation. They will not be assessed again under the Regulation. For example, substances, which are used mainly as pesticides, are not considered for listing on priority lists under this Regulation. However, "existing" substances, which are, for example, used as active substances in plant protection products as well as for industrial purposes, will be considered under both Directive 91/414 and Regulation 793/93.

The Commission has published each priority list in the Official Journal of the European Communities. If a substance produced or imported appears on a priority list, the companies concerned are required to provide further information.

Mixtures of substances may be included on priority lists, if the mixtures themselves appear on EINECS. They will then be treated under the Regulation just like other priority substances.

Each substance on a priority list is allocated to a Member State for detailed risk assessment on a voluntary basis. The Member State appoints a "Rapporteur" to carry out an assessment of the risks. This work includes, amongst other tasks

- the evaluation of the information submitted by Industry;
- the evaluation of other available information;
- the identification of the need for further data and/or testing to be imposed on Industry.

Risk Assessment

The Member State "Rapporteur", acting on behalf of the Community, performs the evaluation of the environmental risks and puts forward recommendations for appropriate measures.

The division of work between Member States should in principle allow a Member State, which had already begun work on an "existing" substance, to continue its work within the Community. Member States, which have not carried out any work on "existing" substances, should start to collaborate at Community level and, in this way, acquire in this way an experience similar to that of the other Member States.

The evaluation of risks is based on Regulation 1488/94, which was adopted by Commission in 1994 and follows in principle the criteria previously adopted for "new" substances in Commission Directive 93/67. This should ensure that all substances are judged on the same basis.

The Regulation is supported by a more detailed Technical Guidance Document, published in 1996, which indicates how the assessment should be performed. The Technical Guidance Document does not have a legal status which, given the continuous developments in the methodology of risk assessment, facilitates a more rapid review and revision than would be the case if it was a formal legal text.

A risk assessment for chemical substances entails four major steps: hazard identification, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation.

Hazard identification is the identification of the adverse effects (acute and also longer-term effects), which a substance has an inherent capacity to cause on human health and the environment.

Dose (concentration) - response (effect) assessment is the determination of the relationship between dose or level of exposure to a substance, and the incidence and severity of an effect. In some cases, a dose - response relation for health effects in

humans or effects on the environment can be established on the basis of actually measured data. In general, results from laboratory tests have to be used.

Exposure assessment is the determination of emissions, pathways, and rates of movement of a substance and its transformation or degradation, in order to estimate the concentrations/doses to which human populations or environmental spheres (water, soil and air) are or may be exposed. It describes magnitude, duration, and route of exposure to the nature, size, and classes of the human populations (including occupational and public exposure routes) and environmental compartments exposed. To assess the likely exposure, the "Rapporteur" will consider the properties of the substance and its fate in the environment. He will consider how much is produced, how it is stored, transported, used (e.g. in a few closed systems or in many dispersive uses) and disposed of. From this and other information, the "Rapporteur" will predict realistic worst case levels of human or environmental exposure.

Risk characterisation is the estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental sphere due to actual or predicted exposure to a substance, and may include 'risk estimation', i.e. the quantification of that likelihood.

The risk assessment should also include the characterisation of the uncertainties inherent in the process, especially when quantitative results are not feasible.

Many substances have already undergone some form of risk assessment, for example in the OECD or IPCS. The "Rapporteur" should not in principle duplicate work already carried out. In some cases such a report may be used as the basis of the assessment, but it will be necessary to review those data in the light of information reported by companies under the Regulation and it may still be necessary to require additional information.

The "Rapporteur" will send the assessment to the Commission services, which will circulate it to other Member States. This will ensure, for example, that each Member State has the opportunity to comment on any assessment carried out in other countries. The assessments are discussed by an expert group before being submitted to the Regulatory Committee for opinion before publication.

It should be noted that in drawing conclusions on the risk assessment some value judgement is involved.

The "Rapporteur" drafts a risk assessment report for consideration by the Member States and, where appropriate, formally requests further delivery of data and/or testing. Any further testing is carried out according to good laboratory practice as laid down in Directives 87/18 and 88/320 and where possible will avoid or limit use of animals as per Directive 86/609. Although in principle further testing should be carried out by all companies, such testing, where necessary, should be carried out by only one company on behalf of all.

It may happen that while some base set data elements are missing, other data are available as a result of tests not listed in Annex V of Directive 67/548 which might compensate for the missing data. The "Rapporteur" should use expert judgement in deciding whether or not to agree to a derogation from completion of the base set,

considering the relevance of the test, its inherent quality, the accuracy and detail of the report, the extent to which statistical methods have been applied and advise other Member States of his decision. If the "Rapporteur's" decision is contested, the issue could ultimately be resolved by a vote, but preferably such an issue should be resolved through bilateral discussion.

The "Rapporteur" prepares a draft assessment and proposes further data delivery and testing, whereas the formal decisions are taken by a Committee of Member States, which finally delivers an opinion on the report, which is then published. Decisions are taken by majority voting as laid down in article 148(2) of the Treaty of Rome (establishing the European Communities). Provisions exist for resolving a situation where the Committee fails to deliver an opinion on such draft proposals.

According to Regulation 1488/94, which outlines the principles of risk assessment for "existing" substances, the risk assessment concludes one of the following

- more information and/or testing is needed to complete the risk assessment (and arrive at one of the other conclusions);
- the substance is of low current concern and no further action is needed;
- there is a potential risk to human health and the environment,

for each protection goal (e.g. population, environmental sphere).

Risk Reduction Strategy (or Risk Management). Links with the other Community instruments

The situation with "existing" substances is such that they remain on the market as before, unless specific action is taken. Regulation 793/93 does not directly provide for risk reduction action though it may trigger it.

If the conclusion of the risk assessment of an "existing" substance is that the risks are not adequately managed, the "Rapporteur" is required to propose a strategy to reduce these risks. On the basis of the risk evaluation and of the recommended strategy, the Commission then submits for opinion to the Regulatory Committee a draft Recommendation of the measures to be taken.

Where the strategy recommends marketing and use restrictions under Directive 76/769, an analysis of the advantages and drawbacks of the substance is also required and the availability of the replacement substances should be considered.

Since the provisions of Regulation are not more specific, a second Technical Guidance Document was published in June 1998 to assist the "Rapporteur" in this additional analysis. The guidance on the risk reduction strategy outlines the possible measures that can be taken during the life cycle of the substances to reduce exposure, the available instruments as well as the criteria effectiveness, practicality, economic impact and monitorability which should be considered in selecting a strategy.

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Other than restrictions on marketing and use, risk reduction measures could involve redesigning processes, licensing of certain operations, recommendations for establishment or revision of the classification, occupational exposure limits (OELs), emission limit values and/or effluent monitoring as well as making available accurate information and safety training. The classification of a substance may trigger a series of controls in industrial installations and for hazardous waste. Actual setting of OELs or environmental emission limits is beyond the scope of this exercise and is carried out under other legislation. In addition to recommending regulatory control, consideration may be given to such non-traditional approaches as voluntary agreements, information programs, guidance and technical standards, and economic instruments.

It should be noted that for a substance which has not been classified as dangerous (i.e. which does not appear in Annex I of Directive 67/548) a provisional classification must be provided during the data collection phase, if data exists supporting such a classification. During the risk assessment procedure, this classification will be examined by the competent expert group working for the Regulation and then submitted to the competent expert group working for Directive 67/548. If the substance is classified as dangerous, it will then be included in Annex I of this Directive. On the other hand, as a result of the work done under the Regulation, an already published classification could be revised.

In conclusion, the Regulation establishes, in Article 11, a link between the Regulation itself and the Community measures in force which can help in diminishing the threats posed by the substance under scrutiny. These are (non-exhaustive list)

- Directive 67/548 relating to the classification, packaging and labelling of dangerous substances;
- Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations;
- Directive 89/391 on the safety and protection of health of workers at work which places an obligation on employers to evaluate the risks to the health and safety of workers arising from the use of new and "existing" chemicals;
- Directive 90/394 on the protection of workers from the risks related to exposure of carcinogens at work;
- Directive 92/85 on the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding;
- Directive 94/33 on the protection of young people at work;
- Directive 98/24 on the protection of the health and safety of workers from the risks related to chemicals agents at work;
- Directive 92/59 on general product safety which provides for temporary restrictions on products in emergency situations;
- Directive 76/768 relating to cosmetic products;

- Directive 79/117 prohibiting the placing on the market and use of Plant Protection Products containing certain active substances;
- Directives 86/362, 86/363 and 90/642 providing for maximum pesticide residue limits in agricultural products and foodstuffs;
- Council Directive 76/116 and 97/63 relating to fertilisers.

It should however be pointed out that Article 11, while establishing a link with other legislative measures, draws a clear line between the activities to be carried out in the framework of the Regulation and those taking place in other contexts, such as the ones previously described. These follow-up risk management activities, which are supposed to take place in the framework of other instruments, should then be the subject of new legislative proposals to be presented by the Commission. The nature of this link is non-automatic.

Therefore, once the complex and comprehensive risk assessment activities are completed and where appropriate risk reduction measures are recommended and published in the Official Journal, the precise tasks described in the provisions of the Regulation are to be considered accomplished.

Of course there is an important monitoring role still to be played in order to ensure that the follow-up actions envisaged are fully accomplished by all stakeholders.

The international context

This mainly concerns the requirement under Article 8(2) of Regulation 793/93 that priority substances shall be selected considering, inter alia, work done and programs in other fora.

In order to avoid duplication of effort regarding future work and to go as far as possible in mutually recognising existing work done in other fora, interaction between the Community program and other programs is necessary at the various stages of the process, from defining priorities through to accepting risk assessments for those substances selected as priority. Programs at OECD and UN are conceptually similar to the "existing" substances program and susceptible to interaction rather than the other Community programs which have a different objective.

Interaction between the EU and OECD on "existing" substances is well established, with formalised contact both at the stage of determining priority substances for assessment and in the discussion of individual risk assessments for both programmes. However, these arrangements have failed to prevent some duplication of activities. There are currently ongoing discussions between the EU, OECD and the UN's International Programme of Chemical Safety (IPCS) with the aim of improving co-ordination between them.

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3. THE PRACTICAL OPERATION OF THE REGULATION

Three expert groups and one committee, chaired by the Commission, are established in support of the process envisaged in the Regulation:

- the "Risk Assessment Technical Meeting",
- the "Risk Reduction Strategy Meeting",
- the "Meeting of the Competent Authorities",
- the Regulatory Committee established under Article 15.

All these expert groups and the committee are composed of representatives of the EU Member States and EFTA Countries. Several observers are also invited to participate, except for the Article 15 Committee. These are

- Industry, represented by CEFIC, by other Industry associations which are not members of CEFIC, i.e. AISE (detergents), CONCAWE (oil companies), EUROMETAUX (non-ferrous metals), as well as by companies producing or putting on the EU market the assessed substances;
- NGOs, i.e. EEB, BEUC, TUTB and, since mid 1998, Friends of the Earth, Greenpeace and WWF;
- OECD and IPCS.

"Risk Assessment Technical Meetings"

The risk assessment process and the preparation of the risk assessment report are appraised by the "Risk Assessment Technical Meeting".

Each risk assessment report is submitted by the Member State "Rapporteur" to the Technical Meeting for a preliminary discussion.

The EU report is then presented at the OECD SIDS (Screening Information Data Set) Initial Assessment Meeting (SIAM).

One or more discussions follow the preliminary discussion at the "Technical Meeting".

The comprehensive risk assessment report is then finalised and a summary risk assessment report is prepared for publication in the Official Journal.

"Risk Reduction Strategy Meetings"

Whenever appropriate and (in principle) as soon as the need is identified, the Member State "Rapporteur" should commence work on risk reduction measures. A draft proposal should then be presented in the form of a comprehensive risk reduction strategy and a summary risk reduction strategy (which will be incorporated into the Official Journal publication).

These draft proposals are examined and discussed by the "Risk Reduction Strategy Meeting".

"Meetings of the Competent Authorities"

All the risk assessment reports and risk reduction strategies are endorsed by the Competent Authorities.

The Competent Authorities are designated by Member States to participate in the implementation of the Regulation, in collaboration with the Commission. Each Member State can designate one or more Competent Authority.

The Regulatory Committee

Regulation 793/93 provides in its Article 15 for the establishment of a Regulatory Committee composed of representatives of Member States and chaired by the representative of the Commission.

The main responsibilities of this Committee are to deliver an opinion on

- the adaptation of certain annexes of the Regulation to technical progress;
- the adoption of certain implementing measures in respect of the Regulation.

The latter is by far the most important task entrusted to the Committee. The implementing measures concerned are

- priority lists (Article 8);
- designation of Member State "Rapporteur" for each priority substance (Article 10(1));
- decisions to request manufacturers or importers to provide further information on a given substance (Article 10(2));
- decisions to impose on manufacturers or importers further testing on a given substance (Article 10(2));
- recommendations on the results of the risk evaluation and where necessary on the risks management measures to be implemented (Article11);
- additional testing on any EINECS substance (Article 12(2)).

According to the principles established in Council Decision 87/373 which lays down the procedures for the exercise of the implementing powers conferred on the Commission, the Committee referred to in Article 15 of Regulation 793/93 can be considered of a "mixed" nature, its features belonging at the same time to procedure III a and III b.

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4. STAGES IN THE OPERATION OF THE REGULATION

Council Regulation (EEC) No 793/93 of 23 March 1993 (OJ No L 84, 5.4.1993, p.1) on the evaluation and control of the risks of "existing" substances entered into force on 4 June 1993. In order for the Regulation to become fully operational a number of necessary stages had to be completed. These include:

- the Commission Regulation (EC) No 1488/94 of 28 June 1994 (OJ No L 161, 26.6.1994, p.3) laying down the principles for the assessment of risks to man and the environment. The aim of this Regulation was to ensure that a harmonised risk assessment is being conducted throughout the EU;

- the Technical Guidance Document in support of Commission Directive 93/67 on risk assessment for new notified substances and Commission Regulation (EC) No 1488/94 on risk assessment for "existing" substances, published in 1996 (739 pp). This Document is, of course, much more detailed than the above mentioned Commission Regulation. It will be regularly revised;

- the Technical Guidance Document on development of risk reduction strategies published in 1998 (95 pp).

The first list of priority substances (42 substances) was published in Commission Regulation (EC) No 1179/94 of 25 May 1994 (OJ No L 131, 26.5.1994, p.3), followed by the second list (36 substances) published in Commission Regulation (EC) No 2268/95 of 27 September 1995 (OJ No L 231, 28.9.1995, p.18) and finally by the third list (32 substances) published in Commission Regulation (EC) No 143/97 of 27 January 1997 (OJ No L 25, 28.1.1997, p.13).

5. FINDINGS

110 substances that have been selected as "substances requiring immediate attention because of their potential effect on man on the environment" in the 3 priority lists published in 1994, 1995 and 1997.

The Member State "Rapporteurs" are listed hereunder with the indication of the number of substances they should assess.

Member State	Number of Substances	Finished Risk Assessments
D	33	3
NL	22	5
UK*	21	5
F*	9	1
DK	5	1
FIN, I	4	1 (I)
B, S	3	0
A, E, N	2	2 (A,E)
IRL	1	1
L, PT	0	0

* 2 substances are shared by F and UK.

The complexity of the risk assessment process necessitated a lengthy lead-in time before technical work on individual substances could commence because of the need for the development of two detailed technical guidance documents, one on risk assessment and one on risk reduction.

Out of the total of 110 priority substances, 38 have been or are being discussed. 19 risk assessment reports have been completed. For 14 substances risk reduction measures are recommended; for 3 substances further testing is required and for 2 substances there is no need for risk reduction measures.

To date, the time necessary from the publication of a priority list to the circulation of the first draft of the risk assessment report at the Technical Meeting appears to average between 18 and 29 months. In general, a further 9 to 25 months are needed from the circulation of the first draft until an agreement is reached on the risk assessment report. During 1998, the pace of completion has increased. It is currently taking 9 months to finalise the assessment discussions. This improvement comes as a result of the increased technical competence of the those national experts working on the risk assessment process.

The timescale for the process of determining risk reduction strategies is variable, depending to a large degree on the availability of the Member State "Rapporteur's" resources.

A Commission Recommendation concerning the results of the risk evaluation for 4 substances and strategies for reducing the risks for 3 of them should in principle be published before the end of 1998.

This means that, since 1994, only 4 substances have gone through the whole process foreseen in the Regulation.

After the publication of the Recommendation, work should start in the Commission services, Member States and Industry on the proposed measures. For two substances voluntary agreements are foreseen. For one substance restrictions on its marketing and use are recommended. In this case, DGIII should, according to these conclusions, prepare a Proposal for modification of Directive 76/769.

The operational experience gained so far highlights a number of issues, some linked to the degree of commitment of the key actors, some linked to the lack of qualified resources or, simply, to the lack of resources, some of them structural, and others technical.

Commitment

- Many Member States may have overestimated their ability to implement the Regulation. Given the "voluntary" nature of the scheme established by the Regulation - in practice some Member States have so far chosen priority substances in the light of national interests and of their previous work in other programmes -, there is now a feeling amongst some of the more committed Member States that their share of the burden is disproportionate.

  Moreover, some Member States have had difficulty committing any resources to the programme. This is the case of Luxembourg and Portugal, who have no substances to assess.

- Some companies may not regard this work as a priority because the substances are already on the market. For "new" substances, Industry's interest is to co-operate actively in the risk assessment in order to place its product on the market as quickly as possible, whereas in the case of the "existing" substances Industry tends to be less proactive, awaiting for the results of the assessment before taking any action. The "burden of proof" to show that a chemical is not safe during actual use is on the public authorities (the Commission services and the Member States), which collect and assess all data from Industry and take decisions as to the need for regulatory restrictions.

- Initially, there were considerable delays by Industry in providing the HEDSET, which allows for the selection of the priority substances for assessment, in accordance with Article 3 of the Regulation.

  There have also been delays caused by Industry in delivering additional data before and during the risk assessment process in accordance with Articles 9 and 10 of the Regulation.

  Importers of substances are also known to have difficulties in obtaining the requisite information from producers because they are located in another Member State or outside the EU.

A problem related to the credibility of data has also been raised. Industry has not always submitted all relevant available data during the data collection phases and there is difficulty in continuously updating the data.

- The information regarding the obligations put on producers and importers under the Regulation has not reached all the parties concerned, in particular the small and medium sized firms.

- Lack of enforcement activity in Member States in support of the Regulation has not helped to encourage Industry to improve its compliance with delivery of data.

- Some Member States make substantial contributions to other international risk assessment programmes (e.g. Germany, Sweden and UK to IPCS programme) in parallel to their contribution to the Regulation, thus diverting resources away from EU work.

Resources

- A lack of commitment is reflected by the limited availability of resources in the Member States and the Commission to carry out the necessary activities.

Structural

- The "burden of proof" to show that a chemical is not safe during actual use is placed on the public authorities, the Commission services and the Member States.

- The long and complex stages and procedures foreseen in the Regulation (selection of priority substances, choice of Member State "Rapporteur", collection of information, risk assessment activities, technical evaluation of the risk assessment reports, risk reduction strategies) are one of the major causes for the delays experienced in the operation of the Regulation. However, this problem is not unique to Regulation 793/93, as similar problems have beset the implementation of Directive 91/414 concerning the placing of plant protection products on the market.

- The absence of deadlines for Member States in the Regulation means that Competent Authorities are not working to a target for submitting completed risk assessment reports.

  Some deadlines for Member States and Industry are agreed at Technical Meetings, but they are not always respected.

  Other deadlines are fixed during bilateral contacts between Member States and Industry but the Commission has no means to monitor progress on these.

- A priority setting approach was included in the Regulation in order to draw up lists of "existing" substances, which should be assessed first. However, there are doubts as to whether this approach was applied successfully for the first three priority lists to pinpoint substances of greatest concern.

- The risk assessment process, which determines the need for control for "existing" substances measures, may be too ambitious. The risk assessment is based on an in-depth consideration of the risks to human health and the environment of exposure to substances. The nature, scope and amount of data to be assessed means the risk assessment process is lengthy. The requirement for a Member State "Rapporteur" to seek agreement of other Member States through the Technical Meetings delays the risk assessment process further, but has the advantage that all the Member States acquire the same level of experience.

  On the other hand, it should be pointed out that the comprehensive risk assessment conducted under the Regulation covers the production and current uses of the substance, which is defined by the chemical name, the Chemical Abstracts Service Registry Number (CAS RN) and the EINECS Number. Under current practices, the comprehensive risk assessment will then not cover, in principle, the evaluation of the risks posed by the substance when present as an impurity in another substance or mixture of substances. In the case of cadmium, for example, the risk assessment under the Regulation will not cover the effects caused by the presence of cadmium in fertilisers. This would be covered if the fertiliser itself is evaluated. This situation should be clarified.

  As only the uses of the substance known to the Rapporteur and those involved in reviewing the report are assessed, it could happen that a potential risk is not assessed simply because a particular use of a substance is not common in the EU or not known to the "Rapporteur". A good example of this is acrylamide. The risk assessment under the Regulation was virtually completed when an accident occurred in Sweden, where acrylamide was used or produced in situ, in circumstances which have still to be clarified, during the construction of a railway tunnel. Without this accident, the evaluation would not have focused on the use of the substance as a grouting agent in tunnels, because this use was not known in Europe (acrylamide has been used in chemical grouting agents for a number of years in the USA and Japan). Now the evaluation will be completed by the Member State "Rapporteur", focusing on this use and investigating local environment and worker protection issues. The need to review the risk assessments in the light of new information is therefore apparent.

- The Regulation was not intended to provide for "targeted" risk assessments of substances, which are of immediate concern.

  Moreover, even when it is apparent early on in the risk assessment process that the risks from the substances are confined to one area (e.g. workers), until now a full risk assessment of all areas (workers, consumers and environment) is performed.

- As downstream users of substances are not covered by the Regulation, it can be difficult for suppliers to obtain the exposure and usage information from users because of commercial confidentiality concerns. This, in turn, makes it difficult for the Member State "Rapporteur" to determine appropriate draft proposals for risk reduction measures.

- Once the risk assessment activities are completed by the Member State "Rapporteur" (and where necessary risk reduction measures recommended) there

[redacted]

is no clear provision in the Regulation for providing an adequate follow-up to the problems highlighted in the risk assessment report (and in the risk reduction strategy) forwarded to the Commission. The main problem areas in this respect include

- the confusing situation concerning the choice of the legal act in which the Commission incorporates the results of the risk assessment and the recommended risk reduction strategy;

- the missing automatic or semi-automatic link with the other Community legislative instruments (Directive 76/769 on marketing and use restrictions; worker and consumer protection legislation), which are to take on board the conclusions of the risk assessment for the substance concerned;

- consequently, the fear by the Member State "Rapporteur", after the extensive and resource consuming evaluation carried out on a substance, that the work is not adequately acknowledged.

- Risk assessments on "existing" substances produced for the OECD and IPCS are different from those produced for the EU Regulation. OECD and IPCS "risk assessment reports" consist simply of information on hazard assessment and some uses of the substances (they are in fact initial risk assessment reports), whereas the EU risk assessment reports are comprehensive, taking account of all the exposure scenarios for a particular substance. Because the same terminology is applied to all three types of assessment, the risk assessment process for the EU Regulation appears slow and cumbersome in comparison to the other two.

This has an important consequence in that it is not possible at the moment to avoid duplication of work between different international organisations, i.e. the same substance is sometimes assessed by a non-EU OECD Member Country and an EU Member State.

- The management of Regulation relies on two separate Commission services; DGXI/E/2's role is essentially a policy and administrative one and DGJRC.IHCP.ECB's role is both technical and managerial. DGJRC.IHCP.ECB provides all of the technical advice on policy issues which DGXI requires. As well as organising the Technical Meetings, DGJRC.IHCP.ECB holds all the factual scientific information relating to the Regulation. The management of the Regulation therefore is essentially a joint effort. However, the geographical separation of DGJRC.IHCP.ECB and DGXI has mitigated against the shared understanding of priorities and objectives.

Technical

- The risk assessment process requires a high level of scientific and technical expertise. Some Member States are not able to deliver the planned risk assessments because they lack the requisite human resources and/or scientific and technical expertise. The annual CEFIC Seminar (April 1998) highlighted the problem of scarcity of experienced eco-toxicologists.

6. DISCUSSION

Chemicals are useful and toxic at the same time. It is in fact the dose which causes toxic effects: sugar and salt, if consumed by the kilogram, may be as lethal as milligrams of cyanide or strychnine. In addition to their toxicity, chemicals may also be explosive, flammable or corrosive. Yet others may have deleterious effects on our environment, such as chlorofluorocarbons.

Given that all chemicals are potentially dangerous, it was reasonable that precautions are taken to assess each chemical and to ensure that appropriate steps are taken to reduce the potential risks associated with their use to an acceptably low level. For instance, many drugs are highly toxic chemicals, but as long as they are packaged correctly (to protect children, for example), and as long as the dose levels are controlled and recommended conditions of use are followed carefully, the risk to the public is acceptably small.

Similarly, many household cleaning products are potentially very dangerous - for example, bleach and ammonia - but provided they are packaged correctly in solid, strong containers with child-proof fastenings and are clearly labelled, with recommendations for safe use clearly displayed, they can safely be used in the home.

At the time of adoption, the Regulation was seen as a milestone in Community legislation, as it set up a complete and unified framework for the systematic evaluation of the risks posed to man and the environment from "existing" chemical substances. On the basis of this evaluation, recommendations for risk reduction measures can be made and thereby fed into the numerous legislative instruments ensuring risk reduction.

The "burden of the past"

Over the last two years the Regulation has come under increasing political pressure. The Regulation has not yet provided the fruitful output, which was hoped for in 1993, thereby prompting discussions about its usefulness.

In many different fora, the concept of "the burden of the past" has arisen. The reasoning behind this concept is as follows: there are 100,106 "existing" chemicals; for the majority of these chemicals little data is available; furthermore, there is no practical possibility to assess the risks of all of these chemicals within the near future. The immediate concern is therefore that man and the environment are potentially exposed to a large number of chemical substances for which the hazardous properties and risks are unknown.

As previously mentioned, according to a CEFIC calculation, the estimated lowest figure for the number of "existing" substances which represent the "burden of the past" under Regulation 793/93 is 1,200 (see item in Section 2 on the *Potential number of substances for assessment under the Regulation*).

Chemicals framework legislation

Some Member States would like over-arching legislation which sets out the basic principles governing all EU legislation concerned with chemicals, including "existing", "new", pesticides, biocides and other chemical preparation (intentional mixtures) etc. All chemicals legislation would be based on an identical principles, e.g. placing the burden of proof on industry. This is potentially a time consuming option, which could exacerbate delays in assessing chemicals further, but would have clear advantages in terms of harmonising the basic principle involved in chemical assessment. Nevertheless, simply re-assembling existing legislation into a new common Directive would not in any way speed up the process of risk assessment.

Persistence and bioaccumulation

These characteristics are put forward by certain Member States and NGOs as a basis on which risk reduction strategies should be determined without the need for a risk assessment. Currently they are already taken into account during the priority setting process, which is used under Regulation 793/93, and by the current risk assessment. However, the properties are not given the degree of importance as certain Member States are proposing.

Mixtures

Regulation 793/93 has come in for some criticism because the approach used is that chemicals are considered on an individual basis, while most exposure to chemicals is actually exposure to mixtures. However, intentional mixtures are covered by the Directive 88/379 on the classification, packaging and labelling of dangerous preparations. The problem of unintentional mixtures is much more difficult to address. There is indeed an urgent need to acquire much more data on exposure to chemicals for human health and the environment (be it individual susbstances of mixtures) and an improved collection of epidemiological evidence.

Hazard versus risk

Risk assessment is not an easy concept to understand, but it is of major importance since it is a key element of the chemicals control programme. The final goal of this programme is to manage or control a chemical - to have emission values to water, to control it in the workplace, to control it as a waste product – but, before those management decisions can be made, it is necessary to assess and evaluate the chemical.

A risk assessment involves four steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation. The first two steps, the hazard identification and the dose-response assessment are usually called the effects assessment or hazard assessment. The goal of the effects assessment or hazard assessment is to determine at which exposure levels the chemical causes no adverse or irreversible effects. In the risk characterisation these levels are compared to the actual expected exposure levels, determined in the exposure assessment, in order to reach a conclusion on the anticipated risk.

That part of the analysis can be done for any particular use pattern of a substance. For an aerosol freshener used in the home, for instance, one can calculate an exposure scenario which will give average concentration of the substance in the air in a home under normal conditions, and by comparing that to the concentrations known to be toxic or known to have deleterious effects, one has, in very simple terms, conducted a risk assessment.

The distinct steps of hazard assessment and risk assessment provide different levels of knowledge of the potential risk of a chemical. This distinction can exploited to use the results of the hazard assessment to determine a need for a risk assessment. It is therefore important to maintain and exploit this distinction.

Grouping of substances

There are two different ways of grouping chemicals for the purpose of priority setting:

- based on chemical structure similarity;
- based on similar use patterns.

The basis of grouping chemicals according to chemical structure is that substances with similar structures may have similar chemical properties, though this would only hold true for limited classes of chemicals. Thus, by grouping substances in this way, the hazard assessment on these classes would be carried out more efficiently. The advantage of grouping according to use pattern is that the exposure assessments of all the chemicals are considerably lightened. It would therefore be an advantage to attempt to group chemicals using both criteria.

The DGJRC.IHCP.ECB has already clustered the EINECS chemicals based on chemical structure. Furthermore, a use-clustering of the HPVCs has also been carried out. The difficulty is how to summarise this information in a simple way, which assists in choosing those groups of chemicals which need the most attention. This problem is being worked on by the DGJRC.IHCP.ECB in the context of preparations for the fourth priority list.

The "burden of proof"

The US Chemical Manufacturers Association (CMA) has been challenged by the Vice President of the USA to carry out an extensive testing programme to address the concern that little data is available on most of the US High Production Volume (HPV) chemicals. This challenge is the consequence of a growing awareness of the "burden of the past" in the US. The testing programme will result in Screening Information Data Sets (SIDS) or possibly even hazard assessment reports in the form of SIDS Initial Assessment Reports (SIARs), which will be subject to the OECD review. This leads to the question of possible co-operative action between the US, Japan and the EU on data generation. The US initiative may result in the testing of approximately 200 chemicals/year. If this initiative is followed by similar initiatives in the EU and Japan, possibly 400 chemicals can be tested and initially risk assessed per year.

"Targeted" risk assessments

Focusing on the real areas of concern seems to be a possible way forward to substantially accelerate the ongoing risk assessment procedures. Indeed, if there is an indication that a substance presents potential risks only to a specific area, to workers for example, or if a substance has been already extensively studied in other fora, it is possible that a comprehensive risk assessment, as foreseen by the Regulation, would be unnecessary. A "targeted" risk assessment can then be conducted, which is generally less extensive and therefore prepared in a shorter time, compared to the comprehensive risk assessment. However, the length of time to undertake a "targeted" risk assessment may still be substantial.

"Targeted" risk assessments are being conducted under the supervision of different Commission services which are responsible for different pieces of legislation based on the outcome of risk assessment, but do not have a uniform or consistent way of endorsing them.

7. RECOMMENDATIONS

A basic principle for the implementation of the recommendations is that the "burden of proof" to show that a chemical is not safe during actual use should be placed on Industry. An attempt has been made to develop the recommendations so that Industry is requested to play a more active role on the testing and evaluation of their chemicals, but in such a way that Industry's evaluations undergo a review by the Member States.

The preliminary recommendations are based on the findings in Section 5 and the discussion in Section 6. These can be summarised as the following key elements underlying the recommendations

- it is essential to define the actual size of problem that the Regulation is trying to address (i.e. the number of "existing" substances which constitute the "burden of the past" and what is currently known on those chemicals, before any more detailed solutions can be developed);
- the problem of the lack of information on "industrial chemicals";
- the need to develop strategies to improve and streamline the risk assessment and risk reduction process.

Recommendations for "existing" substances on the current priority lists

a. To review the priority status of the substances

It is necessary to establish which of those substances on the current Priority Lists, which have not yet been examined, really are "of concern" and need to be assessed first.

b. To review options for expediting completion of risk assessments

Possible options include: checking the possibility and viability of grouping substances even if they have been allocated to different Member States "Rapporteurs"; challenging Industry to provide initial risk assessments on a voluntary basis; requesting Industry and "Rapporteurs" to use external contractors for the completion of the risk assessments.

c. To clarify the commitment of Member States' in order to ensure effective operation of the Regulation and mobilise the necessary resources

In order for the chosen solutions to be achievable, it is essential that Member States' commitment be determined, in terms of political support and in terms of actual resources, both to completing work on the assessments for the remaining substances on the current priority lists and working on "existing" substances in future.

Recommendations for other "existing" substances on the market

d. To clarify the extent of the "burden of the past"

In order to ensure that appropriate and realisable solutions are developed for assessing those remaining substances which are "of concern", it is essential to ascertain the number of "existing" substances which constitute the "burden of the past". It is also essential to create an inventory of what data is available on these chemicals and what data is not available.

e. To revise the Annexes to Regulation 793/93 to include all High and Low Production Volume chemicals based on Industry data held at DGJRC.IHCP.ECB

Under the three data collection phases of Regulation 793/93 producers and importers of "existing" substances produced or imported in volumes exceeding 10 tonnes per year have been required to submit a HEDSET to the Commission. The Commission database on "existing" chemicals, IUCLID, thereby contains the definitive list of substances, naming all producers and importers which produce or import substances in volumes exceeding 10 tonnes per year.

By incorporating some of this information into the Regulation, there will be both a transparent and definitive legal reference of those EINECS substances above 10 tonnes per year which are on the market. This could be used, in future, for example, to require Industry to provide data for the substances which are produced or imported in volumes in excess of 10 tonnes which are not contained in the Annexes, in a procedure similar to the one implemented for "new" chemicals under Directive 67/548. This would require an amendment to the Regulation.

f. To assess the issue of how best to deal with those "existing" substances manufactured or imported in quantities of less than 10 tonnes per year

The first issue which needs to be addressed is how many "existing" substances manufactured or imported in quantities of less than 10 tonnes per year are really relevant in terms of Regulation 793/93. It could be argued that *any* substance produced in volumes below 10 tonnes per year is not of relevance, as it is at most a local environmental problem, a site-specific worker protection problem or possibly an infrequent potential consumer problem. Most "new" chemicals which are produced in volumes below 10 tonnes are speciality chemicals, notably colorants, which have very specific uses. If this is extrapolated to "existing" chemicals, then it might be assumed that very low volume "existing" chemicals are speciality chemicals with unique or very restricted uses.

The second issue that needs to be explored is whether "existing" substances manufactured or imported in quantities of less than 10 tonnes per year need to be risk assessed. Community legislation currently in place might be sufficient because it already requires risk reduction based on hazard. It could be argued that only those substances which do not automatically get regulated by these legislative instruments should be risk assessed.

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A third issue is how to gather more information about "existing" substances produced or imported in less than 10 tonnes per year in order to address concerns. Possible options to be explored include a mandatory registration system for EINECS chemicals at 1 tonne production volume (current limit is 10 tonnes); and a challenge or mandatory programme regarding the use of any chemical in a consumer product to report the identity of the substance to the Commission.

In exploring the options it is essential to remember the following:

- the Commission's resources are finite and if more work is to be done on "existing" substances, less must be done elsewhere (e.g. on "new" substances);
- if rules are changed for reporting substances, these should be changed in such a way that there is greater consistency between the different substance classes covered by different pieces of EU legislation.
- "targeted" risk assessments could be the best solution either as soon as a specific concern with regards to such a chemicals is identified, or as a part of a mandatory "self assessment" scheme similar to the "self classification" under Directive 67/548.

g. To review those "existing" substances which constitute "the burden of the past" to see if their hazardous properties have been assessed, and if not, secure Industry commitment for an initial risk assessment under the supervision of Member States as a matter of priority

This requires placing the burden of proof on Industry, making the information generated by Industry publicly available and establishing an efficient review system for the work carried out by Industry. Indeed, it has to be born in mind that the authorities will still have the task to control and verify the assessments submitted by Industry and that a mechanism has to be found to guarantee acceptability and credibility of Industry's work. A possible way forward could be to have the assessments done by outside experts / consultants whose independence would have to be monitored. The costs for this could be borne by Industry.

h. To seek international co-operation to share the initial risk assessment of "existing" chemicals which represent the "burden of the past"

The separate, but related, initiatives of the United States government and of the International Council of Chemical Associations (ICCA) have been cited recently in the press and others are being discussed in the EU, BIAC and various national chemical industry associations. They all involve a significant increase in the pace of closing SIDS gaps and arriving at an initial assessment of the hazard of HPV chemicals. They all recognise that the OECD HPV Chemicals Programme is instrumental in reaching international consensus on the content of these assessments and their supporting SIDS dossiers. The ICCA initiative rests heavily on working as far as possible under the OECD framework; that of the United States is focused on generating SIDS test data on HPV chemicals, but will also contribute the US input to the OECD programme.

The US is willing to complete SIDS testing on the US HPV chemicals by 2004 under its Vice Presidential initiative. ICCA is urging its member companies to work together to fill SIDS and undertake initial hazard assessments on approximately 1000 HPV chemicals by the end of 2004. The details of how this will be done by the chemicals industry are still under discussion; however, the objective is to contribute to the OECD HPV Chemicals Programme to make the results internationally acceptable and to ensure that the burden is equitably shared in the industry.

i. On the basis of the initial risk assessment, rank the "existing" substances according to whether they are "of concern", "further information is needed" or are "not of concern"

To ensure that in future, efforts and resources are directed appropriately towards those "existing" substances which are of most concern.

j. To draw up further priority lists from those "existing" substances which are "of concern"

These priority lists should contain groups of substances with similar structures and/or use patterns. Concern can also be linked to monitoring evidence, collected, stored and made available through a central archive, held for example at the EEA.

k. To review options to speed-up the completion of risk assessments in future

In addition to the above mentioned recommendations, the options should include making more use of "targeted assessments" and giving the whole procedure much more flexibility. The rigid application of the complete risk assessment procedures for all possible cases (as suggested by the Technical Guidance Document, even if it is evident that there is no concern for many areas) is one of the reasons for the slow progress made so far.

l. To exploit the distinction between hazard and risk assessment

The distinction between the hazard and risk assessment can be exploited to develop a community policy on persistent, bioaccumulative and toxic substances. Such a policy would consider the work carried out under the UN ECE and the UNEP on POPs and should include the possibility to examine the risk posed by existing chemicals to the marine environment. The policy should elaborate conditions which would enable a link between the hazard assessment and possible risk reduction measures, without requiring completion of a risk assessment.

The development of such a policy should consider the potential effects related to endocrine disrupters.

m. To expand the involvement of concerned industry sectors

Carry out comprehensive consultation with industry sectors concerned in order to receive their feedback, and to consider whether special measures would be needed to take account of the possible implications for SMEs of any changes to the legislation or to the risk assessment procedures.

n. ***To review the need for better internal co-ordination within the Commission services in order to improve efficiency, effectiveness and consistency of approach in both the processing of risk assessments and the determination of risk reduction strategies for chemicals***

The review should highlight the need in future for the following: one Commission body, such as the current Technical Meeting, to consider all risk assessments of "existing" chemicals both under Regulation 793/93 and other procedures ; one Commission body for determining the most appropriate tools for implementing risk reduction measures on these existing chemicals; and, a unique Commission database for all chemicals which gives a reference to relevant legislation including ongoing developments.

Furthermore the review should highlight the need for closer co-operation between the technical group working on classification and labelling and the technical group on risk assessment. For example, during the risk assessment process it would be useful to know if a substance had been evaluated for a specific effect for classification and labelling purposes, even if it has been decided that it does not have the specific effect.

o. ***To identify specific research needs which would make possible the development of assessment tools in areas of current concern, which are not currently covered***

One area of research priority is the potential effects of mixtures of chemicals to man and the environment.

Another area of research priority is endocrine disrupters and in particular their potential synergistic effects.

GLOSSARY OF TERMS/ABBREVIATIONS IN ALPHABETICAL ORDER

CAS RN: Chemical Abstracts Service Registry Number attributed by the Chemical Abstracts Service to substances referred to at least once in the scientific literature.

Competent Authorities: In the context of legislation on "new" and "existing" chemicals, each Member State designates one or more Competent Authorities to participate in implementation in collaboration with the Commission. The Commission holds a meeting of the Competent Authorities for Regulation 793/93 on a regular basis (normally twice a year). Competent Authorities are responsible for the endorsement of all risk assessments reports and risk assessment strategies.

EINECS: European Inventory of Existing Commercial Chemical Substances, deemed to be on the European Market between 1st January 1971 and 18th September 1981. The definitive list of 100,106 "existing" chemicals which in principle are governed by Council Regulation (EEC) 793/93. Closed list.

EUSES: European Union System for the Evaluation of Substances. This computer program is a decision support instrument to assist the risk assessor to carry out the exposure and effects calculations as defined in the TGD.

Existing Substances: Substances listed in EINECS (100,106 substances, closed list).

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 which a substance has an inherent capacity to cause.

HEDSET: Harmonised Electronic Data SET. This is the Commission Data Entry Programme which has to be used under Council Regulation (EEC) 793/93 to submit summary information on chemicals. The Expanded HEDSET is a term for a yet to be developed HEDSET which is based on a format which is being developed by the Commission and the US EPA for submitting comprehensive data-sets to both authorities.

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

IPCS: International Programme on Chemical Safety, a joint programme of ILO, UNEP and WHO, established in 1980. Part of its activities involves the publication of both Environmental Health Criteria (EHC) and Concise International Chemical Assessment Documents (CICAD) on the evaluation of risks posed by chemicals.

IUCLID: International Uniform Chemical Information Database. This is the Commission database used to store and distribute the information collected under Council Regulation (EEC) 793/93.

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

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New Substances: Substances not listed on EINECS. These substances are in the "European List of Notified Chemical Substances" (ELINCS) (> 2100 substances, ever growing list) following notification to Competent Authorities of placing on the market.

Notification procedure for a new substance: Submission of a technical dossier to the Competent Authority of a Member State, containing information specified by the sixth amendment to Directive 67/548/EEC.

OEL: Occupational Exposure Limit. Most often an OEL refers to the airborne concentration of a substance averaged over a reference period, such as an 8 hour workshift, or over a 15 minute period during a work shift where peak exposures may occur, which if not exceeded is unlikely to lead to adverse health effects in exposed workers, when exposed daily over a standard working lifetime.

OECD: Organisation for Economic Co-operation and Development.

Outcome of risk assessment: One or more of the following conclusions/results for each human population and environmental protection goal defined under Regulation 1488/94:

- need for further information and/or testing
- at present no need for further information and/or testing and no need for risk reduction measures
- need for limiting the risks.

PHASE I, II, III: The systematic approach for the collection of information to be submitted by Industry in a step-by-step procedure according to production or import volume. Phase I concerned all HPV chemicals, which are listed in Annex I of Council Reg. (EEC) 793/93. The reporting period for Phase I ended June 4, 1994. For Phase II all HPV chemicals, which are not listed in Annex I, had to be reported by June 4, 1995. For Phase III a reduced HEDSET (Chapter 1 only) for all LPV chemicals had to be submitted by June 4, 1998.

Priority Lists: Lists of substances prioritised for risk assessment owing to potential concerns for man and the environment and for which a comprehensive risk assessment should be carried out, as defined under Regulation (EC) 1488/94.

"Rapporteur": The authority, appointed by the Government of each Member State, which is responsible for carrying out a risk assessment on an "existing" substance and for proposing risk reduction measures, where relevant.

Regulatory Committee: Established in Article 15 of Regulation 793/93, this Committee is composed of representatives from the EU Member States and chaired by the representative of the Commission. Its opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty of Rome.

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

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Risk Assessment Report: A written report of the risk assessment as defined under Regulation (EC) 1488/94 , for each prioritised substance, drafted by the "Rapporteur", discussed and agreed at Risk Assessment Technical Meetings and ultimately published in both summary and comprehensive report formats.

Risk Assessment Technical Meeting: An expert group composed of technical expert representatives of the EU Member States, and EFTA Countries, given the task of discussing and agreeing upon the content and conclusions of each risk assessment report. Several observers (Industry, NGOs and international organisations) are also invited to participate.

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.

Risk Reduction Strategy: Recommended measures proposed by the "Rapporteur" in order to reduce the risks, to be discussed and agreed upon at the Risk Reduction Strategy Meeting

Risk Reduction Strategy Meeting: An expert group composed of representatives of the EU Member States, and EFTA Countries, given the task of discussing and agreeing upon each risk reduction strategy presented by the "Rapporteur". Several observers (Industry, NGOs, and international organisations) are also invited to participate in the discussions.

SIAM: SIDS Initial Assessment Meeting organised by OECD at which the SIAR is presented.

SIAR : SIDS Initial Assessment Report. This is the name of the assessment reports discussed in the framework of the OECD "existing" chemicals programme. The EU risk assessment reports enter the OECD programme as SIARs.

SIDS : Screening Information Data Set. This is the internationally accepted minimum data-set required for carrying out a risk assessment.

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

TGD: Technical Guidance Documents on Risk Assessment and Risk Reduction Strategies provide technical guidance in support of Council Regulation (EEC) 793/93. The TGD on Risk Assessment lays down the methodology agreed by Member States, for carrying out a risk assessment in accordance with Commission Regulation 1488/94/EC and Commission Directive 93/67/EEC.

UN: United Nations.

Voluntary agreement: For the purpose of this Regulation, the concept of voluntary approaches by Industry as a substitute or complement to legislation. The agreement concerns a well-defined scope of application and normally includes a timetable for implementation.

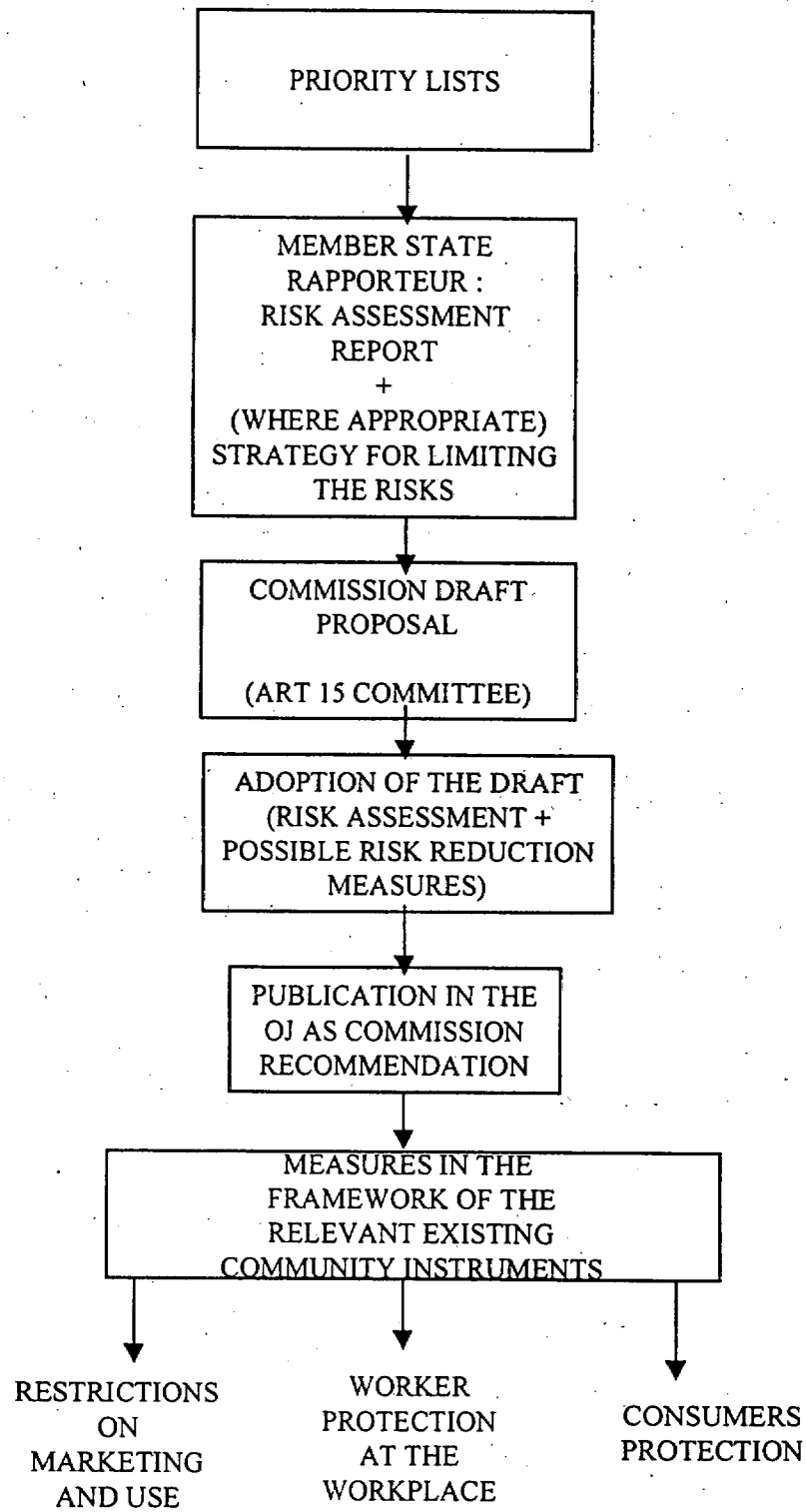
Official Journal References of Community legislation Referred to in the text of the report:

Council Directive 67/548/EEC	OJ No. 196, 16/08/1967 p. 0001 - 0005	On the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
Council Directive 76/116/EEC	OJ No. L 024, 30/01/1976 p. 0021 – 0044	On the approximation of the laws of the Member States relating to fertilisers
Council Directive 76/768/EEC	OJ No. L 262, 27/09/1976 p. 0169 – 0200	On the approximation of the laws of the Member States relating to cosmetic products
Council Directive 76/769/EEC	OJ No. L 262, 27/09/1976 p. 0201 - 0203	On the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations
Council Directive 79/117/EEC	OJ No. L 033, 08/02/1979 p. 0036 – 0040	Prohibiting the placing on the market and use of plant protection products containing certain active substances
Council Directive 79/831/EEC (6th amendment of Council Directive 67/548)	OJ No. l 259, 15/10/1979 p. 0010 - 0028	6th amendment of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
Commission Decision 81/437/EEC of 11 May 1981	OJ No. L 167, 24/06/1981 p. 0031 – 0038	Laying down the criteria in accordance with which information relating to the inventory of chemical substances is supplied by the Member States to the Commission
Council Directive 83/189/EEC	OJ No. L 109, 26/04/1983 p. 0008 - 0012	Laying down a procedure for the provision of information in the field of technical standards and regulations
Council Directive 86/362/EEC	OJ No. L 221, 07/08/1986 p. 0037 – 0042	On the fixing of maximum levels for pesticide residues in and on cereals
Council Directive 86/363/EEC	OJ No. L 221, 07/08/1986 p. 0043 - 0047	On the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin
Council Directive 86/609/EEC	OJ No. L 358, 18/12/1986 p. 0001 - 0028	On the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes
Council Directive 87/18/EEC	OJ No. L 015, 17/01/1987 p. 0029 - 0030	On the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances
Council Directive 87/373/EEC	OJ No. L 197, 18/7/1987 p. 0033 - 0035	Laying down the procedures for the exercise of implementing powers conferred on the Commission
Council Directive 88/320/EEC	OJ No. L 145, 11/06/1988 p. 0035 - 0037	On the inspection and verification of Good Laboratory Practice (GLP)
Council Directive 88/379/EEC	OJ No. L 187, 16/07/1988 p. 0014 - 0030	On the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
Council Directive 89/391/EEC	OJ No. L 183, 29/06/1989 p. 0001 – 0008	On the introduction of measures to encourage improvements in the safety and health of workers at work
Council Directive COM 316 FINAL SYN 119 (proposal for 8th amendment to Council Directive 76/769/EEC)	OJ No. C 318, 20/12/1989 p. 0010	Re-examined proposal for a Council Directive amending for the 8th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provision of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations
Council Directive 89/677/EEC	OJ No. L 398, 30/12/1989 p. 0019 - 0023	8th amendment of Council Directive 76/769/EEC on the restrictions of marketing and use of certain dangerous substances and preparations

Official Journal References of Community legislation Referred to in the text of the report:

Council Directive 90/394/EEC	OJ No. L 196, 26/07/1990 p. 0001 - 0007	On the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC
Council Directive 90/642/EEC	OJ No. L 350, 14/12/1990 p. 0071 – 0079	On the fixing of maximum levels for pesticide residues in an on certain products of plant origin, including fruit and vegetables
Council Directive 91/414/EEC	OJ No. L 230, 19/08/1991 p. 0001 - 0032	Concerning the placing of plant protection products on the market
Council Directive 92/32/EEC (7th amendment of Council Directive 67/548/EEC)	OJ No. L 154, 05/06/1992 p. 0001 - 0029	7th amendment of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
Council Directive 92/59/EEC	OJ No. L 228, 11/08/1992 p. 0024 – 0032	On general product safety
Council Directive 92/85/EEC	OJ No. L 348, 28/11/1992 p. 0001 – 0008	On the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)
Council Regulation (EEC) 793/93	OJ No. L 084, 05/04/1993 p. 0001 - 0075	On the evaluation and control of the risks of existing substances
Commission Directive 93/67/EEC	OJ No. L 227, 08/09/1993 p. 0009 - 0018	Laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC
Commission Regulation (EC) 1179/94 (1st list of priority substances under Council Regulation (EEC) 793/93)	OJ No. L 131, 26/05/1994 p. 0003 - 0004	Concerning the first list of priority substances as foreseen under Council Regulation (EEC) 793/93
Council Directive 94/33/EC	OJ No. L 216, 20/08/1994 p. 0012 – 0020	On the protection of young people at work
Commission Regulation (EC) 1488/94	OJ No. L 161, 29/06/1994 p. 0003 - 0011	Laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) 793/93
European Parliament and Council Directive 94/60/EC	OJ No. L 365, 31/12/1994 p. 0001 – 0009	Amending for the 14th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations
Commission Regulation (EC) 2268/95 (2nd list of priority substances under Council Reg. 793/93)	OJ No. L 231, 28/09/1995 p. 0018 - 0019	Concerning the second list of priority substances as foreseen under Council Regulation (EEC) 793/93
Commission Regulation (EC) 143/97 (3rd list of priority substances under Council (EEC) Regulation 793/93)	OJ No. L 25, 28/01/1997 p. 0013 - 0014	Laying down the procedures for the exercise of implementing powers conferred on the Commission
European Parliament and Council Directive 97/63/EC	OJ No. L 335, 06/12/1997 p. 0015 – 0016	Amending Directives 76/116/EEC, 80/876/EEC, 87/284/EEC and 89/530/EEC on the approximation of the laws of the Member States relating to fertilisers
Council Directive 98/24/EC	OJ No L 131, 05/05/1998 p. 0011-0023	On the protection of the health and safety of workers from the risks related to chemical agents at work.

COUNCIL REGULATION (EEC) no 793/93 ON THE EVALUATION AND CONTROL OF THE RISKS OF EXISTING SUBSTANCES



LIST OF STAKEHOLDERS

COMPETENT AUTHORITIES

Austria
Belgium
Denmark
Finland
France
Germany
Greece
Ireland
Italy
Luxembourg
Netherlands
Portugal
Spain
Sweden
United Kingdom

Norway

European Free Trade Association Secretariat (EFTA)
European Surveillance Authority (ESA)

EUROPEAN COMMISSION

DIRECTORATES GENERAL INVOLVED

Environment, Nuclear Safety and Civil Protection
Joint Research Centre
Industry
Employment, Industrial Relations and Social Affairs
Agriculture
Enterprise Policy, Distributive Trades, Tourism and Social Economy
Consumer Policy Service

INDUSTRY

Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (AISE)
European Association of Metals (EUROMETAUX)
European Chemical Industry Council (CEFIC)
Oil Companies European Organisation for Environment, Health and Safety (CONCAWE)

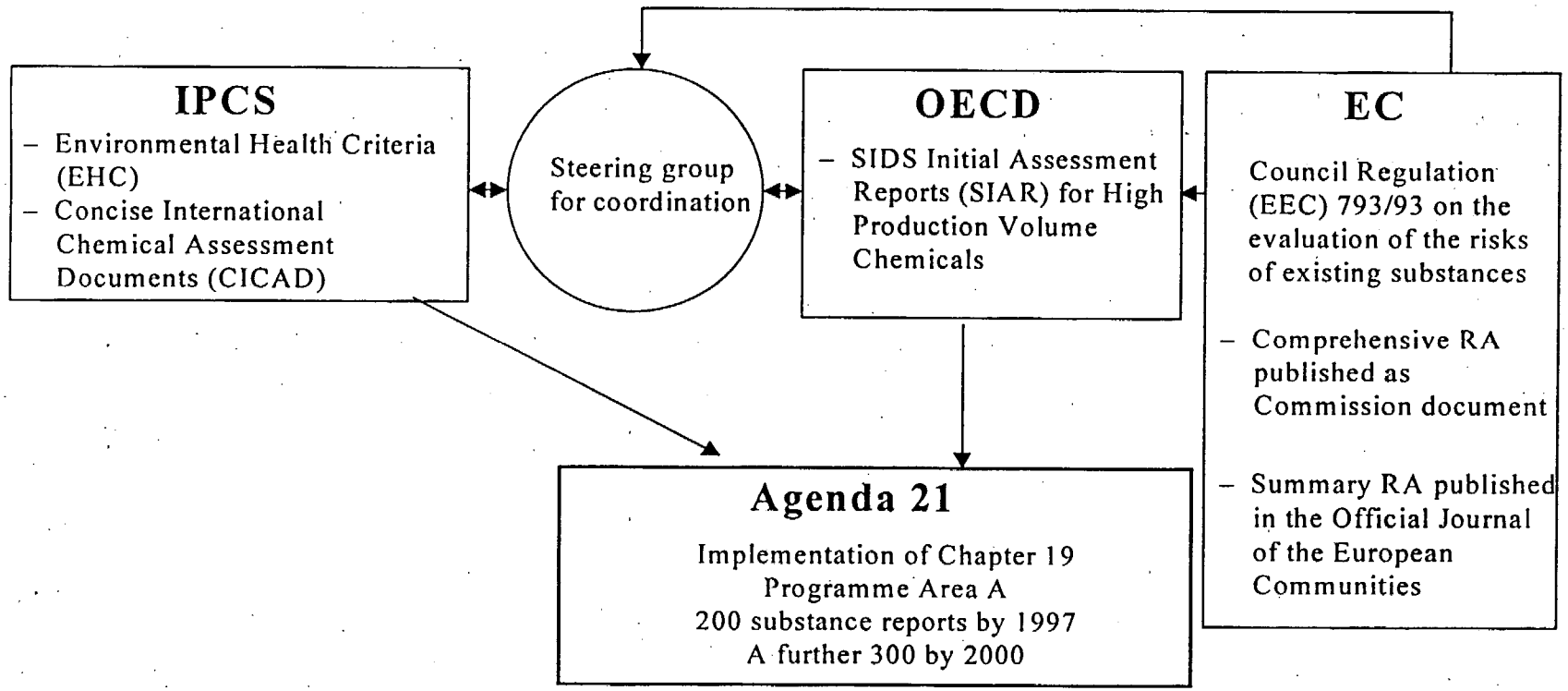
NGOs

Bureau Européen des Unions de Consommateurs (BEUC)
European Environmental Bureau (EEB)
Friends of the Earth
Greenpeace International
European Trade Union Technical Bureau for Health and Safety
World Wildlife Fund for Nature (WWF)

INTERNATIONAL ORGANISATIONS

International Programme on Chemical Safety (IPCS)
Organisation for Economic Co-operation and Development (OECD)

Links between international programs carrying out risk assessments (RA) on existing chemicals



Annex 4

Findings

on the Operation

of

Directive 76/769/EEC

on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

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1. BACKGROUND

1.1 Context

The Treaty of Rome (1957) envisaged from the outset the creation of an internal European market and the main tasks of the Community were purely economic. Consequently, the first legislative actions on chemicals taken by the Community were motivated by the efforts to complete the internal market by harmonising specifications that otherwise could create obstacles to the free movement of goods.

Article 100a of the Treaty, introduced by the Single European Act in 1987, provides for the approximation of provisions applying in Member States through Community measures adopted by qualified majority. It requires that the Commission in its proposal concerning health, safety, environment protection and consumer protection take as a base a high level of protection.

Many Directives and Regulations pursuing the goals of creating a common market and of ensuring chemical safety and environmental protection have been adopted during the last 30 years, among others, Directive 76/769/EEC on restrictions on the marketing and use of certain dangerous substances and preparations. This Directive was introduced in 1976 to deal with situations where classification and labelling of chemicals were not sufficient to protect health and the environment and Member States were introducing national restrictions on the marketing and use of chemicals thus creating barriers to trade. The Directive sets out detailed rules for restrictions on marketing and use harmonising the legislation throughout the Community and at the same time providing for a high level of protection of man and the environment. It is complemented by a number of other Directives limiting the marketing and use of chemicals in particular fields e.g. Directive 76/117/EEC limiting the marketing and use of certain dangerous chemicals in agriculture, Directive 76/768/EEC setting down rules for the use of chemicals in cosmetics and Directive 73/204/EEC governing the use in detergents.

Restricting the marketing and use of dangerous substances and preparations is only one instrument used by the Community to control the risks to health and to the

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environment of chemicals. Other parts of the Community legislation deal with the protection of health and the environment and of the health and safety of workers. Examples are Directive 96/61/EC concerning integrated pollution prevention and control and Directives 90/394/EEC and 98/24/EC on protection of health and safety of workers from risks related to chemical agents at work.

1.2 Objectives

The objectives of Directive 76/769/EEC are, according to Article 100a of the Treaty, to guarantee free movement of goods within the single market and at the same time provide a high level of protection of man and the environment. These objectives are clearly spelled out in the recitals to the Directive: rules concerning the placing on the market of dangerous substances and preparations must aim at protecting the public, and particular persons using such substances and preparations. The restrictions should contribute to the protection of the environment from all substances and preparations which have characteristics of ecotoxicity or which could pollute the environment. They should also aim to restore, preserve, and improve the quality of human life. Harmonised rules should remove the obstacles to trade and the functioning of the internal market created by different provisions in the Member States.

2. DESCRIPTION OF THE DIRECTIVE

2.1 Structure

The Directive consists of two main articles and an annex. In the articles it is stated that the Directive is concerned with restricting the marketing and use of dangerous substances and preparations listed in the Annex and that Member States shall take all necessary measures to ensure that these dangerous substances and preparations may only be placed on the market or used subject to conditions specified in the Annex. In the Annex the substances are listed and the restrictions specified.

The Directive is constantly amended to add further substances to the Annex. Up to date, it has been amended 18 times providing for restrictions on 42 substances or groups of substances (covering about 900 individual substances in total). Proposals for amending Directives are adopted by The Council and the European Parliament according to the co-decision procedure.

A Committee procedure to adapt the Directive to technical progress has been introduced to take account of new scientific knowledge on risks of chemicals or the development of less dangerous substitutes for restricted substances. According to this procedure restrictions on substances already included in the Annex to the Directive can be changed by Commission Directives. This procedure is considerably quicker and simpler than the co-decision procedure. The proposals are approved by the Member States on the basis of a qualified majority followed by formal adoption by the Commission. Up until now, this procedure has been used four times to adapt the Directive to technical progress.

2.2 Scope

The Directive covers the placing on the market and use of certain dangerous substances and preparations. In certain cases it also applies to articles containing dangerous substances. Examples are products containing asbestos or certain plastic products containing cadmium.

The provisions of the Directive are not applicable to transport of dangerous substances and preparations, for exports to non-EU countries, to transports in transit regime, nor to marketing and use for research and development or analysis purposes.

The first substances to be included in the Annex to the Directive were polychlorinated biphenyls and terphenyls (PCB and PCT) and monomer vinyl chloride. The reason for introducing harmonized provisions were, apart from the establishment of an internal, market, the dangers to human health associated with the use of these substances. The substances subsequently introduced into the Annex by the first seven amendments to the Directive adopted between 1976 and 1985, are all dangerous to human health and

especially to the health of children. Examples of such substances are certain flame retardants used to fire-proof textiles and garments (tris (2,3 dibromopropoyl) phosphate, tris-aziridinyl phosphinoxide and polybrominated biphenyls (PBB)), certain dangerous substances used in toys and jokes (e.g. benzene, bensidine, volatile esters of bromoacetic acids etc.). Also the restrictions on the use of asbestos fibres were introduced during this time.

Restrictions on substances dangerous especially to the environment were first introduced in the early 1990s following an increased public concern about the risks posed by chemicals to the environment and the entry into force of the Single European Act. Restrictions on substances used as biocides and dangerous to the aquatic environment such as mercury, arsenic and tin compounds were included in the Annex by the eighth amendment. Other examples of substances dangerous to the environment included in the Annex are pentachlorophenol (PCP) (mainly used for wood-preservation), cadmium and hexachloroethane (used in non-ferrous metal industries).

Restrictions especially directed to the use by consumers of dangerous substances was introduced in the mid 1990s by the 14th amendment. The initiative was taken in the context of the programme "Europe against cancer" and is focusing on cancer causing substances. Substances classified as carcinogenic, mutagenic or toxic to reproduction category 1 and 2 (c/m/r) are, subject to an assessment of the risks and advantages of the substances, included in the Annex and banned for consumer use. The list of c/m/r substances in the Annex is constantly up-dated by amending Directives as new substances are classified under Directive 67/548/EEC.

2.3 Provisions

The provisions in the Directive are constructed according to two main principles. They either provide for a ban, with or without excemptions, on the marketing and/or use of the substance, or provide for controlled use.

A total ban on a substance has only been introduced in the Directive in very few cases. The more common approach is a ban with exemptions. A ban with exemptions means that marketing and use of the substance are prohibited except for applications that are expressly allowed.

Controlled use means that marketing and use of a substance and the preparations and products containing it are allowed except those which are expressly forbidden. This means that only those products and applications will be limited which present a special risk and where safer substitutes exist. This approach is the predominant one used in the Directive.

The choice of strategy depends of course of the nature of the risk, e.g. whether the effects are life threatening, irreversible, long-term, global etc., but also on the complexity of the situation. The scientific uncertainties about the risks, technical knowledge in general about the different applications of the substance, as well as information on safer substitutes influence the choice of strategy. Finally, the benefits of the proposed strategy i.e. the reduction in risk and the costs of the measure should be in proportion one to the other.

Although following the two main strategies, the specific provisions on each substance vary considerably in the Directive as illustrated by the following:

- The ban on marketing and use is total. This is the case for PCB and of some substitutes to PCB the so called Ugilecs.

- In other cases certain exemptions are granted, e.g. when no replacement substances are available for certain applications, as in the case of pentachlorophenol where exemptions from the ban were granted for four specific uses. The exemptions may be permanent or limited in time (fixed date or end-of-use period of products concerned).

- The marketing and use is banned only in relation to the general public, whereas professional users may continue to use the substance for certain applications or as an intermediate. This provision is often combined with specific requirements for labelling

- The use is controlled in the sense that the marketing and use is only banned for specific applications (e.g. in textiles), or for uses posing a particular risk (e.g. treatment of industrial waters), or as component together with other materials, but otherwise substances can be used.

- Limit values are also set e.g. the restrictions only apply when the content of a certain substance in the final product reaches certain threshold values.

- Finally, marketing and use is allowed only when specific labelling and safety requirements are observed.

2.4 Sources of limitations

The initiative by the Commission to propose a new amendment limiting the use of a substance not previously restricted or to adapt existing provisions to technical progress can have many different sources.

Notifications under Directive 83/189/EEC

A proposal from the Commission is usually triggered by a notification from a Member State under Directive 83/189/EEC of its intention to unilaterally introduce limitations at national level. Directive 83/189/EEC lays down a procedure for the provision of information in the field of technical standards and regulations; it gives to the Member States and the Commission the possibility of objecting to a notified national proposal because of its likely trade effects. In fact, proposals for most of the amendments of Directive 79/769 have had their origin in notifications from the Member States under Directive 83/189.

International organisations

Many international organisations are actively involved in questions of chemicals safety and control, and protection of human health and the environment. Among them are organisations of the UN (WHO, FAO, UNEP, UNECE, ILO), the OECD, the Council of Europe, and several organisations pursuing the protection of the marine environment like the North Sea Conference, OSPARCOM, and HELCOM. Many Member States of the European Union are also members of these organisations. In some cases, the Union itself is a formal member, too. In cases where not all of the Member States are contracting parties to an organisation or when some of the EU

Member States decide to follow the guidelines established by international organisations and others do not apply the same rules, the functioning of the internal market can be disrupted and there is a need to introduce harmonised provisions at Community level. The 15th amendment to Directive 76/769/EEC on hexachloroethane follows an initiative in PARCOM to phase out the use of hexachloroethane in production of non-ferrous metals.

Council Resolutions

Declarations and Resolutions from the Council of the EU have been major driving forces during the establishment, the development, and the definition of long term objectives in policy of chemicals control, and health and environment protection. Resolutions on specific topics have been adopted, e.g. on cancer prevention (1990) which motivated a major part of Directive 94/60/EC amending for the 14th time Directive 76/769/EEC by prohibiting the placing on the market for use by the general public of substances that are classified as carcinogenic, mutagenic and toxic to reproduction. Another resolution concerned cadmium (1988) and led to Directive 91/338/EEC amending for the 10th time Directive 79/769/EEC by restricting marketing and use of cadmium for plating and in polymers as pigment and stabiliser.

Existing Substances Regulation

If the result of the evaluation under Regulation (EEC) 793/93 is a recommendation to limit the marketing and use of a priority substance, the Commission shall propose Community measures in the framework of Council Directive 76/769/EEC. The details of the strategy are further developed in the frame work of Directive 76/769/EEC and the strategy can be implemented either by an amendment following the co-decision procedure or as an adaptation to technical progress by Committee procedure.

In practice, as risk assessments under the Existing Substances Regulation are fairly new and the procedure has initially been lengthy only a few risk assessments have been concluded. A proposal for measures within the framework of Dir. 76/769/EEC concerning one group of substances, short chain chlorinated paraffins (SCCP), is expected shortly. On the basis of the progress achieved recently, it is also expected that the process will accelerate and that results from risk evaluation under regulation 793/93 will be at the origin of an increasing number of Community initiatives

concerning restrictions on marketing and use in the future.

New Substances Notification

Any new substance to be placed on the market has to be notified by the manufacturer, distributor or the importer to the national competent authority. "Notification" includes the submission of detailed data and only after approval of the notification dossier may the substance be marketed. It is obvious that, as for existing substances, Member States and/or the European Union can, on the basis of the technical dossier submitted during the notification and the risk assessment carried out by them, take actions concerning safety requirements. These can include restrictions on marketing and use under Directive 76/769/EEC. Up to now one notification of a new substance has led to such a measure: a family of PCB-substitutes (Ugilecs) banned by the 11th amendment.

Safeguard Clauses

Several Directives and Regulations concerning chemicals control and safety contain safeguard clauses. They allow a Member State, when it has justifiable reasons to consider that substances or preparations that have been accepted as satisfying the requirements of the Directive concerned nevertheless constitute a danger for man or the environment, can temporarily take measures, e.g. prohibit the placing on the market or subject the substance to special conditions in its territory. It must immediately inform the Commission and the other Member States of such action and give reasons for its decision and the Commission must take a decision thereon. A possible measure following such an action is a proposal of an amendment to Directive 76/769/EEC. One example is the 13th amendment to Directive 76/769/EEC prohibiting the marketing for consumers of aerosols which contain substances that are (provisionally) classified as flammable or extremely flammable. This amendment follows the application of the safeguard clause of the Aerosols Directive by one Member State.

2.5 Risk assessment and cost benefit analysis

In the process to elaborate a proposal for further restrictions on the marketing and use of dangerous substances and preparations it is important to make sure that the proposal fulfils the general objectives of Directive 76/769/EEC to establish an internal

market in the product and to provide a high level of protection of man and the environment.

It is also important that the proposal is proportionate i.e. that the costs of the measure are proportionate to the benefits. In the Communication from the Commission on 'An Industrial Competitiveness Policy for the European Chemical Industry: an Example' (Com(96) 187 final) actions to improve the regulatory framework are explicitly mentioned as part of the measures to improve the competitiveness of the chemical industry. The Commission has committed itself to carry out risk assessments and adequate analyses of the costs and benefits prior to any proposal or adoption of a regulatory measure affecting the chemical industry.

Risk assessment

Risk assessments of chemicals are carried out under different legislative frameworks such as Regulation 793/93 on Existing Substances and Directive 98/8/EC on the placing on the market of biocidal products. These programmed assessments are very comprehensive, and, although being extremely valuable sources of information, tend to be rather time-consuming.

In most cases, proposals for harmonised restrictions on marketing and use have to be developed under time constraint. The Commission has to react within a limited period of time e.g. to notifications by Member States of unilateral actions, to immediate threats to health or the environment or to initiatives by international organisations disturbing the internal market. Targeted risk assessments have been developed for application primarily to urgent problems arising in the context of Directive 76/769/EEC.

Due to the constraint in time under which the assessment has to be carried out a targeted risk assessments is different from a programmed assessment in two major aspects: the scope of the assessment and the data availability.

A targeted risk assessment is limited in scope. The assessment could focus e.g. on those areas that would be directly concerned by the proposed measure to restrict

marketing and use or the assessment could be limited to certain applications of the substance suspected to be major sources of risk, to certain populations such as consumers or to critical effects of the substance. The targeted assessments have to rely mostly on already available data. The time constraint does not allow new data to be generated. Toxicological experiments or exposure measurements do often take considerable time. For example, studies on chronic toxicity or cancer could take up to two years to complete.

Targeted risk assessments are carried out in the frame work of Directive 76/769 by independent consultants

- interactively and transparently with active and co-operative contributions from all parties such as industry (producers, users etc.), Member State authorities, the scientific community, interest groups, consumers, etc.
- according to the Community's established procedures for risk assessment. The generally accepted standards for risk assessments are not lowered. For the areas of concern, the actual risk assessment should follow as closely as possible the established Community principles as laid down in Directive 93/67/EEC, Regulation (EC) No 1488/94, and the supplementary Technical Guidance Documents.
- with quality assurance and peer review. Where appropriate and in accordance with the Commission Communication on consumer health and food safety COM(97)183 final, the Scientific Committee on Toxicity, Eco-toxicity and Environment is consulted to give its scientific opinion on the targeted risk assessment.

Analysis of advantages and drawbacks

Risk assessment provides only part of the information necessary for risk management. To establish that the proposed measures are proportionate the advantages and drawbacks of adopting restrictions and using replacement substances or other alternative solutions must be analysed. Furthermore, an economic evaluation of the benefits and costs linked to a proposed measure is a systematic approach that provides a coherent way of organising thoughts about the policy problem and policy options and helps to organise information that will be of importance to political decision

makers in choosing between options (how effective a policy will be, what the costs and benefits are, and who bears them).

The advantages of a proposed restriction can be understood to mean the positive implications of the restriction. Clearly positive is the extent to which the risks identified during the risk assessment will be limited, taking into account any increase in risk to human health and the environment arising from an increasing use of replacement substances. The risk reduction can have positive effects on future costs of environmental remediation and health care presently incurred in dealing with the existing risks. There may be positive effects and reduced costs in matters linked to occupational safety, treatment of waste and landfill sites, quality and use of formerly contaminated products, as well as medium and long-term advantages resulting from the development of alternative technologies, the production and marketing of substitutes, increase of long-term competitiveness, creation of new jobs. Administrations and control authorities might experience less costs than when using other risk reduction strategies (e.g. monitoring of emission limits achieved by end-of-pipe technologies).

Drawbacks are understood to mean the negative implications of the restriction. They include possible new risks due to the substituting chemicals, a range of costs to industry (investments, development of alternatives, compliance costs), notably the producers, processors and users of the substance to be restricted, costs to the consumers due to e.g. higher price, poorer performance of substitutes, closing down of production facilities, loss of amenity to consumers, costs to society as a whole, e.g. administrative costs of enforcing the restriction, loss of employment, transfer of benefits to other countries/regions, etc.

In principle, an analysis of advantages and drawbacks will start off with a qualitative analysis, where advantages and drawbacks are described but not quantified or valued. The analysis should then move on to quantification to increasing degrees, depending on what is needed to make a convincing comparison between advantages and drawbacks. Due to uncertainties, it will usually be difficult to fully quantify advantages and drawbacks that are only indirect consequences of an envisaged restriction.

In the context of the comparison of advantages and drawbacks also the availability of less dangerous substitutes has to be addressed. It is not possible or necessary, except in certain cases, to carry out full assessments of available substitutes. However, the analyses should provide enough information to assure that restrictions on one substance do not create new, possibly more serious risks and that the substitutes are technically and economically feasible.

The analysis of advantages and drawbacks in the frame work of Directive 76/769 are, in analogy with the targeted risk assessments, carried out by independent consultants. However, the analysis procedure is less well developed not least because of the absence to date of any accepted set of Community procedures in the field. Initial guidance is given in the Technical Guidance Document on development of risk reduction strategies. The work should be done in a transparent way involving all stakeholders.

Work to further develop the methodology for targeted risk assessments and cost benefit analyses in the frame work of Directive 76/769 is on-going. This work is presented in the DG III Working paper on Risk Management in the framework of Council Directive 76/769/EEC (Doc. 98/RiMa03).

3. EVALUATION

Directive 76/769/EEC has been evaluated against the general objectives in relation to the internal market and to health and the environment set by the Treaty. The capacity of the Directive to meet these objectives is of course depending on the practical operation of the Directive and this is why the practical operation has also been evaluated in terms of procedures and the structure of the legislation.

3.1 Internal market

According to Article 100a of the Treaty one objective of the Directive is to establish an internal market with chemicals circulating freely without any barriers to trade. The Directive provides for total harmonisation in the area covered by the provisions of the Directive. However, Article 36 of the Treaty gives the Member States the right to

introduce restrictions under certain conditions to protect man and the environment. In the areas outside the scope of the Directive the Member States can, after having notified the Commission and Member States under Directive 89/183/EEC, introduce national provisions restricting the marketing and use of chemicals. The measures should not constitute arbitrary barriers to trade and should be justified and proportionate. If the unilateral restrictions introduced by a Member State solves a national health or environmental problem without disrupting the internal market harmonised measures are not introduced unless there is a need to raise the level of protection in the Community as a whole. This corresponds to the principle of subsidiarity established in Article 3b of the Treaty and further reinforced in a protocol to the new Amsterdam Treaty.

After 20 years of practical operation the Directive has generally proven effective in relation to the objective on internal market. It has been possible to meet the need to introduce Community wide harmonised restrictions when Member States have planned to unilaterally introduce national restrictions that would have disrupted the internal market. In recent years, all proposals for harmonised restrictions have been adopted without any Member State voting against.

However, in three cases certain Member States have used the possibility under Article 100a §4 to request derogations from the Community legislation to keep stricter national legislation in force providing a higher level of protection of man and the environment. The requests concern the provisions on PCP, cadmium and creosote. Two requests for derogations from the provisions on PCP have been confirmed whilst a third is pending, as is the requests concerning cadmium and creosote, mostly due to lack of scientific evidence of the necessity to keep stricter legislation given the already high level of protection provided by the Community legislation.

The Amsterdam Treaty facilitates for Member States to request derogation from the provisions in the Directive and apply stricter national legislation to further protect health and the environment. The new Treaty also provides for a stricter regime for the Commission to react to the requests for derogation. This presents a challenge both in terms of potentially more numerous requests for derogation and in terms of the shorter time available for the Commission to make a decision.

Certain initiatives taken in international organisations such as Marine Conventions to phase out the use of dangerous substances threaten to fragment the internal market. It has been shown that harmonised provisions through out the Community can be provided by the Directive also in these cases. However, the question about competence to negotiate and enter into international agreements has not been adequately clarified. Decisions taken in such organisations may still pose a problem with respect to the internal market especially where all Member States are not contracting parties to the organisation. One example that could be mentioned in this context is a PARCOM Decision to phase out the use of short chained chlorinated paraffins.

3.2 Protection of health and the environment

The Directive shall, according to Article 100a of the Treaty, provide a high level of protection to man and the environment.

The protection of the public and particular persons using dangerous substances and preparations is stressed in the recitals of the Directive. The vast majority of the provisions in the Directive aim at protection of human health, and is providing a high level of protection especially to consumers and vulnerable groups as children. For example, more than 850 substances are banned for consumer use and about 15 % of the entries in the Directive are concerned with protection of the health of children.

The need for timely adoption of provisions reducing unacceptable risks to health and the environment is evident. Although the time for adoption normally can be deemed as acceptable in relation to transposition time, transition periods etc, the date for application of the provisions can be delayed e.g. if there is a need to develop new testing methods for the enforcement of the provisions. One example is the Directive restricting the marketing and use of nickel in cheap jewellery. The Directive is not to be applied before testing methods have been adopted by the European standardisation organisation (CEN). The development of testing methods for nickel has taken unacceptably long time, partly due to the procedures of CEN. Another example of a long and difficult processes to adopt a Directive is the review of the provisions on

asbestos. In this case unclear science, the need to consider the substitutes and a considerable economic impact for certain countries of the proposed measures have contributed to the long time to find an acceptable solution.

Adoption of amendments adding further substances to the Directive by the co-decision procedure provides for the democratic principles being respected. In most cases amendments can be adopted and enter into force within an acceptable timeframe. However, the time needed to introduce a ban by the co-decision procedure has shown overly resource intensive and time consuming in certain cases. This is evident especially when the over-all principle to ban certain substances has already been established as is the case when newly classified c/m/r substances are added to the list of cancer causing substances banned for consumer use in the Annex to the Directive and where the Commission is obliged to submit a proposal within six months. Another example of the co-decision procedure being perceived as too slow is when actions have to be taken to reduce immediate health risks to children. Where the current procedure allows for adoption by the Committee procedure, as was the case with the fourth adaptation to technical progress on lamp-oils posing an acute risk to the health of small children, a Directive can be developed and adopted within a reasonable time. If the co-decision procedure is needed, as in the case of phthalates in toys and child care articles, the time for adoption will take considerable longer time.

Another factor with a potential to cause delay in introducing protective measures is uncertainties about the nature and degree of the risk. This can under certain circumstances make the introduction of protective measures difficult and lengthy. It is often difficult to estimate the exposure to substances in different parts of the Community, the topography and climate vary widely and the Member States have different views of what is the required level of protection. If the science is not giving a clear answer and the proposed restrictions on marketing and use have a serious economic impact the process to negotiate a new Directive can take considerable time. This has been the case in the review of the provisions on asbestos and cadmium.

Finally, as pointed out earlier, provisions aiming purely at the protection of the environment are not as frequent in the Directive as provisions on substances dangerous to health. This is certainly a consequence of the general perception of risk

being more focussed on health risks during the early days of the Directive. Also the fact that the knowledge about environmental risks has only gradually increased during the last decade contributes to that relatively fewer substances dangerous to the environment have been restricted.

4. IMPROVEMENTS

Three main areas for improvement have been highlighted in the evaluation of Directive 76/769/EEC. The first issue concerns the functioning of the Directive in relation to the objective on internal market and the cases where certain Member States have requested derogations under Article 100a §4. The second main issue concerns the effectiveness of the Directive in terms of the time needed to meet the requirements to protect health and the environment. Finally, certain difficulties in the practical operation of the Directive have been highlighted for improvement.

The internal market

In the three cases where Member States have requested derogations under Article 100a §4 and the Directive has been unable to provide harmonised rules for the whole Community, solutions respecting the objectives of the Directive are actively sought by the Commission.

- It is intended that an internal market in PCP be established by a review of the provisions on PCP raising the level of protection for the whole Community. It is also intended that the request for a derogation on cadmium a solution be provided by introducing a higher level of protection in the Directive. These changes are foreseen in the near future in the context of the review of the PCP and cadmium provisions for the new Member States.
- The Commission also has planned to provide a solution in the cases of creosote. A review of the provisions of creosote is planned following new information on health dangers that has recently been made available. The review has to be co-ordinated with a review of the classification of creosote under the Directive

67/548/EEC on classification, packaging and labelling of dangerous substances and preparations.

Protection of health and the environment

The effectiveness of the Directive to meet the requirements to protect health and the environment could be further improved. Certain factors have been identified causing delays in the adoption and application of proposed provisions.

- The introduction of harmonised testing methods.

The experiences, especially from the Directive on nickel in cheap jewellery, show that development of testing methods should be under the control of the Commission and Member States in order to guarantee a result within a reasonable time frame. The R&D work could be done by independent, governmental or industry research institutes. Validation of the testing methods could be done by appropriate independent bodies, in particular the JRC, in collaboration with independent technical bodies in the Member States. The Working Group on restriction on marketing and use consisting of Member State experts and stakeholders could function as steering committee. That provides also for a transparent procedure that would facilitate the final adoption of the testing methods.

- Procedure for adoption of amendments

The co-decision procedure is being perceived as overly resource intensive and time consuming for adding substances newly classified as c/m/r (carcinogenic, mutagenic and toxic to reproduction) to the Annex of the Directive. The general principle to ban c/m/r substances for consumer use was already introduced in 1994 by the 14th amendment to the Directive. Newly classified substances could instead be added to the Annex by the Committee procedure adapting Directive 76/769/EEC to technical progress. As mentioned earlier, the 14th amendment will be subject to review following the new information on creosote. A change of procedure to make possible a more speedy up-dating of the Annex with regard to c/m/r substances will be raised in the context of that review. Also in the cases where urgent actions are needed to meet immediate threats to health or the environment a simpler and less time consuming

procedure should be possible. Transparent procedures are ensured by the operation of the modus vivendi between the three Community Institutions and by the commitment of the Commission vis-à-vis the European Parliament on transparency.

- Different views of Member States on preferred/appropriate level of protection.

A clear picture of the risks posed by the substance of concern and of the consequences of the proposal is a of utmost importance for the possibility to build consensus about a proposal. It will facilitate the introduction of restrictions that have earlier showed difficult and time-consuming e.g. on substances dangerous to the environment. Although the methodology for targeted risk assessments and cost benefit analyses in the frame of Directive 76/769 is still under development these tools have proven successful. Since 1995, when the concept was introduced, no Member State has voted against the Commission's proposals on restrictions on marketing and use.

However, in some on-going work, e.g. the revision of the provisions on asbestos and cadmium, the process to find commonly acceptable solutions has taken many years and has been difficult.

Further efforts have to be made to develop methodologies for cost benefit analyses and targeted risk assessments that provide a sufficiently good basis for the proposals within a reasonable time frame. The efforts to develop an appropriate methodology for targeted risk assessments and especially for cost benefit analysis in the frame of Directive 76/769/EEC will continue. To improve cost benefit analyses there is a need to agree overall Community principles and also to find a way to performing independent peer review of cost benefit studies. Two seminars have already been organised with a broad representation of Member State experts, stakeholders, academia etc. A report on risk management in the context of restrictions on marketing and use has been prepared and a third seminar to further develop the concept is planned.

Proposals should be based on work carried out by independent scientific expertise involving the Scientific Committee on Toxity, Ecotoxity and the Environment in order to ensure that independant, good quality and transparent scientific bases have

been taken into consideration. This will not only facilitate the adoption of new restrictions but will also remove much of the incentive for the Member States to request derogations under Article 100a. The concept should also be promoted in international organisations like the Marine Conventions. A uniform approach to restrictions on marketing and use will decease the effects on the internal market. Efforts to develop internationally harmonised methods for risk assessments and cost benefit analyses are being made in the frame of OECD and the transatlantic business dialogue (TABD).

However, in many cases science can not provide a full answer. Knowledge about e.g. long term effects of chemicals on health and the environment may be missing or the exposure is difficult to estimate. Nevertheless, in most situations the information available is sufficient to provide a sufficient basis for a decision. It is possible to justify the introduction of restrictions on marketing and use and to make sure that the proposals are proportionate.

In some cases the science is unclear. The risk assessment shows that important scientific knowledge is missing, that the uncertainties are considerable and that serious concerns can not be excluded. According to the Rio Declaration on Environment and Development the lack of full scientific certainty, where there are threats of serious or irreversible damage, shall not be used as a reason for postponing cost-effective measures.

A precautionary approach in the Directive to introduce cost effective measures when there is a well founded suspicion of unacceptable risk will improve the Directive with regard to the objective on a high level of protection of the environment and to further decrease the incentive for Member States to request for derogations under Article 100a §4 to keep stricter national legislation.

This approach has been taken in the review of the provisions on asbestos and of the provisions from which the new Member States have derogations. The possibility to find solutions acceptable to the majority of Member States based on a transparent operation of the principle as defined in the Rio Declaration is high.

Practical operation of the Directive

The main weaknesses in the daily operation of the Directive are concerned with the complexity of the Directive and certain difficulties to interpret the Directive with regard to both the scope and the provisions. The Commission has included in its work programme for 1999 a proposal to recast Directive 76/769/EEC. A recast will introduce a modernised and simplified approach providing for clear definitions, a well defined scope and a safe guard clause.

- Definitions

In a modernised Directive necessary definitions could be introduced and the provisions drafted in a clear and easily understandable language.

- Scope

The scope of the Directive could by clarified particularly in relation to the area being harmonised by the Directive. Within the harmonised area the Member States can not introduce legislation deviating from the provisions of the Directive. Another example were the scope could be further clarified is in relation to goods containing or being treated with dangerous substances (reference: Court judgement of the 1.10.98 in affair C-127/97)

- Safeguard clause

The functioning of the Directive could be improved by the introduction of a safeguard clause making it possible for the Member States to take temporary measures if needed to protect health and the environment from immediate danger.

- Furthermore, the provisions could be presented in the new Directive in a structured way facilitating the daily use of the Directive.

By proposing a new modernised and improved Directive the Commission can put into practice the principle of simplify existing legislation and thus making this legislation more easily understandable by all parties involved. A simplified legislation contributes to a more homogeneous implementation by the Member States of the provisions and to a higher legal certainty.