COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 08.09.1999
COM(1999) 178 final

Three yearly report on the implementation of Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, as amended by Directive 92/32/EEC

(presented by the Commission)

Contents

1 Introduction

1.1 Why this report?

Directive 67/548/EEC as amended by Directive 92/32/EEC (hereinafter "the Directive") lays down the respective duties of the Commission and the Member States with regard to the implementation of the procedures for the notification of new substances in the European Union. (A short introduction to the Directive is given in the next paragraph.)
Article 32 of the Directive requires the EU Member States and the Commission to prepare a report on the implementation of the Directive every three years, starting from three years after its implementation. Since the Directive became effective as from the beginning of November 1993, the first report on this implementation is now due.

This report gives an impression of the implementation of the Directive in the Member States with regard to legal aspects (how is the Directive implemented in national legislation) as well as other aspects: the number of notifications and risk assessments, the number of process orientated research and development (PORD) exemptions, the notification procedure in practice, data sharing, etcetera. Furthermore, the report gives an overview of general thoughts or comments of the Member States on the operation of the Directive. In addition, Member States were asked to give their view with regard to a number of issues that have all been identified as issues of concern.

The three yearly report can, by giving an overview of the implementation of the Directive in the various Member States, help the European Commission and the Member States to identify problems encountered with the implementation of the Directive, to identify priorities for future actions and to implement associated legislation in the future.

1.2 Short introduction to the Directive

In the 1970s, many EU Member States introduced notification procedures for new substances prior to these substances being placed on the market. The aim of these procedures was to undertake an a priori assessment of a new substance before it was marketed, thereby allowing the necessary measures to be taken to protect man and the environment from exposure to unacceptable risks.
However, one consequence of the introduction of divergent national procedures was the distortion of the EU market, because manufacturers and importers of chemical substances were subject to different requirements in different Member States. Furthermore, information submitted on a substance in one Member State was not communicated to other Member States whereas the substance itself could, as internal borders began to disappear, quite easily be transported and used across the European Union. In these circumstances, the most effective course of action was to establish a harmonised EU-wide system of notification whereby the same

procedures would be applied across the Member States and wherein the information collected would be exchanged between all national authorities.

The EU-wide scheme for the notification of new substances was introduced as part of the sixth Amendment to Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances. The 6th Amendment was adopted by the Council of Ministers of the European Union in September 1979.

In the light of more than 10 years' experience implementing the 6th Amendment to the Directive, a 7th Amendment to Directive 67/548/EEC (Directive 92/32/EEC) was adopted by the Council of Ministers on 30 April 1992. The 7th Amendment became effective as from the beginning of November 1993 in all Member States. The notification procedures described in the next paragraph correspond to those laid down under the 7th Amendment.

1.3 Way of working

This report is based upon two main sources of information: data gathered from the European Commission (ECB: European Chemicals Bureau in Ispra, Italy) and data gathered from the Member States.

In close co-operation with the Commission's Directorate General (DG) XI (Unit E.2: Chemical Substances and Biotechnology), it was determined which data from ECB were required. ECB was asked to provide Arcadis Heidemij Advies Consulting Engineers (the Netherlands) with statistical information on notifications and risk assessments over the period November 1993 - December 1996, per Member State per year, distinguishing between:

- notifications of EU and non EU manufacturers;
- notifications per use category and desired effect category;
- notifications of dangerous substances;
- notifications covered by sole representatives;
- polymer notifications;
- risk assessments per conclusion.

The other important source of information were data provided by the Member States (over the same period as mentioned above). A questionnaire, asking for qualitative as well as quantitative aspects of the national implementation of the Directive was sent to all the Member States and to Norway. It was decided to include only Norway and not to involve other European Economic Area (EEA) countries, since Norway is in fact the only EEA country that has implemented the Directive.

The questionnaire asked for:
- a description of the administrative system in each Member State;
- the way Directive 67/548/EEC as amended by Directive 92/32/EEC, and the related Directives 93/67/EEC (laying down the principles of risk assessment) and 93/105/EEC laying down the information requirements on polymers) are implemented in national legislation;
- co-operation and information exchange in practice;
- issues arising out of the implementation of the Directive.

The questionnaire is enclosed to this report as appendix 2.

The questionnaire was filled in by every country that received it, except Luxembourg. In bilateral contacts with Luxembourg it became clear that the Competent Authority did not feel the need to fill in the questionnaire, since there is relatively little experience with the Directive in this country.

Data gathering (from ECB as well as from the Member States) took place in the beginning of 1997 (January and February). March and April were used to analyse the data gathered and to prepare the report. The months May and June were used to consult with the European Commission (ECB and DG XI) and the Competent Authorities (during the 53rd meeting of the Competent Authorities for New Substances, June 1997, in The Hague). The final version of the three yearly report was drafted in August and September.

1.4 Structure of the report

Chapter 2 starts with a description of the administrative system and the procedures related to the Directive, on EU/EEA level as well as on national level. The description of the procedures on EU/EEA level is a summary of the article *The notification of new substances in the European Union,* (P.M. Murphy, P. Rigat, DG XI, European Commission, 1994).
In chapter 3, the implementation of the Directive in national legislation is shortly described per Member State.
Chapter 4 describes the data on notifications and risk assessments under the Directive, provided by the European Commission (ECB).
Chapter 5 deals with other aspects of the implementation of the Directive, mainly referring to research and development exemptions and to the notification procedures in practice.
Chapter 6 gives an overview of 'issues of concern' arising out of the implementation.
In chapter 7, the results of the NONS project (a European enforcement project on the Notification of New Substances) are summarised, thus giving an impression of the way the Directive is enforced in the European Union.
This report ends with a summary and conclusions with regard to the implementation of the Directive over the last three years (chapter 8).

2 The administrative system and procedures

2.1 Administrative systems and procedures on EU/EEA level

Substances liable for notification
A substance is subject to notification if:
- it is placed on the EU market (either on its own or in a preparation);
- it is not on the European Inventory of Existing Commercial chemical Substances (EINECS)
- it is not covered by one of the exemptions granted under the Directive.

Exemptions
The following substances are exempted from the harmonised EU notification procedures:
- additives and substances for exclusive use in animal feedingstuffs;
- substances used exclusively as additives or as flavourings in foodstuffs;
- active ingredients used exclusively in medicinal products for human or veterinary use (not including chemical intermediates);
- substances for exclusive use in plant protection products and which are subject to the evaluation procedures foreseen under Article 6 of Directive 91/414/EEC;
- cosmetic ingredients when only marketed incorporated in cosmetic products.

In addition to those substances which are exempted from the notification procedure, the Directive also recognises further categories which are considered as being notified and hence not subject to the harmonised EU notification procedures:
- polymers (with the exception of those which contain in combined form 2% or more of any substance which is not on EINECS);
- substances placed on the EU market in quantities of less than 10 kg per year;
- substances for scientific research and development;
- substances for process-orientated research and development.

Submitting a notification
For substances liable for notification, manufactured within the EU, it is the manufacturer who must submit the notification and is regarded legally as the notifier.
For substances produced by a given manufacturer outside the EU, the situation is slightly more complicated. An individual importer bringing new substances directly into the EU can submit a notification dossier in the Member State were the import takes place. However, if each separate importer were to submit a notification, this could result in the submission of numerous repeated notifications for the same substance. The Directive therefore allows the manufacturer to designate a legal entity, person or company, based in the EU as his *sole representative* for the purpose of submitting a notification for that substance.

Before notification: preparatory steps

Once it has been determined that a substance must be notified and the company legally responsible for submitting the notification as been identified, the next step is to compile a *notification dossier*.

Before embarking upon the generation of a notification dossier, potential notifiers should identify precisely the substance which is to be notified. Furthermore, to avoid duplicate animal testing a potential notifier must, before carrying out animal testing, contact the Competent Authority in the Member State were he intends to notify to enquire whether the substance has been notified previously. Where the substance has been notified previously, the prospective and the previous notifier are obliged to take all reasonable steps to avoid animal testing and reach an agreement on the *sharing of data*. In some Member States the provision even goes further, with the two parties being obliged to share the data.

The notification dossier

The essential contents of a notification dossier for a new substance includes:

- A *technical dossier*, describing the intrinsic properties of the substance, the extent of which varies with the quantity of the substance to be placed on the market. With regard on the information to be provided on intrinsic properties, there are three possible testing packages to be carried out, depending upon the amounts which will be marketed annually across the EU: more than one tonne per year, less than 1 tonne but greater than 100 kg, less than 100 kg but more than 10 kg. The testing packages corresponding to these marketing levels are laid down in Annexes VII A, B and C to the Directive, respectively. In summary, the larger the amount placed on the market, the more testing is required.
- A proposal for the *classification and labelling* of the substance. In addition to the notification procedure for new substances, the Directive is also concerned with the classification, packaging and labelling of dangerous substances. Criteria for the classification of substances are laid down in Annex VI to the Directive. When notifiers submit a notification dossier, they are requested to submit a proposal for the classification and labelling of the substance.
- A proposal for a *safety data sheet* for substances classified as dangerous. The Directive requires that all substances which are classified as dangerous should at the time of first delivery to a customer be accompanied by a safety data sheet, containing the information necessary to protect man and the environment.
- A *statement* from the extra-EU producer in the case where the sole representative procedure is being employed.

The notification dossier may also include, at the request/discretion of the notifier:

- A provisional *risk assessment*, carried out by the notifier.
- A *request* to be exempted for one year from the data sharing requirements imposed by the Directive.

Role of the national Competent Authorities

Once the notifier has put together all the elements in the notification dossier, the notification must be submitted to the national Competent Authority in the Member State were the notifier is located.

The national Competent Authority receiving the notification dossier has the following duties/powers with regard to the notification:

- To check that the notification conforms the requirements of the Directive and, if necessary, to carry out sampling for control purposes, to require the notifier to

supply samples of the substances for verification testing and to take appropriate measures relating to safe use of the substance.
- To inform the notifier within a fixed period after receipt of the dossier (60 days for substances to be marketed in quantities of greater than one tonne per year and 30 days for quantities of less than one tonne per year) to whether the dossier conforms with the Directive and if not, what changes are to be made.
- To carry out a *risk assessment* on the notified substance. The Directive recognises four potential administrative actions following the risk assessment carried out by a Competent Authority, from conclusion (i) (= the substance is of no immediate concern) to conclusion (iv) (= immediate recommendations for risk reduction are necessary).

Role of the European Commission (European Chemicals Bureau)
The national Competent Authority receiving the notification dossier sends the following information to the Commission (European Chemicals Bureau):
- A summary of the notification dossier in electronic form (SNIF: Summary Notification Interchange Format), usually within a period of four to six weeks after their acceptance by a Competent Authority, including:
- A proposal for the formal classification and labelling of the dangerous substance as it should eventually be introduced into Annex I of the Directive (immediately with the notification dossier the first proposal and after six months the final proposal, taking into account any comments of the other Competent Authorities).
- A risk assessment report, carried out by the Authorities, containing recommendations for further tests or risk reduction measures (usually submitted several weeks later than the notification dossier).

Upon receiving the information transmitted from the Competent Authority first receiving the notification dossier, the ECB checks the contents of the dossier and stores the information in the new substances database. Copies of the summary notification dossier are sent out on a weekly basis to the Competent Authorities in the other Member States, together with any comments from the ECB.
In case of receiving a notification for a dangerous substance, the formal proposal of the Competent Authority for the entry to be included in Annex I to the Directive is communicated by the ECB to the other Member States which have six months to send comments to the originating Authority.
Upon receipt of the risk assessment the ECB circulates it to the other Member States all of which can (as for the notification dossier) comment and request changes and modifications.

Follow-up to notification
As a general rule, the notifier is obliged to inform the Authority to whom the notification dossier was submitted of any changes to the information included in the notification and of any new data of which he may become aware and which are relevant to the risk assessment of the substance.
Whereas the testing requirements for up to one tonne per year are clearly set out in the Directive (Annexes VII A, B and C), at 10 tonnes per year, the Authorities review the dossier and a request for further testing is entirely discretionary. At 100 tonnes per year the notifier is obliged to carry out a supplementary testing package (according to the schedule set out in level 1 of Annex VIII to the Directive). Similarly, when marketed quantities reach 1000 tonnes per year, notifiers are again

required to carry out a supplementary testing package (according to Annex VIII, level 2).

2.2 Administrative system and procedures on national level

2.2.1 Austria

Competent Authority
The Competent Authority is Department I/2 within the Federal Ministry for the Environment, Youth and Family ("*Bundesministerium für Umwelt, Jugend und Familie, Abteilung I/2*").

Other involved authorities
Other authorities involved in "running the system" are the Chemical Substances Department ("*Chemikalienabteilung*") of the Federal Environment Agency ("*Umweltbundesamt*") and the "*Bundeskanzleramt, Abteilung VI/2*".

Enforcement authorities
The supervision and enforcement of national legislation concerning the Directive is in hands of the nine (decentralised) states. Within these federal states, enforcement is carried out by the Chemical Inspectorate ("*Chemicalieninspektionen*"). These inspectors may check manufacturing process and operating facilities and may take samples in required amounts of substances, preparations and finished products.

2.2.2 Belgium

Competent Authority
According to a Royal Decree of 24 May 1982 (published on 2 July 1982), the Minister or Secretary for Public Health and Environment ("*Minister/Staatssecretaris van Volksgezondheid en Leefmilieu*") is the Competent Authority for the implementation of the Directive. The Minister/Secretary is advised by the Commission for Dangerous Products ("*Commissie Gevaarlijke Produkten*"). This is an interdepartmental commission in which the Ministry of Public Health and Environment, the Ministry of Economic Affairs, the Ministry of Labour and the Ministry of Agriculture are represented.

Other involved authorities
The Commission for Dangerous Products, who carries out risk assessments for full notifications, can ask for the advice of the Council of Health ("*Hoge Gezondheids Raad*"), consisting of academic experts.

Enforcement authorities
According to a Ministerial Decree of 14 September 1993, inspectors of the Ministry of Public Health and Environment, the Ministry of Economic Affairs, the Ministry of Labour and the Ministry of Agriculture are responsible for the control and enforcement of the relevant legislation of the Directive.

2.2.3 Denmark

Competent Authority
The Ministry of Environment and Energy is responsible for implementation of the legislation of the Directive. The responsible policy department is the Chemicals Division ("*Kemikaliekontoret*"). All administrative activities relating to notification of new substances are carried out by the Notification Group within this Chemicals Division.

Other involved authorities
The Chemicals Division may obtain expert advice from various institutions under other ministries, such as evaluation of toxicological and eco-toxicological data, in order for the Chemicals Division to have the best possible grounds to form opinions and decisions on. Any advisory committees do not exits in this area.

Enforcement authorities
The Chemicals Inspectorate ("*Kemikalieinspektionen*") is in charge of control and enforcement of all Danish chemical legislation - substance and product wise - also the national regulation on new substances deriving from the Directive.

2.2.4 Finland

Competent Authority
The Competent Authority for new substances is the National Product Control Agency for Welfare and Health ("*Sosiaali- ja terveydenhuollon tuotevalvontakeskus, STTV*"), which is an agency under the Ministry of Social Affairs and Health.

Other involved authorities
Other involved authorities and institutes are:
- the Ministry of Social Affairs and Health (Occupational Safety and Health Department): their task is the assessment of occupational safety measures;
- the Finnish Environment Institute: their task is the assessment of environmental risks;
- the Safety Technology Authority: their task is the assessment of fire and explosion hazards.

Enforcement authorities
The "*STTV*" has the overall responsibility to control the enforcement of the notification of new substances. According to the Finnish legislation a municipal supervisory authority is locally responsible to control the enforcement.

2.2.5 France

Competent Authority

Two authorities are appointed as Competent Authority in the French legislation :

- the Chemical Substances and Preparations Office ("*BSPC - Bureau des Substances et Préparations Chimiques*") at the Ministry of Environment, which deals mainly with environmental issues of the notification dossiers;
- The Chemical Control Department ("*Service Contrôle des Produits*") at the National Institute for Research and Safety ("*Institut National de Recherche et de Sécurité; INRS*"), which deals mainly with human health (workers).

Other involved authorities

The Ministry of Environment is advised by a national committee of experts (Commission of Chemical Ecotoxicity Evaluation, 41 members from university, industry, laboratories and state departments) which meets every month.
For consumer risk assessments, the Competent Authorities require the advice of the Ministry of Health.

Enforcement authorities

The following inspectorates are the most involved in the enforcement of the Directive (control actions):

- "*DGCCRF*" (Ministry of Financial Affairs): controlling free-trade, fraud and consumer products;
- "*DRIRE*" (Research, Industry, Environment): implementing environmental policy in industrial plants and facilities;
- "*DGD*": general custom department ("*Direction Générale des Douanes*");
- Labour inspectors: (Ministry of Labour) occupational affairs.

2.2.6 Germany

Competent Authority

The responsibility for the implementation of the Directive and it's Amendments rests with the Ministry of Environment, Nature Protection and Nuclear Safety ("*Ministerium für Umwelt, Naturschutz und Reaktorsicherheit*"). The notification procedure is administrated by the Chemical Notification Unit within the Federal Institute for Occupational Safety and Health ("*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Anmeldestelle Chemikaliengesetz*").

Other involved authorities

Other involved authorities are experts from:

- health ("*Bewertungsstelle Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinärmedizin, BgVV*");
- environment ("*Bewertungstelle Umweltbundesamt, UBA*");
- occupational safety and health ("*Bewertungsstelle Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA, Abt. Gefährliche Stoffe*").

These authorities receive the notification dossier for assessment (plausibility/validity for the tests submitted, risk assessment and conclusions).

Enforcement authorities
The 16 Federal States ("*Bundesländer*") carry out the monitoring of the relevant legislation of Directive 67/548/EEC and its Amendments in their own responsibility. They have installed a system of control unites in their area. These control units are not only responsible for new chemicals, but also for occupational health and safety in general.

2.2.7 Greece

Competent Authority
The Division of Environment, Section of Dangerous Substances and Preparations/Articles, in the General Chemical State Laboratory (GCSL), depending administratively from the Hellenic Ministry of Finance, is appointed for the implementation of Directive 67/548/EEC and its 7th Amendment. The Competent Authority is carrying out all the activities needed to run the system.

Other involved authorities
There is no other authority or institute involved. The Competent Authority has the possibility to invite scientists with recognised expertise in toxicity and ecotoxicity areas for consultations. Their judgement is used where needed.

Enforcement authorities
The GCSL with some 70 dependant regional branches and local offices, spread along the country, is in charge of the controls and inspections needed to ensure the implementation of the regulation for new and existing dangerous chemical substances and preparations. The nominated inspectors of the GCSL are conducting inspections at places of production, storage and in general circulation/distribution of chemical products, in order to check:
- conformity to the provisions concerning notification requirements of new substances;
- conformity to the requirements for labelling, packaging and safety data sheets of dangerous substances;
- conformity to any other provisions of the legislation.

2.2.8 Ireland

Competent Authority
The Irish Competent Authority is the National Authority for Occupational Safety and Health ("*Health and Safety Authority: HSA*"). At the working level, the Directive is the responsibility of the "*Hazardous Substances Assessment Unit*".

Other involved authorities
There are no other authorities involved, although the HSA does have a "*Substances Advisory Committee*" which is consulted on new legislation and scientific or policy matters. To date it has not been consulted on the Directive.

Enforcement authorities
The HSA is in overall charge. The enforcement activities are carried out by inspectors of the "Hazardous Substances Assessment Unit". The inspectors have a wide range of enforcement powers available.

2.2.9 Italy

Competent Authority
The Competent Authority is the Prevention Department ("*Dipartimento della Prevenzione*") within the Ministry of Health ("*Ministero della Sanità*"). This ministry works in consultation with other ministries involved in this field (ministries of Industry, Environment, and Labour).

Other involved authorities
Another involved Italian authority is the Notification Unit within the Health Institute ("*Istituto Superiore di Sanità*").

Enforcement authorities
The enforcement of relevant legislation concerning the Directive is in hands of the Prevention Department within the Ministry of Health.

2.2.10 Luxembourg

Due to lack of experience with notifications, Luxembourg did not respond to the questionnaire.

2.2.11 Netherlands

Competent Authority
According to the Dutch Chemical Substances Act the Ministry of Housing, Spatial Planning and the Environment (*"Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer"*) together with the Ministry of Social Affairs and Employment are the authorities responsible for the implementation of the Dangerous Substances Directive 67/548/EEC. By Regulation of 19 September 1986, the Minister authorised the Chemical Substances Bureau ("*Bureau Milieugevaarlijke Stoffen, BMS*") with the mandate to act on behalf of the Minister regarding articles dealing with the notification procedure.
According to the most recent modification of the regulation concerning the Chemical Substances Bureau, the bureau is part of the National Institute of Public Health and Environmental Hygiene ("*Rijksinstituut voor Volksgezondheid en Milieuhygiëne, RIVM*"). BMS has the responsibility to take decisions on the compliance of the notification dossiers and on the necessity for additional testing.

Other involved authorities
In the notification procedure, technical and scientific advice is provided by RIVM and the Institute for Applied Technology (TNO).

Enforcement authorities
The Environmental Inspectorate (*"Inspectie Milieuhygiëne"*) of the Ministry of Housing, Spatial Planning and the Environment and the Labour Inspectorate (*"Arbeidsinspectie"*) of the Ministry of Social Affairs and Employment are the responsible authorities to control and enforce the relevant legislation of Directive 67/548/EEC and its Amendments.

2.2.12 Portugal

Competent Authority
The Competent Authority for the implementation of Directive 67/548/EEC is the Directorate General for Environment (*"Direcção-Geral do Ambiente"*) from the Ministry of the Environment through its Division of Industrial Risks and Chemical Substances (*"Divisão de Riscos Industriais e Compostos Químicos"*).

Other involved authorities
The Competent Authority is advised by the National Institute for Health (from the Ministry of Health) and the University of Science and Technology of Lisbon.

Enforcement authorities
The authorities which are in charge for the enforcement of relevant legislation concerning the Directive are:
- the General Direction for the Environment, Inspection of the Environment (*"Direcção-Geral do Ambiente, Inspecção do Ambiente"*) and Regional Bodies for the Environment (*"Direcções Regionais do Ambiente e Recursos Naturais"*), both from the Ministry of the Environment;
- the General Inspectorate of Economical Activities (*"Inspecção-Geral das Actividades Económicas"*), of the Ministry of Economy;
- the General Direction for Customs (*"Direcção-Geral das Alfândegas"*), of the Ministry of Finances; and regional bodies of Industry and Energy (*"Delegações Regionais da Indústria e Energia"*), under the responsibility of the Ministry of Economy.

2.2.13 Spain

Competent Authority
The responsible department for the supervision and enforcement of Directive 67/548/EEC is the Ministry of Health and Consumer Affairs (MSC). It takes policy decisions at national level. The Chemical Notification Unit, allocated in the Subdirectorate General for Environmental Health of the Ministry, carries out the administrative and technical activities relating to notification. Since January 1997, the Ministry of Environment is involved also in the technical activities concerning environmental issues in this area.

Other involved authorities
There are no other authorities involved.

Enforcement authorities
The Autonomous Communities are responsible for the inspections and control of chemical substances according to the Spanish National Law (Art. 24.2 R.D. 363/95). The co-ordination on this matter is made by the MSC through the Council for the National System of Health and the Commission of General Directors of Autonomous Communities and the General Director for Public Health of the Ministry.

2.2.14 Sweden

Competent Authority
The National Chemicals Inspectorate ("*KemI*") is appointed as the Competent Authority in Sweden. "*KemI*" is the governmental agency, under the Ministry of the Environment and National Resources, responsible for carrying out chemicals control. The inspectorate issues regulations based on the act and the ordinances. The inspectorate has recently made a reorganisation. All work within the inspectorate is divided into four Programme Areas. Work concerning notification of new substances is in Area C "Classification & Labelling; Notifications", which also includes work concerning classification and labelling. Most of the work at the inspectorate is performed in projects or processes (continued work). Notification of new substances is such a process.

Other involved authorities
Other involved authorities are the National Inspectorate of Explosives and Flames, the National Board of Occupational Safety and Health and the Swedish Environmental Protection Agency. Scientific experts from scientific institutes are not regularly involved, but may be used on a case-by-case basis.

Enforcement authorities
The National Chemicals Inspectorate is in charge of the enforcement.

2.2.15 United Kingdom

Competent Authority
The Competent Authority is the Health and Safety Executive (HSE) and the Department of the Environment acting jointly. This means that for the notification process two departments handle the dossier and communicates with the European Commission in a co-ordinated manner, although HSE provide the core administration of the notification system. HSE deal with human health matters and the Department of Environment handle environmental issues.

Other involved authorities
Currently there are no other authorities or institutes involved in "running the system", but as from 1 April 1997 the Environment Agency has taken on the role of one half of the joint Competent Authority from the Department of Environment in respect of the Directive.

Enforcement authorities
With the exception of some aspects of the Directive relating to supply to the general public, all enforcement is carried out by inspectors of the Health and Safety Executive. For chemicals supplied to the general public from shops, enforcement is carried out by Local Authority Inspectors.

2.2.16 Norway

Competent Authority
The Norwegian Pollution Control Authority (appointed as Competent Authority), is responsible for the administrative system and for the co-ordination of work done by other authorities, institutes, and advisory committees. The responsible Department is the Department of Chemicals and Hazardous Waste, where the work is mainly done by the Division for Chemicals Hazardous to Health, and the Division for Environmentally Hazardous Chemicals.

Other involved authorities
A number of other authorities are involved:
- The Product Register: responsible for storing the notifications, for copying , distribution and collection of confidential information, and for the development and maintenance of datasystems;
- The National Labour Inspectorate: responsible for the assessment of Material Safety Data Sheets and risk assessment concerning Occupational Health;
- The Directorate of Fire and Explosion Prevention: responsible for the assessment of the data and risk assessments concerning flammability;
- The Norwegian Petroleum Directorate: responsible for the assessment concerning use of new substances offshore;

National Institute of Public Health: assess the toxicological data and do risk assessments concerning human health.

Enforcement authorities
The Norwegian Pollution Control Authority (Control Department) is responsible for the enforcement (control actions) of the Directive. The enforcement may be done in co-operation with The National Labour Inspectorate, the Directorate of Fire and Explosion Prevention and (when new substances are used offshore) by The Norwegian Petroleum Directorate.

3 The implementation: legal aspects

3.1 Introduction

This chapter summarises how in each country the Directive is transposed into national legislation. The four main items are:

- how is Directive 67/548/EEC as amended by Directive 92/32/EEC implemented into national legislation (including a description of the implementation of Directive 93/67/EEC (laying down the principles of risk assessments) and Directive 93/105/EEC (laying down the information requirements on polymers);
- how are updates of Annex I and Annex V implemented into national legislation;
- are there any additional national regulations (such as notification requirements for substances marketed in quantities less than 10 kg/year, legal charges for a notifications);
- what are the sanction possibilities.

3.2 Austria

How is the Directive transposed in national legislation?
The Directive came into force on 1 March 1997 by the Chemical Substances Act 1996 (CSA; "*Chemikaliengesetz*"). The most important elements of the Directive were in force since 1989 in the previous CSA.

How are updates of Annex I and Annex V transposed in national legislation?
Updates of Annex I and V are transposed by means of the Chemical Decree ("*Chemikalienverordnung*") and the Notification Decree ("*Anmeldeverordnung*").

Additional national regulations
Additional national legislation to the CSA are the Chemical Decree ("*Chemikalienverordnung*") and the Notification Decree ("*Anmeldeverordnung*").

Sanctions
Penalties on those that do not comply with the relevant national legislation can be imposed from 5.000 to 200.000 ATS (350 to 15.000 ECU).

3.3 Belgium

How is the Directive transposed into national legislation?
In Belgium, the Directive is not yet transposed into national legislation. The procedure to do so has been started in 1993. Despite this delay, the Commission for Dangerous Products has applied the principles of the 7th Amendment since November 1993.

How are updates of Annex I and Annex V transposed into national legislation?
Updates of Annex I and V are transposed by adaptation of the Royal Decree of 11 January 1993 respectively the Royal Decree of 24 May 1982.

Additional national regulations
As soon as the Directive is transposed into national legislation, previous and prospective notifiers will be obliged to share data in Belgium. The Commission for Dangerous Products will act as a mediator.
Belgium imposes fees for a notification. The legal charge is 160.000 BF (4.000 ECU)for full notifications and varies from 20.000 to 85.000 BF (500 to 2.000 ECU) for reduced notifications.

Sanctions
Penalties on those that do not comply with the relevant national legislation can be imposed to a maximum of 5 years in prison or a fine of maximum 100.000 BF (2.500 ECU). The amount has now been indexed.

3.4 Denmark

How is the Directive transposed into national legislation?
The Directive has been transposed in "Statutory Order from the Ministry of Environment and Energy, no. 1002 of 14 December 1995 on Notification of New Chemical Substances". Both Directives 93/67/EEC and 93/105/EEC have also been transposed in this Order. The 7th Amendment was originally transposed in Statutory Order no. 831 which came into force on 31 October 1993. Order 1002 is the amended version of Order 831.

How are updates of Annex I and Annex V transposed into national legislation?
Annex I of 67/548/EEC is implemented in its own statutory order: the "Statutory order on the List of Dangerous Substances", which is amended whenever a new adaptation on Annex I has been agreed to between the Member States.
Annex V of 67/548/EEC is implemented into national legislation whereby it is given that physico-chemical, toxicological and ecotoxicological studies shall be carried out in accordance with the requirements.

Additional national regulations
Manufacturers and importers have to submit information to the Danish Environment Protection Agency on the identity of the substance, the classification and labelling data and the estimated quantity of sold or imported new substances in quantities less than 10 kilogram per year. Denmark also requires that a new substance which is exported outside the European Union, must be notified.
Denmark imposes a fee for a notification. The legal charge is 67.625 DKK (9.100 ECU) for full notifications and varies from 9.100 to 15.775 DKK (1.200 to 2.100 ECU) for reduced notifications and PORD applications.

Sanctions
The penalties for not complying with the statutory order 1002 is a fine from 5.000 to 500.000 DKK (700 to 67.000 ECU), detention or imprisonment for up to 2 years.

3.5 Finland

How is the Directive transposed into national legislation?
The Directive is transposed in the Finnish Act on Chemicals (744/1989, 1412/1992), in the Chemicals Decree (675/1993) and in different decisions of the Ministry of Social Affairs and Health. The Directive was incorporated in national legislation during 1992 and 1993.
The act, the decree and some of the decisions came into force on 1 August 1993. The provisions concerning the notification of new substances came into force on 1 January 1994 together with the EEA-agreement (Agreement on European Economic Area).

How are updates of Annex I and Annex V transposed into national legislation?
Updates of Annex I are implemented in the Decisions of the Ministry of Social Affairs and Health. Latest update includes Commission Directive 94/69/EEC adapting to technical progress for the 21st time Council Directive 67/548/EEC. Test methods including all technical adaptations are implemented by making a reference to the Annex V of the Directive 67/548/EEC in the Decision of the Ministry of Social Affairs and Health concerning criteria for classification and labelling of chemicals (article 2 "Testmethods").

Additional national regulations
There are no additional regulations to the Directive, except legal charges for a notification. The legal charge for a full notification varies from 10.700 to 21.500 FIM (1.800 to 3.700 ECU). The charge for a reduced notification varies from 1.100 to 3.400 FIM (200 to 600 ECU).

Sanctions
In the Act on Chemicals, penalties are described in article 52 (fines, depending on the case, or a maximum of two years in prison).

3.6 France

How is the Directive transposed into national legislation?
The implementation of the Directive is achieved in the French law by its transposition into two regulations :
Regulation for the worker protection
The Directive was implemented into a law ("*Code du travail*") Articles L 231-6, L 231-7 and two acts, the "*décret" n° 94/181*" of 1st March 1994 (published in the French Official Journal on 2 March 1994) and the "*arrêté*" of 20th April 1994 (published in the French Official Journal on 8 May 1994). This regulation (which came into force on 8 May 1994) includes a section which requires the Competent Authority to perform a risk assessment according the principles of Directive 93/67/EEC. Directive 93/105/EEC has also been transposed in this regulation.

Regulation for the environment protection
The Directive was implemented by the law n° 77-771 of 12 July 1977 on the control of chemicals, the decree modified n° 85-217 of 13 February 1985 on the control of chemicals and the order of 31 October 1985 on the dossiers for control of chemicals. A new draft of the law, including the modifications linked to the 7th Amendment of Directive 67/548/EEC is still under discussion. However, this delay does not prevent the implementation of the Directive provided for by regulation for the workers protection.

How are updates of Annex I and Annex V transposed into national legislation?
Annex I and Annex V are not published at this time in the French Official Journal. The regulation makes reference to the appropriate adaptation to technical progress (ATP) and gives the number and the date of the Official Journal of the European Communities where they can be found as a whole.

Additional national regulations
There is no legal requirement in the French regulation for any new substance marketed in quantities less than 10 kg/year. For new substances for research and development purposes (10 - 100 kg/year) a register has to be prepared but no specific announcement to the Competent Authorities is required.
France (INRS) imposes fees for notifications. The legal charges vary from 33.000 to 44.000 FF (5.000 to 6.700 ECU) for full notifications and vary from 5.500 to 11.000 FF (800 to 1.700 ECU) for reduced notifications. A rebate is given when a risk assessment is required and provided by the notifier. There are also charges for changes to another level of notification.

Sanctions
With regard to the *Regulation for worker protection*, those who do not comply with the regulation (notification and labelling of chemicals) can be fined 25.000 FF (3.800 ECU) and more, depending on the number of exposed workers.
With regard to the *Regulation for the environment protection*, those who do not comply with the law n° 77-771 on chemicals control can be penalised with a fine of:
- 30.000 FF (4.500 ECU) if they do not notify a new chemical;
- with a fine of 500.000 FF (76.000 ECU) and/or 2 years imprisonment if they do not notify a new chemical which is classified as dangerous.

3.7 Germany

How is the Directive transposed into national legislation?
The 7th Amendment was transposed in the German Chemical Act ("*Chemikaliengesetz, ChemG*") on 25 July 1994 and came into force on 1 August 1994. In Article 12 of the CSA the principles of risk assessment are laid down as required by Directive 93/67/EEC. The Chemical Substances Sampling Decree ("*Prüfnachweisverordnung, ChemPrüfV*") was brought out on the basis of article 20 of the CSA. Article 6 contains the elements of Directive 93/105/EEC concerning information requirements on polymers.

How are updates of Annex I and Annex V transposed into national legislation?
The Hazardous Substances Ordinance (*"Gefahrstoffverordnung, GefStoffV"*) was brought out on the basis of article 3a of the Chemical Act. As far as Annex I of Directive 67/548/EEC (article 28 and 29) were updated on the technical progress, it is in force on the first day of the 9th month after it is published in the German Federal Gazette.
Article 2 of the *"ChemPrüfV"* lays down that in each case Annex V of Directive 67/548/EEC is to be applied in its most recently published version.

Additional national regulations
Additional national regulations with reference to article 13(2) (substances marketed <10 kg) and article 13(2)(5) (R&D exemptions) of the Directive are not in force.
Information on vapour pressure and acute toxicity for Daphnia has to be provided for reduced notifications of substances marketed from 100 - 1000 kilogram per manufacturer per year (in accordance to Annex VIIB).
Further, information has to be provided by a notifier for substances which are not marketed (intermediates) or which are only marketed outside the EU market (article 16b *"ChemG"*).
Legal charges for a notification are submitted in accordance to the *Chemikalien-Kostenverordnung*. The charge is 10.000 DM (5.200 ECU) for a full notification and 2.500 to 6.000 DM (1.300 to 3.100 ECU) for a reduced notification. In particular situations (e.g. when a higher input is needed form the Competent Authority) the fee can be doubled. The fee may be reduced by up to 1.000 DM (510 ECU) when documents were stored electronically or on a magnetic data carrier.

Sanctions
Sanctions possibilities are defined in article 26 and 27 of *"ChemG"*: fines up to 100.000 DM (52.000 ECU), or imprisonment from 2 till 5 years or a financial penalty.

3.8 Greece

How is the Directive transposed into national legislation?
The Directive is incorporated in the Greek law by the Common Decision of Ministers 378/94, published in the Greek Official Journal. By this procedure, provisions set by the corresponding Directive are brought as they stand into the Greek law, where administrative measures enabling the implementation are also incorporated.
By the same way, responsibilities of the CA and obligations of the notifier for any additional information needed, concerning risk assessment reports (Directive 93/67/EEC) and all requirements for the notification of new polymers (Directive 93/105/EEC) are incorporated in the national legislation (Common Decision of Ministers 17/95 and 378/94 correspondingly) together with the necessary administrative measures for the enforcement.
The Common Decision of Ministers 378/94 was published in the Greek Official Journal on 20 September 1994 and came into force on the same date.

How are updates of Annex I and Annex V transposed into national legislation?
Adaptation to Technical Progress (ATP) Directives for Annex I and Annex V are incorporated within the provided deadlines by Common Decision of Ministers, and related by reference to the Decision 378/94. Such Decisions are always published in the Greek Official Journal.
In this publication, Annex I is not annexed to the decision and instead a reference is made to the corresponding EEC publication, on grounds that this Annex contains also the Greek version.
In the case of Annex V all newly adopted or modified testing methods are annexed to the decision and published.

Additional national regulations
There are no additional elements to what is specifically required by the Directive, but only the obligation to submit the notification dossier (except for the studies) in the Greek language. Articles 13 and 15 are transposed as they stand.

Sanctions
Economic penalties, varying from 100.000 to 5.000.000 Drachmas (330 to 16.500 ECU) can be imposed to those who place chemical substances on the market not in conformity with the legislation with regard to the classification, packaging, labelling and safety data sheets. Accordingly, penalties from 500.000 to 10.000.000 Drachmas (1.650 to 33.000 ECU) can be imposed to those who place a new chemical substance on the market without the prior submission of the notification dossier required.

3.9 Ireland

How is the Directive transposed into national legislation?
The Directive is implemented in one specific Statutory Instrument: the European Communities Regulations 1994, S.I. 77 of 1994. It was incorporated into national legislation on 7 April 1994, and came into force on the same day. These regulations implement all of the requirements of the Directive other than the duties which are placed on Member States in the Directive.
Directive 93/67/EEC is implemented by a statement in S.I. No 77 of 1994 (giving effect to the Directive), article 7(3) of the regulations (further information, verification and confirming tests for substances) and article 10(1)(g) of the Regulations (submission of a preliminary risk assessment).
Directive 93/105/EEC is implemented by a statement in S.I. No 77 of 1994 (giving effect to the Directive) and by requirements of a number of articles, which indicate that information requirements on polymers are those of annex VIID of the Directive.

How are updates of Annex I and Annex V transposed into national legislation?
Updates of Annexes I and V are implemented in national legislation by the "referral" method: giving a definition of these annexes in the Regulation. This means that the user of the legislation has to read the Directive to find the relevant information.

Additional national regulations
There are no additional requirements incorporated in national legislation with respect to the Directive, other than legal charges for a notification. The charge is 4.000 IP (5.000 ECU) for full notifications and 350 - 500 IP (440 to 630 ECU) for a reduced notifications and a PORD applications. There is an extra charge of 2.000 IP(2.500 ECU) if an adequate risk assessment has not been provided. There are also charges for Annex VIII level 1 and 2 test packages.

Sanctions
An inspector can seize, remove or retain any substance which in his or her opinion does not comply with the requirements of the Regulations. In cases of non-compliance, the person placing the substance on the market could be prosecuted. The fine of the event of a successful prosecution is 1000 IP (1.250 ECU), shortly to be increased to 1500 IP (1.900 ECU). If it is necessary for the Authority to dispose of a substance seized under the Regulations, the costs of such disposal shall be borne by the owner of the substance.

3.10 Italy

How is the Directive transposed into national legislation?
The Directive was implemented by a legislative decree of 3 February 1997 (n. 52). The decree was published in the Italian Official Journal on 11 March 1997 and came into force 15 days later. The Directives 93/67/EEC and 93/105/EEC were also implemented by this decree.

How are updates of Annex I and Annex V transposed into national legislation?
Both Annexes are implemented into national legislation by a decree signed by the Ministry of Health on 28 April 1997. The decree came into force in July 1997.

Additional national regulations
There are no particular provisions in the Italian legislation with regard to research and development exemptions. For substances marketed in quantities less than 10 kilogram per year information is requested in accordance with the provisions listed in Annex VII, points 1 and 2. As far as data sharing is concerned, the Ministry of Health (in co-operation with the Ministry of Industry), will issue a specific decree concerning the procedures to be followed.

Sanctions
Article 36, points 1 and 2, of the Italian legislative decree foresees penalties up to L 10.000.000 (5.100 ECU), depending on the seriousness of non-compliance with the provisions of labelling and packaging of dangerous substances; in very serious cases imprisonment is also foreseen (up to six months).
Point 4 of the same article foresees penalties from L 5.000.000 to L 30.000.000 (2.550 to 15.300 ECU), depending on the seriousness of non-compliance with a notification. The same penalties are applied for non-compliance with the provisions concerning the advertisement, the safety data sheet and the risk assessment.

3.11 Luxembourg

Due to lack of experience with notifications, Luxembourg did not respond to the questionnaire.

3.12 Netherlands

How is the Directive transposed into national legislation?
The Directive has been implemented on three levels, namely by amending the Dutch Chemical Substances Act (CSA), by amending four enforcement orders on the basis of CSA, and by amending and adding supplementary regulations. The main part of the 7th Amendment will be implemented in the Notification Order CSA and the Order of Packaging and Labelling of Dangerous Substances and Preparations CSA. The 7th Amendment is in force in the Netherlands since 20 June 1994.
Linked to this subject is the implementation of Directive 91/155/EEC on safety data sheets for dangerous preparations (modified by Directive 93/112/EEC) in the Order on Safety Data Sheets. The order also covers the safety data sheets for dangerous substances as indicated in the 7th Amendment.

How are updates of Annex I and Annex V transposed into national legislation?
Updates of Annex I are automatically implemented and come into force on the last date to implement following the dynamic reference in article 19 of the supplementary regulations for packaging and labelling of dangerous substances and preparations.
Updates of Annex V are implemented by specific regulations CSA.

Additional national regulations
There are four additional pieces of legislation in force in addition to what is specifically is required by the Directive. These are:
Premanufacturing notification requirement
In addition to the Directive a new substance must be notified prior to its production, called the premanufacturing notification requirement. New in this aspect means: all substances produced in the Netherlands after 1 January 1987.
Requirement of supplementary test data to justify process orientated research and development (PORD)
The extent of information to be provided in the technical dossier to the Competent Authority of the Netherlands depends on the quantity of the substance placed on the market for process-orientated research and development purposes in the EEA. For three categories (< 100 kg, < 1000 kg or > 1000 kilogram per year per manufacturer) additional information has to be provided.
Announcement for public inspection
The receipt of a notification submitted in the Netherlands will be announced in the Dutch Official Journal. The summary of the dossier without confidential data is made available for public inspection.
Register and record-keeping
Professional manufacturers, or importers of substances and preparations into the Netherlands must register a number of technical and commercial data. Such

registration requirements apply to all substances and preparations into circulation, that means including existing and new substances and preparations.

Legal charges for a notification

At the moment, no legal charges are imposed in the Netherlands. A proposal for the implementation of legal charges has been submitted for official approval. The proposed legal charges are 12.200 - 21.400 DG (5.700 to 10.000 ECU) for a full notification and 5.360 - 8.450 DG (2.500 to 3.950 ECU) for a reduced notification/PORD application.

Sanctions

Penalties for breaches of specified articles of the Chemical Substances Act are based on the Act on Economical Offences to a maximum of 6 years in prison or 100.000 DG (46.750 ECU).

3.13 Portugal

How is the Directive transposed into national legislation?

The Directive was implemented into national legislation by the Decree Law nr. 85/95 ("*Decreto-Lei nº 82/95*") of 22 April and the Specific Regulations nr. 732-A/96 ("*Portaria nº 732-A/96*") of 11 December and nr. 431/96 ("*Portaria nº 431/96*") of 2 September 1996. The Decrees came into force 5 days after their publication.

Directives 93/67/EEC and 93/105/EEC were both transposed into national legislation by the Decree Law nr. 82/95 ("*Decreto-Lei nº 82/95*") of 22 April 1995 and the Specific Regulation nr. 732-A/96 "*Portaria nº 732-A96*") of 11 December 1996.

How are updates of Annex I and Annex V transposed into national legislation?

Annex I was implemented into national legislation by implementation of Directive 93/101/EEC (20th adaptation to the technical progress of Council Directive 67/548/EEC) and Annex V was transposed into national legislation by implementation of Directive 93/21/EEC (18th adaptation to the technical progress of Council Directive 67/548/EEC), through the Specific Regulation 732-A/96. Following TPA-Directives will be transposed by amending Specific Regulation 732-A/96 through new Specific Regulations.

Additional national regulations

For substances marketed in quantities less than 10 kilogram per year, the notifier has to provide the Portuguese Competent Authority with the information as mentioned under annex VIIC points 1 and 2.

With regard to issues like R&D exemptions and data sharing some additional information is requested. This information is not formally requested by the legislation but by the Competent Authority.

Portugal imposes fees for notifications. The legal charge is 1.500.000 - 3.250.000 PTE (7.700 - 16.600 ECU) for a full notification and 250.000 - 350.000 PTE (1.300 - 1.800 ECU) for a reduced notification/PORD application. There can be a reduction on the charge if an adequate risk assessment is included.

Sanctions
Penalties on those that do not comply with the legislation range from a minimum of 50.000 PTE (250 ECU) to a maximum of 500.000 PTE (2.500 ECU). These penalties can reach an amount of 6.000.000 PTE (30.000 ECU) for corporations.

3.14 Spain

How is the Directive transposed into national legislation?
The transposition of the Directive into the national legislation has been done through the Royal Decree "*Real Decreto 363/95, de 10 de marzo, por el que se aprueba el Reglamento sobre notificación de sustancias nuevas y clasificación, envasado y etiquetado de sustancias peligrosas*". This Royal Decree was performed by the Directorate General of Public Health in co-operation with other Ministries involved in the matter. The Royal Decree was published in our Official Journal ("*Boletín Oficial del Estado*") on 5 of June 1995 and came into force on 6 June 1995. For the classification and labelling of substances already marketed there was a period of eighteen months to adopt the new measures, which thus came into force on 6 of December 1996.

How are updates of Annex I and Annex V transposed into national legislation?
When an Adaptation to Technical Progress is published in the Official Journal of the European Communities an Order is elaborated at National level. This Order modifies the former Annex I of the Royal Decree 363/95. The procedure is to add in some cases the new changes to the previous one or replace the entries depending on the modification. This rule is only published in Spanish and does not appear in other community languages. This Annex I includes: Symbols, indications of danger, standard phrases (R and S), EC number, CAS number, common and IUPAC name of the substance.
Annex V of Directive 67/548/EEC was all included in Annex V of the Royal Decree and the later modification will be implemented similarly as in the Annex I through an Order.

Additional national regulations
Spain imposes fees for notifications. The legal charges vary from 460.000 to 820.000 Ptas (2.850 to 5.100 ECU) for a full notification and 130.000 to 260.000 Ptas (800 to 1.600 ECU) for a reduced notification. There can be a reduction if an adequate risk assessment has been provided.

Sanctions
Infractions and sanctions in relation to health are established in a Law "*Ley General de Sanidad, Ley 14/86 de 25 de abril*"). In Article 28 of the Royal Decree 363/95 are defined in a specific way the infractions and sanctions about dangerous substances.
The infractions related to irregularities identified during company inspections are sanctioned with the following penalties:
- Minor offence: up to 500.000 Ptas (3.100 ECU)
- Severe offence: from 500.000 Ptas up to 2.500.000 Ptas (15.500 ECU)
- Very severe offence: from 2.500.000 Ptas up to 10.000.000 Ptas (62.000 ECU) or more .

Sanctions are the competence of the corresponding Autonomous Communities.

3.15 Sweden

How is the Directive transposed into national legislation?
Directive 67/548/EEC as amended by Directive 92/32/EEC (parts concerning notification of new chemicals), Directive 93/105/EEC and Directive 93/67/EEC are implemented in the National Chemicals Inspectorate's regulations ("*KIFS 1994:5*") on notification of new chemical substances, which was published on 10 June 1994 and entered into force on 1 January 1995. The parts concerning classification and labelling from the Directive is implemented in the National Chemicals Inspectorate's regulations ("*KIFS 1994:12*") on classification and labelling of chemical products.

How are updates of Annex I and Annex V transposed into national legislation?
Updates of Annex I and Annex V are implemented as Amendment in the National Chemicals Inspectorate's regulations ("*KIFS 1994:12*") on classification and labelling of chemical products.

Additional national regulations
For substances placed on the market in quantities of less than 10 kg per year the manufacturer or importers must provide available information required by annex VII-C (1) and (2).

Sanctions
Sanctions can contain fines to a maximum of 150.000 SK (17.600 ECU) or imprisonment. Supervisory authorities may issue injunctions under penalty of a fine to ensure compliance in individual cases.

3.16 United Kingdom

How is the Directive implemented in national legislation?
The Notification of New Substances Regulations 1993 (NONS) and the Chemicals (Hazard Information and Packaging for Supply) Regulations 1994 (CHIP), implement Directive 67/548/EEC as amended by Directive 92/32/EEC in Great Britain. Equivalent Regulations implement the Directive in Northern Ireland. Directives 93/67 and 93/105 were implemented as part of NONS in the UK. The UK guidance on NONS includes a "NONS Charter", which is a public commitment of the standards which the Competent Authority has set for itself in carrying out the duties placed on it by NONS. Directive 67/548/EEC as amended by Directive 92/32/EEC (including annexes) was incorporated into national legislation in December 1993 (NONS; in force on 31 January 1994) and January 1995 (CHIP; in force on 31 January 1995).

How are updates of Annex I and Annex V implemented in national legislation?
Annex 1 and Annex V are implemented through Amendments to CHIP legislation nationally.

Additional national regulations
There is nothing in the scope of the national legislation which goes beyond the Directive, apart from in the case of new substances placed on the market in quantities of less than 10 kg per year. Where on the basis of the information available, a substance might reasonably be expected to be dangerous for the environment and is intended to be used outside physical containment, the person responsible for placing the substance on the market has to notify the Competent Authority of any information relating to paragraph 2.3 of Annex VIIC of the Directive.
Fees are imposed for notifications. The legal charge for a full notification (Annex VIIA) is 6.440 BP (8.000 ECU). Cumulative charges for Annex VIII notifications vary from 3.500 - 6.200 BP (4.300 to 7.600 ECU). The charges for a reduced notification vary from 1.000 - 1.260 BP (1.240 - 1.550 ECU). There are rebates if an adequate risk assessment is included: 2.000 BP (2.450 ECU) in case of a full notification and 500 BP (620 ECU) in case of a reduced notification. The charge for a PORD application is 2.000 BP (2.450 ECU).

Sanctions
Penalties for breaches of the UK Regulations can be as high as two years imprisonment or an unlimited fine for breaches of enforcement notices (orders). Otherwise, the limit is a fine of 20.000 BP (24.500 ECU).

3.17 Norway

How is the Directive transposed into national legislation?
Directive 67/548/EEC as amended by Directive 92/32/EEC is implemented as a separate regulation "*Forskrift om forhåndsmelding av nye jemikalier*". The regulation includes Directive 93/67/EEC and Directive 93/105/EEC. Directive 67/548/EEC as amended by Directive 92/32/EEC was incorporated in national legislation on 1 July 1996 and came into force the same day. Until now Dangerous Chemicals have been covered by several Regulations collected in a book named "Health Fire and Explosion Hazard Labelling". Besides there is a booklet "Norwegian Regulations concerning the List of Substances for the Health, Fire and Explosion Hazard Labelling Regulations". These regulations covers most of the EU regulations concerning Dangerous Substances and Preparations.

How are updates of Annex I and Annex V transposed into national legislation?
There is a proposal for bringing new regulations more in line with the EU regulations on chemicals, even if there are a few deviations according to EEA agreement concerning classification and labelling. This will not be reflected in notifications from Norway. The proposed regulations will cover all parts of Directives 67/548/EEC and all Amendments up to date. The regulations will be updated according to new Amendments of the Directive.

Additional national regulations
There is an additional Norwegian regulation concerning labelling of Occupational Air Requirement (OAR figures). When marketing substances in quantities less than 10 kg, the manufacturer or importer must give information concerning the identity

of the substance, data to be used on classification and labelling and yearly quantity put on the market or sold in Norway, and in the EEA-area totally.
At present there are no legal charges for a notification, but soon a proposal on charges will be forwarded.

Sanctions
The Norwegian legislation (Product Control Act) gives the possibility to impose several types of penalties to those that do not comply with the Act or regulations laid down pursuant to the Act. A substance, or a product containing the substance, may be prohibited to be put on the market. If decided, the manufacturer/importer must recall a product from the market. The Ministry of Environment may impose a coercive fine.

3.18 Conclusions

3.18.1 The implementation of the Directive

The information gathered from the Member States made clear that Directive 67/548/EEC as amended by Directive 92/32/EEC on the notification of new substances has been implemented in all Member States, including the countries that recently joined the European Union (Austria, Sweden, Finland) and Norway. This conclusion is supported by the following facts:

1. Directive 67/548/EEC as amended by Directive 92/32/EEC has been transposed into the national legislation of all Member States (except in Belgium, were the implementation procedure has been started and the principles of the 7th Amendment have been applied since November 1993). This includes the implementation of Directive 93/67/EEC (laying down the principles of risk assessment) and Directive 93/105/EEC (laying down the information requirements on polymers) and the implementation of updates of Annex I (list of dangerous chemicals) and Annex V (methods for the determination of physico-chemical properties, toxicity and ecotoxicity).
2. The administrative system and the procedures belonging to the Directive are 'operational' in all Member States. Each Member State has assigned a Competent Authority and there are controlling authorities in each Member State. Most of these authorities have experience with notification- and risk assessment procedures, have an active role in informing chemical trade and industry on the requirements of the Directive and in enforcing the Directive.

3.18.2 Additional national regulations

Most of the Member States have elements in their national legislation in addition to what is specifically required by the Directive. The most important are:

- legal charges for notifications (all Member States except Austria and Sweden; charges are being prepared in Greece, Italy, the Netherlands and Norway);
- the obligation to notify new substances marketed in quantities less than 10 kg per year (Austria, Denmark, Italy, Portugal, Spain, Sweden, UK, Norway);
- the obligation for previous and prospective notifiers to share data, in order to avoid duplicating testing on vertebrate animals (Austria, Belgium, Denmark, Germany, Greece, Italy, Spain);
- additional requirements with regard to PORD exemptions such as additional testing and the obligation to register (France, Netherlands, Portugal);

Furthermore, some Member States have additional legislation with regard to export requirements (Austria, Denmark, Germany), pre-manufacturing requirements (Netherlands) and the yearly monitoring of the market quantities of new, notified substances (Austria).

3.18.3 Overview of charges and sanctions

This paragraph gives an overview of the various national regulations with regard to charges for notifications and sanctions, as indicated per Member State in the previous paragraphs.

Charges for a notification

All Member States except Austria, Greece, Italy, the Netherlands and Sweden impose charges for a notification (in Greece, Italy, the Netherlands and Norway charges are being prepared). Table 3.1 shows that there are substantial differences in the charges per Member State.

Some Member States give a reduction if an adequate risk assessment is supplied by the notifier (Denmark, France, Portugal, Spain, UK). Ireland charges extra if a risk assessment is required but not provided.

Some Member States impose charges for PORD notifications as well (Denmark, Germany, Ireland, Netherlands, UK).

Table 3.1: legal charges for a notification (ECU)

	full notification			reduced notification	
	Annex VIIA	Annex VIII, level 1	Annex VIII, level 2	Annex VIIB	Annex VIIC
Austria	no charges	no charges	no charges	no charges	no charges
Belgium	4.000	> 4.000[1]	> 4.000[1]	2.000	500
Denmark	9.100	> 9.100[2]	> 9.100[2]	2.100	1.200
Finland	1.800	2.300	3.700	600	200
France[3/4]	5.000	6.700	6.700	1.700	800
Germany	5.200	6.100[5]	12.800[5]	3.100	1.300
Greece[6]	no charges	no charges	no charges	no charges	no charges
Ireland[7]	5.000	> 5.000[1]	> 5.000[1]	630	440
Italy[6]	no charges	no charges	no charges	no charges	no charges
Netherlands[8]	5.700	10.000[5]	9.700	3.950	2.500
Portugal[4]	7.700	12.900	16.600	1.800	1.300
Spain[4]	2.850	3.400	5.100	1.600	800
Sweden	no charges	no charges	no charges	no charges	no charges
UK[4]	8.000	7.600[9]	4.300[9]	1.550	1.240
Norway	no charges	no charges	no charges	no charges	no charges

1 there are additional charges for level 1/2 test packages
2 the charges for amounts > 10 tonnes are not yet fixed
3 there are additional charges for changing the level of a notification dossier
4 a rebate is given when a risk assessment is provided by the notifier
5 maximum amount (charge can be lower, depending on the amount of the substance)
6 a proposal for legal charges is being prepared
7 there is an extra charge if a risk assessment is required and not provided by the notifier
8 proposed charges, not yet legally implemented (charge minus restitution)
9 cumulative charges

Sanctions

Table 3.2 shows that there great differences in sanction possibilities per Member State. The fines for the most severe breaches (not notifying new (dangerous) substances) vary from 2.050 ECU (Ireland) to 76.000 ECU (France). These differences are inherent to differences in criminal law of Member States. However, harmonising sanctions is beyond the scope of the Directive.

Table 3.2: penalties for not complying with national legislation transposing Directive 67/548/EEC as amended by Directive 92/32/EEC

	imprisonment (max.)	financial penalty (ECU)
Austria	-	350 - 15.000 ECU
Belgium	5 years	75 - 2.500 ECU
Denmark	2 years	700 - 67.000 ECU
Finland[1]	2 years	
France	2 years	3.800 - 76.000 ECU
Germany	5 years	max. 52.000 ECU
Greece	-	330 -33.000 ECU
Ireland	-	1.900 ECU
Italy	6 months	2.550 - 15.300 ECU
Netherlands	6 years	46.750 ECU
Portugal	-	250 - 30.000 ECU
Spain	-	3.100 - 62.000 ECU
Sweden	1 year	17.600 ECU
UK	2 years	24.500 ECU
Norway[2]	2 years	

1 maximum imprisonment and/or financial penalty depends on the case (no cases yet)

2 there is no fixed maximum penalty (will be decided by court in each separate case)

4 The implementation: notifications and risk assessments

4.1 Introduction

The figures in this chapter are based on data on notifications and risk assessments, extracted from the New Chemicals Database of the Joint Research Centre, European Chemicals Bureau (ECB) in Ispra. Two remarks with regard to these data should be made:

- The time period is 1 November 1993 - 31 December 1996
- ECB is still receiving notifications that stem from 1996. The ECB data in this chapter include notifications received until 10 March 1997. Figures for 1996 should be regarded as provisional.

4.2 Notifications

4.2.1 Notifications per Member State

Results

- The total number of notifications in the time period November 1993 - December 1996 is 1.050, of which 582 are full notifications (according to Annex VII A, Annex VIII level 1 and 2) and 468 are reduced notifications (according to Annex VII B, VII C and VII D). See table 4.1, figures 4.1 and 4.2.
- These notifications refer to 755 new substances notified for the first time: 383 full notifications and 372 reduced notifications (table 4.2, figures 4.1 and 4.2).
- Most notifications took place in France, Germany, Netherlands, Sweden and United Kingdom. Germany and United Kingdom are 'lead countries' (figures 4.3 and 4.4).
- A comparison between the figures over November 1993 - December 1996 and the time period 1983-1993 of the 6th Amendment (figure 4.5) shows that the difference between the number of notifications and the number of new notified substances sharply decreases after 1993, indicating that the sole representative system (introduced in the 7th Amendment) works.
- The same figure shows a 'peak' of notifications in 1993, indicating that notifiers anticipated the 7th Amendment.
- The number of notifications over the period 1983-1993 in the United Kingdom and Germany were more or less equal. From 1993 to 1996, however, the total number of notifications in the United Kingdom was substantially higher than that in Germany. Again, this difference is probably caused by the sole representative system, enabling notifiers to choose any country within the EU to notify. The preference for the UK might be caused by the fact that German notification dossiers must be filled out in German.

Table 4.1: notifications per Member State per year[1]

	1993	1994	1995	1996	total
Austria	-	-	7	9	16
Belgium	2	16	12	22	52
Denmark	-	-	1	1	2
Finland	-	18	0	3	21
France	6	44	32	38	120
Germany	3	41	90	58	192
Greece	0	0	0	0	0
Ireland	0	6	16	30	52
Italy	10	13	6	17	46
Luxembourg	0	0	0	0	0
Netherlands	0	20	28	36	84
Portugal	3	3	2	0	8
Spain	17	5	4	10	36
Sweden	-	-	59	7	66
United Kingdom	32	95	116	112	355
total	**73**	**261**	**373**	**343**	**1050**

[1] the reference data is the date of notification to the Competent Authority

- = country was not a Member State at that time and therefore no ECB data available

Table 4.2: substances notified for the first time per Member State per year

	1993	1994	1995	1996	total
Austria	-	-	4	6	10
Belgium	2	8	10	20	40
Denmark	-	-	0	1	1
Finland	-	3	0	2	5
France	3	37	28	34	102
Germany	3	35	67	46	151
Greece	0	0	0	0	0
Ireland	0	4	11	21	36
Italy	5	11	5	13	34
Luxembourg	0	0	0	0	0
Netherlands	0	12	21	30	63
Portugal	0	0	0	0	0
Spain	1	1	3	6	11
Sweden	0	0	5	3	8
United Kingdom	26	70	102	96	294
total	**40**	**181**	**256**	**278**	**755**

- = country was not a Member State at that time and therefore no ECB data available

Figure 4.1: full notifications 1993-1996

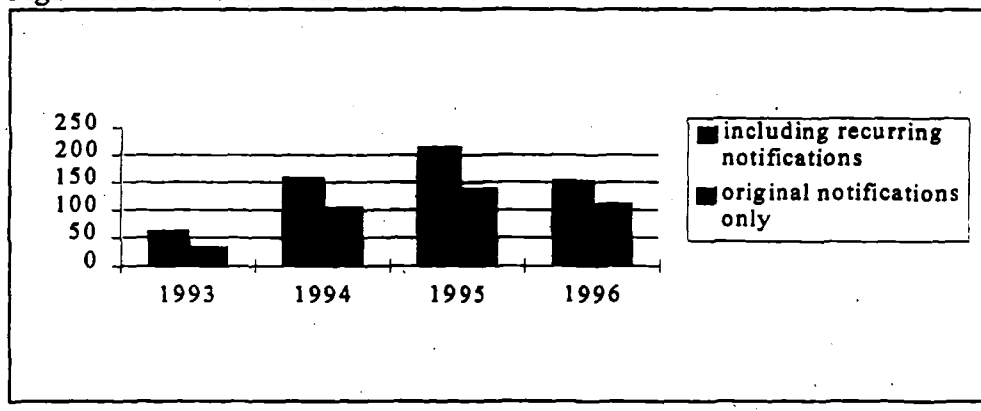


Figure 4.2: reduced notifications 1993-1996

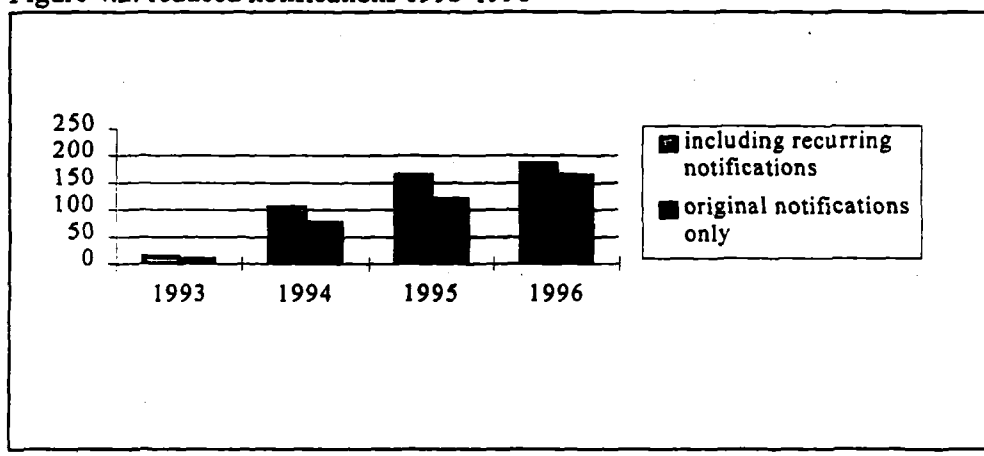


Figure 4.3: full and reduced notifications per Member State

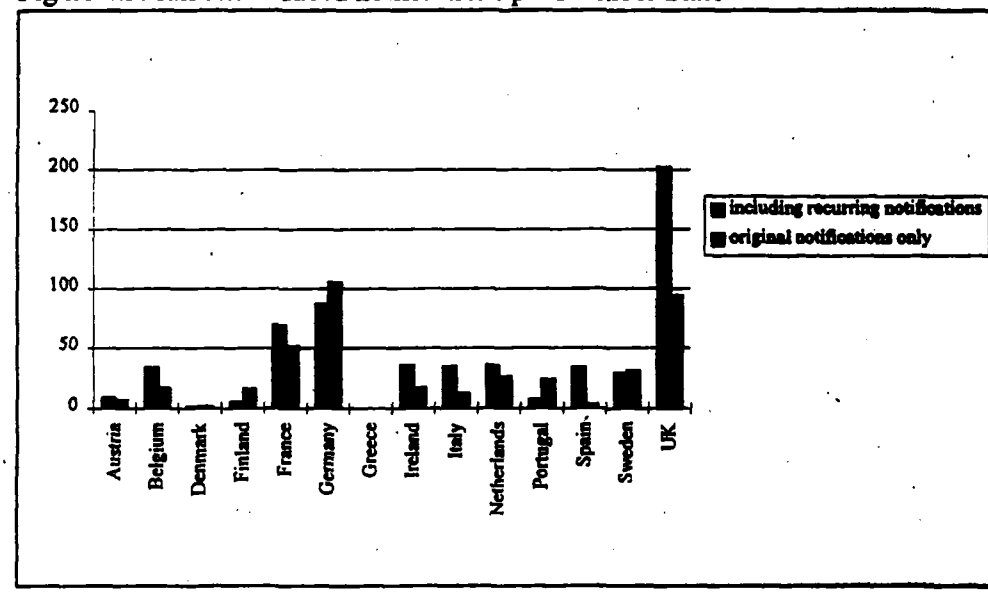


Figure 4.4: notifications per Member State

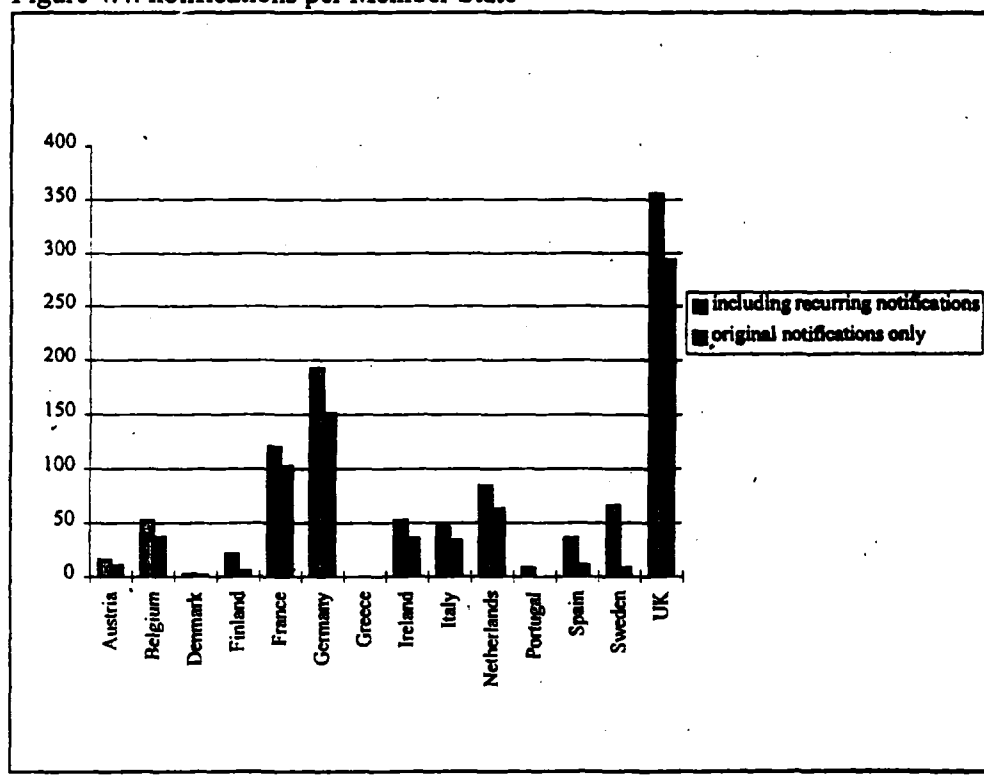
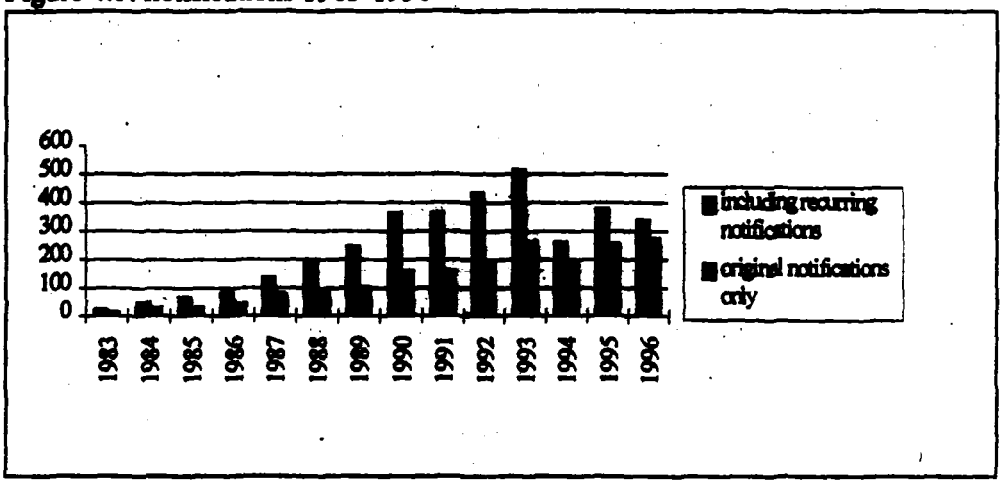


Figure 4.5: notifications 1983-1996



4.2.2 Notifications EU/non EU manufacturers

Results

- There are more notifications done by non EU manufacturers than by EU manufacturers (figure 4.6). The ratio is approximately 60% non European manufacturers (617 notifications) and 40% European manufacturers (423 notifications).
- The 617 notifications of non EU manufacturers refer to 423 new substances (against 423 notifications referring to 323 substances for the EU manufacturers). Probably, the sole representative system is not always used, resulting in more notifications (one per country of export) instead of only one notification. The difference between these figures was far more greater under the 6th Amendment (1.688 notifications referring to 562 new substances).
- Non EU manufacturers are mainly from Switzerland (205 notifications referring to 103 new substances), Japan (200 notifications referring to 132 substances) and the United States (176 notifications referring to 157 new substances).

Table 4.3: notifications from EU manufacturers against non EU manufacturers

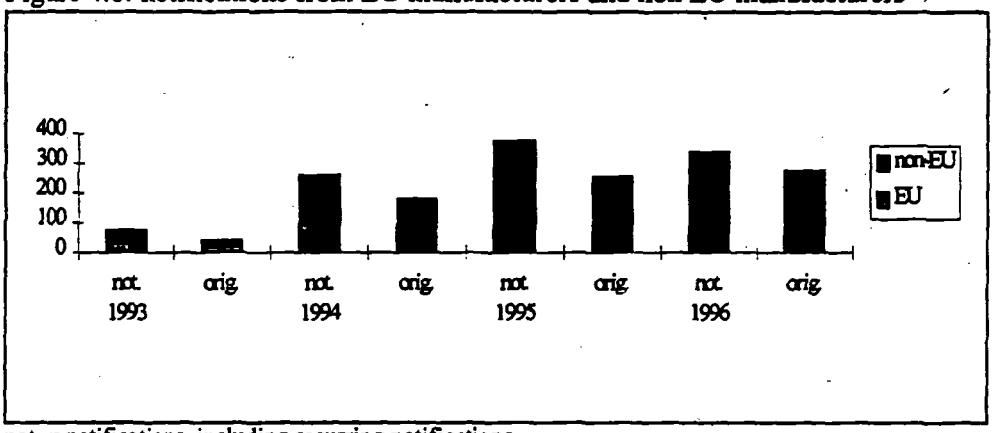
	1993	1994	1995	1996	total
EU manufacturer	33	94	156	140	423
Non EU manufacturer	40	164	217	196	617
EU manufacturer (%)	46%	36%	42%	42%	41%
Non EU manufacturer (%)	54%	64%	58%	58%	59%
total	73	258	373	336	1.040

- ECB is waiting to know the manufacturer's identity for 7 notifications, that is why the total of this table is 1.040 instead of 1.050
- Finish, Austrian and Swedish manufacturers have been considered as EU manufacturers for the complete time period

Table 4.4: substances notified for the first time from EU manufacturers against non EU manufacturers

	1993	1994	1995	1996	Total
EU manufacturer	23	72	120	108	323
Non EU manufacturer	17	107	133	166	423
EU manufacturer (%)	58%	40%	47%	39%	43%
Non EU manufacturer (%)	42%	60%	53%	61%	57%
total	**40**	**179**	**253**	**274**	**746**

Figure 4.6: notifications from EU manufacturers and non EU manufacturers



not. = notifications, including recurring notifications
orig. = original notifications only

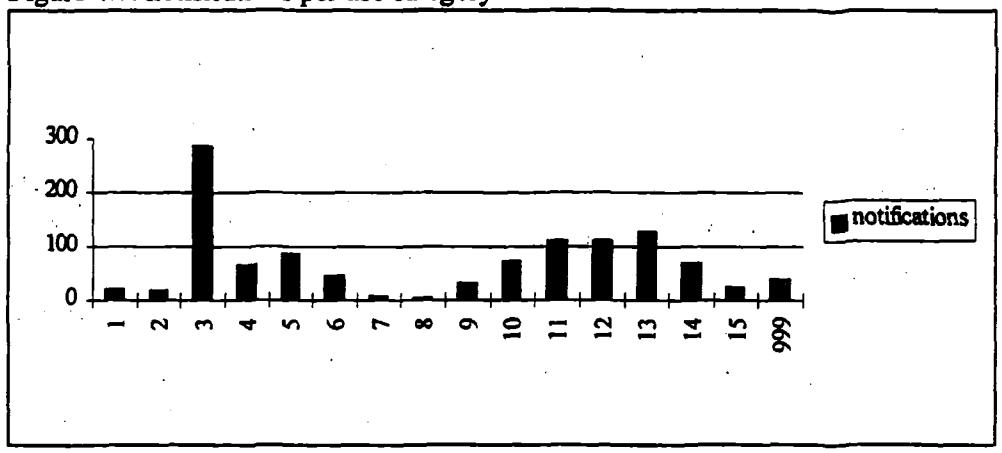
4.2.3 Notifications per use category and desired effect category

See appendix 3 for an explanation of use categories and desired effect categories.

Results

- The most important use categories are 03 (chemical industry: chemicals used in synthesis: 286 notifications), 11 (polymer industry: 112 notifications), 12 (pulp, paper and board industry: 110 notifications) and 13 (textile processing industry: 127 notifications). See figures 4.7 and 4.9.
- The most important desired effect categories are 10 (colouring agents: 256 notifications), 15 (cosmetics: 61 notifications), 33 (intermediates: 268 notifications), 42 (photochemicals: 69 notifications), 43 (process regulators: 83 notifications) and 45 (reprographic agents: 66 notifications).

Figure 4.7: notifications per use category



4.2.4 Notifications of dangerous substances

Results

- There are more notified substances classified as dangerous(521) than non classified (219). See table 4.5.
- Most of the classified substances are in the use categories with the largest number of notifications: 3, 5, 10, 11, 12 and 13. The percentage of classified substances per use category varies from 43% (paints, lacquers and varnishes industry) to 88% (chemical industry: chemicals used in synthesis). See figure 4.9.

Table 4.5: classified against non classified substances per year[1]

	1993	1994	1995	1996	total
classified	26	121	186	188	521
non classified	14	55	67	83	219
classified (%)	65%	69%	74%	69%	70%
non classified (%)	35%	31%	26%	31%	30%
total	**40**	**176**	**253**	**271**	**740**

[1] Not all dangerous substances are yet in Annex 1. These substances are only provisionally classified and labelled according to the first or final proposal of the Competent Authority.

Figure 4.8: classified against non classified substances per year

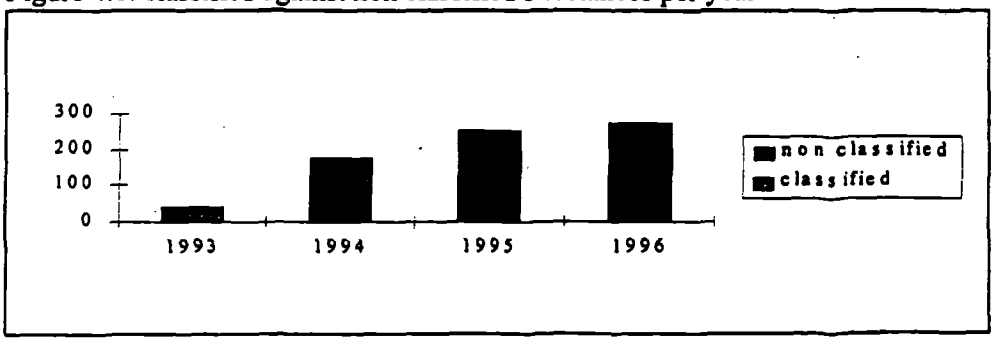
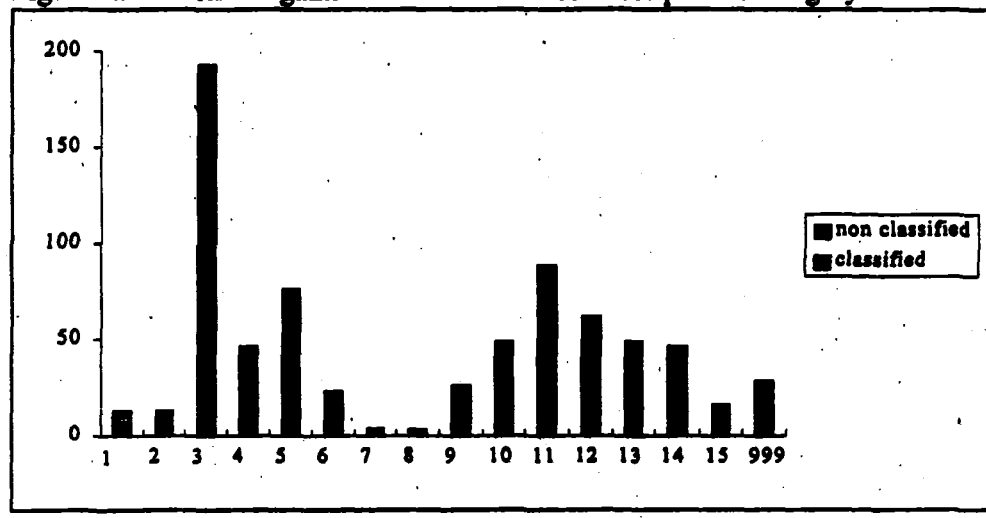


Figure 4.9: classified against non classified substances per use category



4.2.5 Notifications covered by sole representatives

Results

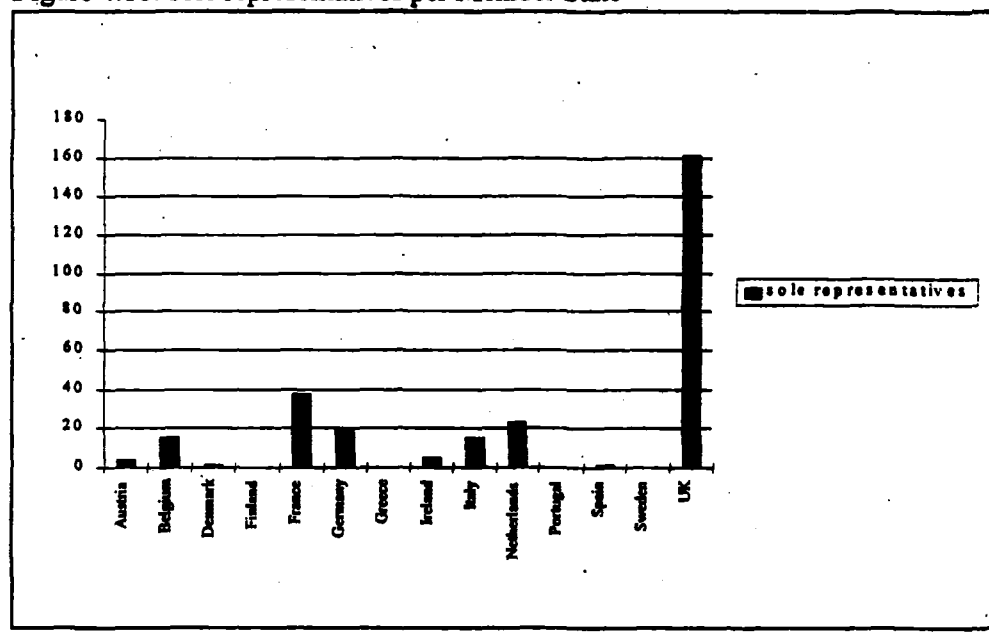
- There are 282 notifications covered by sole representatives.
- The number of notifications covered by sole representatives increases.
- The United Kingdom is by far the country with the most sole representative notifications: more than half of the notifications (57%) are done in this Member State.

Table 4.6: sole representatives per Member State per year

	1993	1994	1995	1996	total	total (%)
Austria	-	-	0	4	4	1%
Belgium	0	3	2	11	16	6%
Denmark	0	0	1	0	1	0%
Finland	-	0	0	0	0	0%
France	0	13	11	13	37	13%
Germany	0	2	13	4	19	7%
Greece	0	0	0	0	0	0%
Ireland	0	2	1	2	5	2%
Italy	1	3	5	6	15	6%
Netherlands	0	7	5	11	23	8%
Portugal	0	0	0	0	0	0%
Spain	0	0	0	1	1	0%
Sweden	-	-	0	0	0	0%
United Kingdom	4	36	54	67	161	57%
total	5	66	92	119	282	100%

- = country was not a Member State at that time and therefore no ECB data available

Figure 4.10: sole representatives per Member State



4.2.6 Polymer notifications

As explained in chapter 2, polymers are exempted from the notification procedure, with the exception of those polymers which contain in combined form 2% or more of any substance which is not on EINECS. The notifications of these polymers are registered separately by ECB. See table 4.7

Table 4.7 polymer notifications per Member State per year.

	1993	1994	1995	1996	total	% of total notifications
Austria	-	-	2	0	2	13%
Belgium	0	1	1	1	3	6%
Denmark	0	0	0	0	0	0%
Finland	-	2	0	0	2	9%
France	2	2	3	0	7	6%
Germany	1	1	2	1	5	3%
Greece	0	0	0	0	0	-
Ireland	0	1	0	0	1	2%
Italy	0	0	0	1	1	2%
Netherlands	0	2	0	3	5	6%
Portugal	0	0	0	0	0	0%
Spain	0	0	0	0	0	0%
Sweden	-	-	0	0	0	0%
United Kingdom	1	4	4	4	13	4%
total	**4**	**13**	**9**	**13**	**39**	**4%**

- = country was not a Member State at that time and therefore no ECB data are available

4.2.7 Circulation of notifications

Results

- The average time period between the date of a notification to the Competent Authority and the reception of the notification by ECB lies between 2 and 4 months (see table 4.8).

Table 4.8 months between notification to Competent Authority and reception of notification by ECB[1]

	0-2	3-4	5-6	7-8	9-10	11-12	>12
Austria		5	2	2			3
Austria (%)		41%	17%	17%			25%
Belgium	7	14	15	3	1		1
Belgium (%)	17%	35%	37%	7%	2%		2%
Denmark			2				
Denmark (%)			100%				
Finland		18	2				
Finland (%)		90%	10%				
France	1	22	29	13	7	10	5
France (%)	1%	25%	33%	15%	8%	12%	6%
Germany		6	30	27	30	35	39
Germany (%)		3%	18%	16%	18%	21%	24%
Greece							
Ireland	16	33					
Ireland (%)	33%	67%					
Italy	24	4	3				1
Italy (%)	75%	13%	9%				3%
Netherlands	3	24	7	2	8	4	14
Netherl. (%)	5%	39%	11%	3%	13%	6%	23%
Portugal		5	1				
Portugal (%)		83%	17%				
Spain	7	18	4				
Spain (%)	24%	62%	14%				
Sweden		14	2	31	16	1	1
Sweden (%)		22%	3%	47%	24%	2%	2%
UK	41	113	16				
UK (%)	24%	66%	10%				
total	**99**	**294**	**115**	**78**	**62**	**50**	**66**
total (%)	**13%**	**38%**	**15%**	**10%**	**8%**	**7%**	**9%**

[1] This table compares the 'date of notification' to the 'date of registration' in the ECB New Chemicals Database. When ECB receives an update, the date of registration of the original notification is overwritten by the date of registration of the update. For this reason, table 4.8 only takes *into account the notifications* for which ECB has not yet registered an update. This explains why the number of notifications in this table differ form the figures in table 4.1.

4.3 Risk assessments

Results

- Most of the 376 risk assessments are carried out by United Kingdom: 156, Germany: 105 and France: 62 (table 4.9 and figure 4.11).
- The majority of the risk assessments (197 or 52%) result in conclusion i (the substance is of no immediate concern), 79 (21%) result in conclusion ii (the substance is of concern and the Competent Authority shall decide whether further information is required), 69 (18%) result in conclusion iii (further information shall be requested immediately) and only 31 (8%) result in conclusion iv (immediate recommendations for risk reduction are necessary). There appear to be differences between Member States with regard to the number of risk assessments resulting in conclusion iv (see figure 4.12). This could indicate that the criteria to reach this conclusion differ per Member State.

Table 4.9: risk assessments per Member State per year

	1993	1994	1995	1996	total
Austria	-	-	0	2	2
Belgium[1]	0	0	0	6	6
Denmark	0	0	0	0	0
Finland	-	0	0	0	0
France	1	26	26	9	62
Germany	3	35	56	11	105
Greece	0	0	0	0	0
Ireland	0	0	0	3	3
Italy	0	1	0	0	1
Netherlands	0	9	13	10	32
Portugal	0	0	1	0	1
Spain	0	1	2	4	7
Sweden	-	-	1	0	1
United Kingdom	15	63	74	4	156
total	**19**	**135**	**173**	**49**	**376**

[1] the Belgian CA sent 6 risk assessment reports on paper in 1996, followed by Snif version at the beginning of 1997

Figure 4.11: risk assessments per Member State

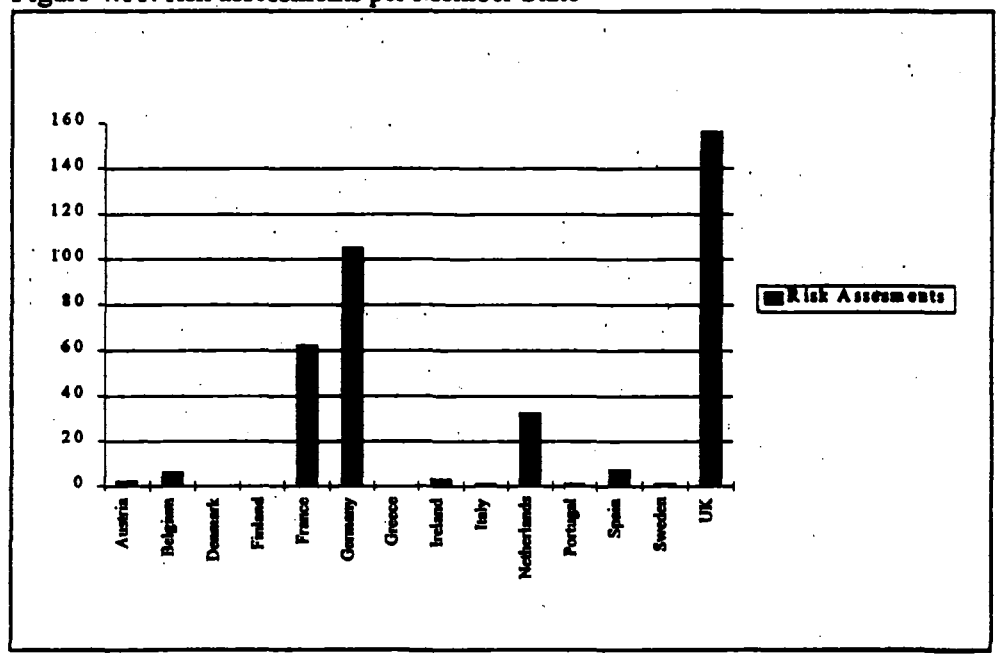
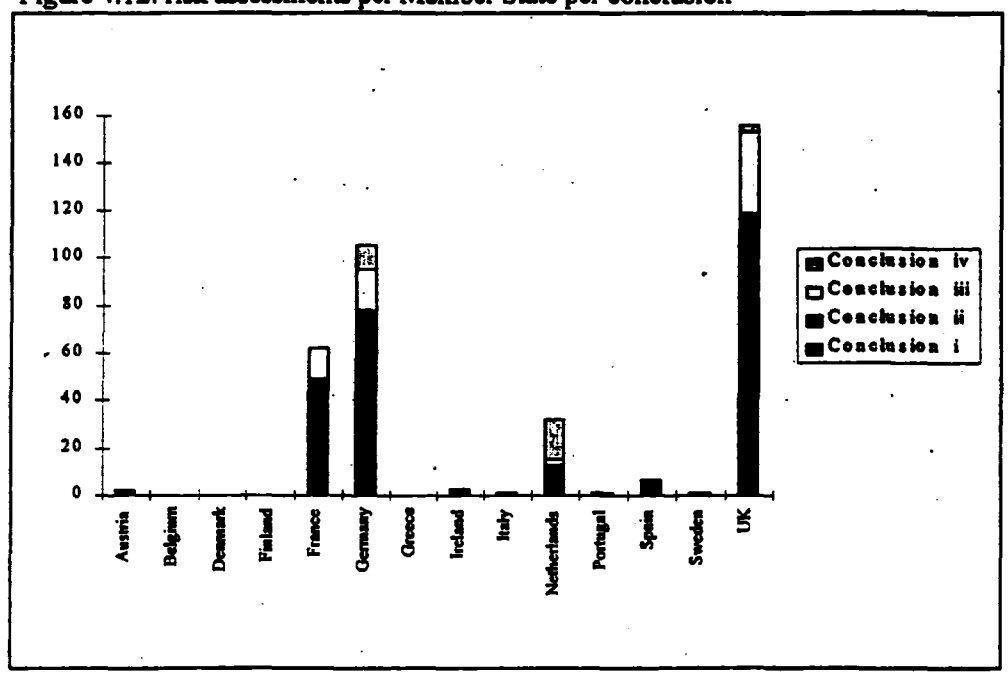


Figure 4.12: risk assessments per Member State per conclusion



5 The implementation: other aspects

5.1 Research and development exemptions

Results

- Under the 7th amendment there were 526 substances for which PORD (process orientated research and development) was actually carried out by companies (that is to say for which information was communicated to the European Commission). Table 5.1 shows that there is a sharp increase of PORD over the years (from 82 in 1994 to 246 in 1996).
- Table 5.1 shows that most of the PORD is carried out by companies in France (16%), Germany (19%) and UK (34%). There is a relatively high amount of PORD carried out in Ireland (9%).
- In 477 of the 526 cases (91%), the PORD carried out by companies leads to an actual PORD exemption approved by a Competent Authority. The number of actual exemptions is substantially higher than under the 6th amendment (477 cases over three years against 199 cases over 10 years). See table 5.2.
- Most of the actual PORD exemptions are in use categories 02 (chemical industry; basic chemicals), 03 (chemical industry; synthesis), 11 (polymer industry) and 33 (pharmaceutical industry). See table 5.3.
- Mark the differences between PORD exemptions and notifications per use category: although there is a small number of actual PORD exemptions in use categories 12 (pulp, paper and board industry) and 13 (textile processing industry) (see table 5.3), there are many notifications in these use categories (see figure 4.7).
- Most of the actual PORD exemptions are referring to larger quantities of substances (weight categories 100-1000 kg/year and > 1000 kg/year). See table 5.4.
- Only 98 of the 519 actual PORD exemptions (19%) result in a notification. Especially in Germany the percentage of notifications related to granted requests is low. It can be stated that approximately half of the actual notifications are full notifications (type VIIA). The majority of the reduced notifications concern type VIIB notifications. See table 5.5.
- 73 of the 518 actual PORD exemptions of which the weight category could be indicated are extended for a further year (14%). A relatively high percentage of extensions is occurring in the UK. Member States did not indicate the number of actual requests for an extension. See table 5.6.
- Practically all announcements of the use of substances for scientific research and development do occur in Austria (most of them refer to quantities less than 100 kg/year). See table 5.7. The great difference between the figures of Austria and the other Member States could be caused by the different ways the announcements for scientific research and development are registered in the various Member States.

Table 5.1: number of substances for which PORD was actually carried out (information communicated to the European Commission)

	total 6th am.	'93	'94	'95	'96	total 7th am.
Austria	39	-	-	3	3	6
Belgium	26	5	4	14	11	34
Denmark	un.	0	1	2	1	4
Finland	un.	-	1	0	4	5
France	33	0	12	22	49	83
Germany	39	0	8	49	45	102
Greece	0	0	0	0	1	1
Ireland	20	1	7	14	23	45
Italy	un.	0	8	5	9	22
Netherlands	32	0	10	9	7	26
Portugal	0	0	0	0	1	1
Spain	1	0	0	4	5	9
Sweden	1	-	-	6	3	9
United Kingdom	-	3	31	61	84	179
Norway	0	0	0	0	0	0
total	**un.**	**9**	**82**	**189**	**246**	**526**

- = not reported/ un.= unknown

Table 5.2: actual PORD exemptions

	total 6th am.	'93	'94	'95	'96	total 7th am.	PORD carried out	actual PORD exemp.
Austria	-	-	-	3	2	5	6	83%
Belgium	-	5	4	14	11	34	34	100%
Denmark	un.	0	0	2	0	2	4	50%
Finland	-	-	1	0	4	5	5	100%
France	33	0	12	22	49	83	83	100%
Germany	39	0	8	49	45	102	102	100%
Greece	0	0	0	0	0	0	1	0%
Ireland	20	1	7	14	21	43	45	96%
Italy	un.	0	8	5	9	22	22	100%
Netherlands	-	0	10	9	7	26	26	100%
Portugal	0	0	0	0	0	0	1	0%
Spain	1	0	0	4	5	9	9	100%
Sweden	0	-	-	6	3	9	9	100%
United Kingdom	100	3	27	51	56	137	179	77%
Norway	0	0	0	0	0	0	0	-
total	**193**	**9**	**77**	**179**	**212**	**477**	**526**	**91%**

- = not reported/ un.= unknown

Table 5.3: actual PORD exemptions per use category

	01	02	03	04	05	06	07	08	09	10	11	12	13	14	16	33	999	tot.
Austr											1					5		6
Belg		3	21		1				2	1			5	1				34
Finl										1	1	1				2		5
Fra	7	10	8		1	2			3		10					42		83
Ger	2		58					2	2	7	19	3		2	2		4	101
Ire																43		43
Italy			9							1	1	2			1	8		22
Neth			10	2		1		3		1	3			4	2			26
Spn		8	1															9
Swe						1			1							6	1	9
UK	7	4	13		2		3		2	6	1		3	1		89		131
total	**16**	**25**	**120**	**2**	**4**	**4**	**3**	**5**	**10**	**17**	**36**	**6**	**8**	**8**	**5**	**195**	**5**	**469**

- See appendix 3 for an explanation of the use categories
- Denmark and Austria could not specify the granted exemptions in use categories
- There were no requests for PORD exemptions in Greece, Norway and Portugal
- The remaining countries could not specify all the granted exemptions (this explains why the total differs from that of table 5.1)

Table 5.4: actual PORD exemptions per weight category[1]

	< 100 kg/year	100-1000 kg/year	> 1000 kg/year	total
Austria	0	3	2	5
Belgium	6	9	19	34
Denmark	0	0	2	2
Finland	0	0	5	5
France	4	46	33	83
Germany	12	54	36	102
Ireland	0	18	25	43
Italy	0	16	6	22
Netherlands	9	11	5	25
Spain	1	4	4	9
Sweden	0	8	1	9
United Kingdom	8	114	57	179
total	**40**	**283**	**195**	**518**

[1] Because Member States did not always indicate the quantity of a PORD exemption, the total in this table (518) is less than the total in table 5.2 (526).

Table 5.5: actual PORD exemptions resulting in a notification[1]

	VIIA	VIIB	VIIC	VIID	VIII lv 1	VIII lv 2	tota l	actual PORD ex.	notifi cation s
Austria	2	1					3	5	60%
Belgium	6						6	34	18%
Denmark	1						1	2	50%
Finland							0	5	0%
France	14	3	2				19	83	23%
Germany	6	3			1		10	102	10%
Ireland	11	5					16	43	37%
Italy	2	2					4	22	18%
Netherland s							11	26	42%
Spain	1						1	9	11%
Sweden		1					1	9	11%
UK							26	179	15%
total	**43**	**15**	**2**	**0**	**1**	**0**	**98**	**519**	**19%**

[1] Because Member States did not always indicate the type of notification, the total in this table (519) is less than the total in table 5.2 (526).

Table 5.6: actual PORD exemptions extended for one year

	< 100 kg/year	100-1000 kg/year	> 1000 kg/year	total	actual PORD ex.	of which extended
Austria	0	0	0	0	5	0%
Belgium	0	0	1	1	34	3%
Denmark	0	0	0	0	2	0%
Finland	0	0	0	0	5	0%
France	0	2	2	4	83	5%
Germany	0	2	3	5	102	5%
Ireland	0	1	0	1	43	2%
Italy	0	2	1	3	22	14%
Netherlands	1	2	0	3	25	12%
Spain	-	-	1	1	9	11%
Sweden	-	1	-	1	9	11%
United Kingdom	-	-	-	54	179	30%
total	**1**	**10**	**8**	**73**	**518**	**14%**

- = not reported

Table 5.7: announcements scientific research and development use

	announcements
Austria	367
Belgium	1
Denmark	1
Finland	0
France	0
Germany	0
Greece	0
Ireland	4
Netherlands	0
Italy	0
Norway	0
Portugal	0
Spain	1
Sweden	0
United Kingdom	-
total	374

- = not reported

5.2 The procedures in practice

5.2.1 The notification procedure

Time period between receiving a notification dossier and marketing the substance

All Member States were asked how they interpret the time period between receiving a notification dossier from a notifier and placing the substance on the market. The following options were defined:

a) time period of 60 days starts immediately after receiving a dossier of information from a notifier
b) time period of 60 days starts immediately after receiving a dossier of information but "the clock stops" when a notifier is asked to provide the Competent Authority with missing information in case of an incomplete notification dossier
c) time period of 60 days starts when the notifier dossier is accepted as being complete
d) otherwise, namely:

The answers make it clear that most of the Member States (10) let the time period of 60 days start when the notification dossier is accepted as being complete (option c). Austria, Belgium, Denmark, Germany and Sweden indicated that the clock stops when a notification dossier appears to be incomplete (option b), but when the dossier is completed, the 60 days period "starts again". In France and the Netherlands, the 60 days period starts immediately after receiving a dossier of information from a notifier (option a).

Time period between the date a substance may legally be marketed and sending the notification dossier to ECB

Furthermore, with reference to the date on which a notified substance may be legally placed on the market, Member States were asked to indicate the number of substances (per year) for which the summary of the notification dossier is usually sent to ECB:

a) more than 20 days *before* that reference date
b) less than 20 days *before* that reference date
c) less than 20 days *after* that reference date
d) more than 20 days *after* that reference date

Mark that the 20 days classification is arbitrary and does not refer to any obligation, stated in Directive 67/548/EEC as amended by Directive 92/32/EEC.

The answers show that most of the Member States send their notification dossiers to ECB less than 20 days after a notified substance may legally be placed on the market (option c). The results are summarised in table 5.8.

Table 5.8: circulation of notifications

	time period: options
Austria	c
Belgium	d
Denmark	c
Finland	d*
France	d
Germany	d
Italy	b
Ireland	b
Netherlands	c
Portugal	c
Spain	c
Sweden	b
United Kingdom	b

* Most new substances were already legally on the Finnish market when Directive 67/548/EEC as amended by Directive 92/32/EEC was transposed into national legislation, but they were regarded as new substances according to the Directive and therefore had to be notified

Circulation of risk assessments reports

Member States were asked to indicate as well if, in case of a notification, the report of a risk assessment is circulated after the summary of the notification dossier:

a) risk assessment reports circulated to ECB together with notification dossier
b) risk assessment reports circulated to ECB after the notification dossier, in .... months
c) no experience with circulation of risk assessment reports

Risk assessment reports appear to be circulated to ECB together with the notification dossier (6 Member States) or after the notification dossier (4 Member States). The time period between both documents varies from 2 to 20 months. See table 5.9.

Table 5.9: circulation of risk assessment reports

	time period: options	months (if option b)
Austria	b	2
Belgium	b	20
Denmark	c	
Finland	c	
France	a	
Germany	a	
Ireland	a	
Italy	a	
Netherlands	b	4
Portugal	a	
Spain	a	
Sweden	c	
United Kingdom	b	5

Germany indicated that most of the risk assessment reports were sent to ECB together with the notification dossier. 12 of the 100 reports were sent later (with an average of 5 months)

5.2.2 Classification of dangerous substances

In case of notifications of dangerous substances, Member States were asked to indicate in how many cases the proposal for classification and labelling of the substance put forward by the notifier did differ from the one recommended by the Competent Authority.

In answering this question, most Member States indicated that agreement on a proposal for classification and labelling is always reached with a notifier in case of a notification of a dangerous substance. For this reason, statistics on first proposals of notifiers are often unknown. A number of Member States can therefore only indicate a percentage over the whole period of the 7th Amendment. See table 5.10.

Table 5.10: proposal for classification and labelling of notifier and Competent Authority differ.

	'93	'94	'95	'96	total
Austria	0	0	0	3	3
Belgium	2	13	8	11	34
Denmark	0	0	0	0	0
Finland	0	0	0	0	0
France					un.
Germany					un.
Greece	0	0	0	0	0
Ireland	2	0	6	10	18
Italy					36%
Netherlands					> 50%
Portugal	0	0	0	0	0
Spain	12	2	4	7	25
Sweden					25%
United Kingdom					10%
Norway	0	0	0	1	1

un. = unknown.

5.3 Other issues

Data sharing

Member States were asked if data sharing between a prospective and a previous notifier was obligatory in their national legislation and if so, in how many cases they were obliged to share data. If data sharing is not obligatory, Member States were asked how many 'bonafide' inquiries for data sharing (actually referring to the same substance) they received.

Table 5.11 shows that data sharing is obligatory in seven Member States (Austria, Belgium, Denmark, Germany, Greece, Italy and Spain). In the other Member States, prospective and previous notifiers are not obliged to share data but they are 'strongly encouraged' by the Competent Authorities to do this. Only a few cases of actual data sharing (as the result of the inquiries, listed in table 5.11) are reported: 1 in Belgium, 1 in France, 7 in Germany, 1 in Italy and 1 in Spain (all in 1996). Presumably there must be a number of cases of actual data sharing in the United Kingdom (taking into account the large number of inquiries), but these are not registered.

Table 5.11: data sharing

	data sharing obligatory?	inquiries for data sharing				
		1993	1994	1995	1996	total
Austria	yes					-
Belgium[1]	yes					1
Denmark	yes	0	0	0	0	0
Finland	no	0	0	0	0	0
France	no	0	0	6	15	21
Germany[2]	yes	0	2	2	3	7
Greece	yes	n.r.	n.r.	n.r.	n.r.	n.r.
Ireland	no	0	0	0	1	1
Italy	yes	n.r.	n.r.	n.r.	n.r.	n.r.
Netherlands[3]	no	0	2	2	2	6
Portugal	no	0	0	0	1	1
Spain	yes	n.r.	n.r.	n.r.	n.r.	2
Sweden	no	0	0	3	4	7
United Kingdom	no	-	72	132	132	336
Norway	no	0	0	0	0	0
total		0	76	145	158	382

- = not reported / n.r. = not registered

1 data sharing will be obligatory as soon as Directive 67/548/EEC as amended by Directive 92/32/EEC is transposed into national legislation

2 in Germany, data sharing is obligatory only in case of avoidance of duplicating testing on vertebrate animals

3 figures for the Netherlands are estimated

Requests for non confidential information

Member States were asked how many requests for the release of non-confidential information (as defined in article 19 of the Directive) they received from the public and from non-governmental organisations under the 6th and 7th Amendment.
None of the Member States received requests from the public and from non governmental organisations. Some Member States reported that they published non confidential information. In France, some 'professional' requests were received under the 6th Amendment from professional users of the substance.

Guidance to trade and industry

Member States were asked in what way they informed trade and industry on the requirements of the Directive.
All Member States indicated that they inform trade and industry. This is done via publication of the legislation in trade press, more detailed publications, guidance reports, information bulletins/newsletters, brochures, meetings, conferences, seminars, etc.
Trade organisations are often used as intermediate, but companies are informed directly as well.

6 Issues arising out of the implementation

All Member States indicated that, in general, their national legislation is sufficient to fully enforce all aspects of Directive 67/548/EEC as amended by Directive 92/32/EEC. Only Belgium indicated problems caused by time consuming legal procedures.
However, several issues of concern were identified. The remarks per issue are summarised in this chapter.

Data sharing
Several Member States mention that not all notifiers are aware of data sharing possibilities, or use this possibility.
This could be caused by:
- lack of efficiency of the regulation (France, Germany);
- lack of knowledge on the part of notifiers (Netherlands, France);
- confidentiality and competition aspects (mostly pharmaceutical industry).

It is indicated by some Member States that data sharing could be improved, thus resulting in less animal testing, by making data sharing obligatory in all Member States (it is now obligatory in seven Member States) and by informing prospective and previous notifiers.
Furthermore, the request from prospective notifiers as to whether a substance has already been notified, cannot always be answered because it is difficult to keep the ECB database up-to-date.
According to the Netherlands, sharing data is only effective at level 1 and 2 of additional testing (Annex VIII notifications), and not at base level testing (because the rationale behind data sharing is reduction of animal testing by preventing unnecessary studies). The Netherlands therefore suggest to drop the requirement for data sharing at base level. This should require an Amendment of the Directive.
The UK is concerned that proper compliance with the notification aspects of the Directive involves a considerable amount of animal testing. UK also notes that the development of entries for Annex I results in new tests and is concerned that one result of the 7th Amendment may be to increase the number of tests.

PORD exemptions
There is a steady increase in the amount of requests for PORD exemptions (the figures in chapter 5 of this report confirm this).
Several Member States are sympathetic to the view expressed by the industry that the one year exemption period is too short (even with the possibility of extension to a second year), especially for pharmaceutical and agrochemical industries (Ireland) and for the production of polymers (Belgium), because the current limits hinder innovation (which may take many years).
It is suggested to extend the maximum allowable exemption period of two years (for defined use categories).
Germany, the Netherlands, Ireland, Greece and Finland stress the importance of further harmonisation of the PORD procedures. Despite the fact that there are EC guidelines, there still is a different approach in Member States. Therefore, it is suggested to adopt a totally harmonised PORD procedure.
The Netherlands have several suggestions for harmonisation under the present legislation. A practical solution under the present legislation is to harmonise the

exemption of scientific research and development and to establish a harmonised set of information, a harmonised questionnaire for PORD and a communication procedure between the Member States regarding PORD in multiple countries. According to the Netherlands a better solution might be a review of the requirements of the Directive, e.g. a reconsideration of the maximum allowable exemption period of 2 years, a legally harmonised PORD-procedure, an extension of the scientific research and development exemption, etcetera.

Confidentiality of data

Regarding confidentiality of data, none of the Member States indicated major issues of concern. Germany, the Netherlands and Ireland stress that the majority of notifiers insists on confidentiality of data. According to Ireland, information currently allowed to be regarded as confidential should therefore remain so. However, explanation to the notifiers of the reasons behind the confidentiality claims leads to a decrease in the number of items claimed to be confidential. Some companies are very concerned about the non-confidentiality status of the identity of the notifier and manufacturer, mostly companies linked to non-EU manufacturers in Japan. Therefore, these companies use a representative in the EU to notify the substance. Thus, the identity of the original importer remains unknown. The Netherlands do not welcome this development.
In addition, Ireland stresses that the channels currently used for transmission of information between Member States and ECB should continue to be used, to ensure security.

Risk assessments

Five Member States (Belgium, France, Ireland, Italy, Netherlands) stress that risk assessment is too time consuming and that their resources are often too limited. Austria and Ireland suggest to limit the amount of substances for which risk assessments must be carried out:

- Annex VIIB and VIIC substances;
- site limited intermediates;
- not dangerous substances;
- substances that will not be marketed within 1-3 years;
- quantities less than 10 tonnes;
- certain use categories.

Even though the principles of risk assessment are established in a separate Directive (Directive 93/67/EEC on risk assessment of new substances), supported by a detailed *Technical Guidance Document*, the risk assessments in different Member States differ in report format and interpretation. It is considered a problem that risk assessments are not dealt with in the same way in all Member States. Due to lack of work capacity, differences are not discussed, which hinders development of an European harmonised working method. A common way of approach should be discussed and agreed upon.

Notification procedure (circulation of notification dossiers)
Six Member States (Belgium, Denmark, Germany, Ireland, Netherlands, Spain) indicate that the current procedures for circulation of notifications are not very efficient and too time consuming.
The suggestions for improvement of circulation efficiency are:
- electronic transmission of the summary notification dossiers and risk assessments between Competent Authorities and ECB (ensuring confidentiality);
- immediate circulation of summary information on new notifications and identification of double notifications;
- ECB should circulate notifications within a fixed period , for example 30 days.

The Netherlands point out the prerequisites for such a centralised electronic database:
- only ECB should be authorised to make changes in the database;
- the Member States have 'read only' authorisation;
- the Member States receive a monthly overview of new and modified dossiers in the database.

Classification of dangerous substances / updating of Annex I
According to article 29 of Directive 67/548/EEC as amended by Directive 92/32/EEC, a proposal for the updating of Annex I (see chapter 2, paragraph 2.2 for an explanation) is forwarded by the European Commission to the meeting on adaptation to technical progress (ATP meeting), in which all Member States are represented. The meeting has to agree on the proposal before Annex I can be actually updated.
Practically all Member States stress that the procedure for updating Annex I is too slow, and therefore also very ineffective and costly.
Several suggestions are made to accelerate the process;
- more meetings of the committee and the development of a clear programme by which the number of "waiting" substances can be diminished;
- a quicker actualisation of Annex I by using the characteristics and classification of the notification.

Germany suggests improvement of the structure of Annex I, so that it enables Chemical Abstracts Service (CAS) and/or EINECS cross reference.
Ireland mentions additional issues concerning the classification of substances that need further discussion between the EC and the Member States:
- a procedure to include the substances registered in the International Uniform Chemical Information Database (IUCLID) in Annex I;
- would it be possible to update Annex I without the need for yearly ATP meetings, which have to be legally transposed by the Member States;
- the legally binding nature of the existing Annex I entry (new information on the substance may not be reflected on the label);
- the internal market versus unilateral action by individual Member States in respect of classification.

The UK urges the EC to carefully review ECB and Member State management of the process of considerations of entries for Annex I .
Furthermore, the UK has been advised by the SMEs that the multilingual single volume version of Annex I, which is currently published in the Official Journal, is of major benefit to them. Since it has been decided to publish monolingual versions in the future, the SMEs suggest publishing the multilingual version on a non-formal basis to supplement the formal monolingual texts. In this respect, the

Commission envisages to compile Annex I and other relevant information in all EU official languages on a CD-ROM for the future.
According to Germany, Competent Authority meetings on EU level are compulsory to decide on proper classification of substances from which risk assessments of Member States differ significantly.

Notification of intermediates
Directive 67/548/EEC as amended by Directive 92/32/EEC does not foresee any special notification requirements for intermediates and therefore the general requirements for new substances are applicable. However, a discussion on the possibility of reduced test requirements for intermediates with limited exposure has recently started. Two Member States (Netherlands, Sweden) state that, if special notification requirements for intermediates were introduced within the framework of the Directive, this would mean an additional burden of administrative work. Several Member States (Belgium, France, Germany, Ireland, Italy, Netherlands, Sweden) mention the problems that industry has with the requirement to notify intermediates. It is difficult to motivate full testing when a substance is consumed completely during the production process. A reduced test package ("Annex VIIE") for intermediates is suggested by Austria, France, Germany, Ireland, Italy, Netherlands and Sweden. Ireland suggests to consider test packages according to Annex VIIB for amounts < 10 tonnes and Annex VIIA for amounts > 10 tonnes.

Packaging and labelling
Greece reports the need for a more harmonised implementation of the requirements of the Directive with regard to packaging and labelling. EU common projects like NONS and SENSE are a good exercise towards a more harmonised approach. There are question marks with regard to the use of the category "dangerous for the environment" (Austria, Netherlands). According to Austria, the label 'dangerous for the environment' is only sufficiently defined for aquatic toxicity. Criteria for terrestric toxicity should be developed.
Germany points out that the guidance with regard to S-sentences (Annex IV) is difficult to handle. Germany suggests to improve guidance by incorporating a clear scheme for the choice of S-sentences.
The Netherlands stress the need for clear instructions and information to industry. Moreover, this Member State proposes a European wide evaluation on the effectiveness of labelling and to reconsider an improvement of the system of classification and labelling.

Safety data sheets
No particular views with regard to safety data sheets were expressed by the Member States, other than that the level of compliance with the EU requirements on safety data sheets is extremely poor: it is difficult to persuade importers, suppliers and manufacturers to improve, particularly if they are located in another Member State (Ireland, Greece).

Guidance to trade and industry
To improve guidance, several suggestions were given:
- guidance should be done at EU level (Ireland);
- although the existing publications are adequate, more guidance will be helpful, such as a non-confidential version of the Manual of Decisions, and a regular newsletter (France, Ireland);

- more guidance on the regulation of new substances for some sectors of the trade business (Denmark).

Belgium, Germany and Netherlands mention that some individual guidance to industry is given by them and found to be helpful. Besides it was mentioned that industry and trade organisations develop their own guidance as well.

Co-operation and information exchange within Member States

There is a close co-operation between the Competent Authority and the controlling authorities within Member States, certainly if these two authorities are one and the same or are within the same organisation (which is the case in a number of Member States: see chapter 2, paragraph 2.2).
Information exchange takes place meetings held on a regular basis (several times a year). If there is no formal structure for co-operation, there are intensive contacts (personal, phone, fax, e-mail).
Industry is usually informed via meetings with trade organisations. Besides there are frequent direct contacts with individual companies.

Co-operation and information exchange between Member States

The Commission established an effective working procedure by means of regular meetings on political and technical issues.
The Netherlands and Ireland suggest continuation, because this working method increases collaboration and mutual responsibility among the Competent Authorities, and furthermore contributes to the harmonisation of the chemical management on new substances in all details.
Ireland is unconvinced that the splitting of meetings into 'scientific and technical' and 'main CA' has been for the best.
All Member States except Greece and Spain indicate that they have direct contacts with other Member States (not via ECB or Competent Authority meetings) on a regular basis, although these contacts are not "institutionalised". The main issues discussed are: notifications (need to notify), questions with regard to the interpretation of the Directive, views on political issues related to the Directive, requests for PORD exemptions, requests for data sharing, requests for information on importers under a sole representative status, change of lead country for a notification (file leader), advice on (eco)toxilogical or physicochemical data.

Toll manufacturing

According to the Netherlands, the European industry would prefer also a 'sole-representative' procedure for toll-manufactured substances because of:

- available adequate technical and toxicological knowledge of the leading company;
- the need for adequate planning of the start of production and delivery of the intermediate by other companies;
- the need for flexibility with respect to the production location;
- safeguards for a continuing process of production and delivery;
- reduced administrative burden: one location with all relevant technical and toxicological knowledge and a co-ordinated approach in the discussion with the Competent Authorities.

The United Kingdom states that industry have consistently argued that the definition of "placing on the market" in the Directive distorts the market for toll manufacturing services.

Multiple notifications
Related to the subject of toll-manufacturing is the present practice that each manufacturer in the EU must notify the substance. The Netherlands already experienced that the lead company in the Netherlands co-ordinated the process of multiple notifications, implying the submission of nearly identical notification dossiers at nearly the same date in different Member States by different notifiers. The Directive states that an accepted notification automatically means acceptance by all Member States. With respect to multiple notifications of a toll-manufactured substance, the acceptance in one Member State immediately overrules the ongoing procedure of compliance in the other Member States. This is an unpleasant consequence of the Directive, because the evaluation of compliance will depend on the applied flexibility.

Sole representative facility
According to the Netherlands, the introduction of the sole representative (SR) - facility for non-EU manufactured substances (see chapter 2, paragraph 2.1 for an explanation) was very effective in reducing the administrative burden, but also created an unequal competitiveness for EU-manufactures lacking the SR-facility. For example, the present SR-facility enables the notifier to cover multiple non-EU manufactures for the same substance.
However, a missing element in the Directive is the lack of restriction to the potential sole representative with the consequence that many notifications are submitted by test houses unaware of the working conditions in EU-companies using the substance or by legal representatives without any chemical knowledge and any self responsibility for a sound chemical management. It is preferred to restrict the SR-facility to importers only.

EINECS and ELINCS
Austria and Germany stress the need for a quicker update procedure for ELINCS. This procedure should provide a way to delete substances no longer on the market from ELINCS. Finland stresses the need for clear EINECS rules, since interpretation of EINECS rules is difficult.

Notification of substances
According to Ireland, the origin of a new substance may be hard to track, thus finding out if the substance has already been notified in a Member State or by a sole representative is difficult, especially for small companies.
In Austria, each notifier is obliged to inform the authorities on the amount of substances placed on the market each year. This procedure is found to be very effective and incorporation in a future Amendment of the Directive could be considered.

Resources
According to Ireland, the Directive and its operation in a harmonised way at EU level should be regarded as a significant success.
Several Member States stress that the resources required by Member States and the Commission to effectively address the body of chemical legislation in the EU must be recognised: because due to limited resources, enforcement of the requirements of the Directive is difficult.

7 The enforcement of the Directive

According to article 32 of Directive 67/548/EEC as amended by Directive 92/32/EEC, the three yearly report is a composite report on the *implementation* of the Directive in the various Member States. However, the enforcement of the Directive is an important issue as well.
For that reason, a summary of the results of the NONS project (*Notification of New Substances*), a European enforcement project on the Directive, is given in this chapter.

In practice, there appeared to be substantial differences in the way the Directive is enforced in the various Member States. Therefore, a European enforcement project on the notification of new substances was carried out, starting in January 1995 and ending in June 1996. The main activity of the project was co-ordinated company inspection, concentrating on dyestuffs, since this is an innovative group of substances with the possibility of having inherently hazardous properties and the potential for high risk of exposure to both workers and the environment, in an industrially very competitive arena. Participating countries were Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy (observer) Netherlands, Norway, Portugal, Spain, Sweden and the UK.

Outcome
Nearly 4.000 substances were checked at 96 companies within the framework of the NONS project. Of the total number of substances checked, 305 i.e. 7,9% could not be identified (163 substances) or were found to be new (142 substances). The inspections revealed that 37% of these new substances were not notified and thus illegally marketed.
The inspections made clear that it takes a lot of time (for companies as well as controlling authorities) to determine the chemical constitution of substances, despite the obligation of companies to provide the controlling authorities with the necessary data.
Of the 66 samples taken within the framework of the NONS project, 29 are analysed. Of these 29, 9 (31%) do not conform with the information provided by the company. More than half of the samples taken (37) are not analysed yet, mainly because the costs of analysis are high and because a total lack of knowledge with regard to the chemical identity makes it very difficult to make valid analyses of samples.
It was found out that 45 of the 96 companies (47%) were thought by the controlling authorities not to be working according to the Directive (marketing not notified substances, no or insufficient labelling and safety data sheets, no or insufficient registration and internal control). Follow up actions after the company inspections consisted of sending hundreds of letters to the inspected companies, mainly concerning requests to provide information on the chemical identity of checked substances, requests to improve labelling and safety data sheets and offering advice.
As a result of the follow up actions, the number of substances that could not be identified, decreased from 644 (directly after the company inspection) to 163.
In 14 cases, the import or production of new, not notified dyes (11) or not identified dyes (3) was prohibited.

Conclusions

The *goals* of the NONS project have been achieved: the project has resulted in a *better awareness* and *better compliance* of the Directive by companies.
For all participating countries, the NONS project has been beneficial as an incentive to initiate an inspection programme for notifiable substances in general and dyestuffs in particular. All participating countries have therefore obtained *more experience* with the enforcement of the Directive. Furthermore, there is *more coherence* in the enforcement approach of the countries that participated in the NONS project, since all company inspections were carried out according to a working method based on the guidance manual, developed by the EU Control Measures Subgroup of the Competent Authorities for the implementation of Directive 67/548/EEC and its Amendments.
The company inspections carried out within the framework of the NONS project made it possible to identify common problems with the enforcement of the Directive and to develop solutions for them, thus leading to *more efficient* and *more effective* enforcement activities.
The project has resulted in a sharing of knowledge and enforcement experience, thus improving the level of information on the Directive.
Last but not least, the international co-operation between the enforcement authorities has resulted in a European enforcement network, stimulating a *better information exchange* between the participating countries.

Recommendations of participating Inspectorates

To companies

The NONS project disclosed that the identification of chemical substances is often difficult and time consuming, because companies are not able to provide the necessary information. Companies should label their substances adequately and have an adequate recording system, enabling them to identify what they supply, to comply with the notification requirements.

To the European Commission and Competent Authorities

It would assist the enforcement authorities if all companies were compelled to provide the data necessary to identify chemical substances. National legislation in Member States could, if necessary, be amended to allow legal steps to be taken against companies who do not provide such data if this power is not already in place. Consideration could be given to clarifying the need for such a requirement in national legislation in future amendments to relevant EU Directives.

Follow up: the SENSE project

In October 1996, a second enforcement project on new substances was started: the SENSE project (*Solid Enforcement of Substances in Europe*), with again practically all Member States participating. The project, that will end in October 1997, focuses again on the Directive, to ensure that gained knowledge and experience do not 'fade away'. The participating Inspectorates have the opinion that the SENSE project should result in an "ongoing" European enforcement structure, supported by the European Commission, based on co-operation and co-ordination. Ideas on how to do this should be elaborated during the SENSE project.

8 Summary and conclusions

Introduction
Directive 67/548/EEC as amended by Directive 92/32/EEC lays down the respective duties of the Commission and the Member States with regard to the implementation of the procedures for the notification of new substances in the European Union.
Article 32 of the Directive requires the EU Member States and the Commission to prepare a report on the implementation of the Directive every three years.
This report is the first three yearly report. It is based upon two main sources of information: statistical information on notifications and risk assessments, gathered from the European Commission (ECB: European Chemicals Bureau) and data gathered from the Member States. A questionnaire, asking for qualitative as well as quantitative aspects of the national implementation of the Directive, was filled in by all Member States (except Luxembourg, were there is relatively little experience with the Directive) and Norway (involved on the basis of the European Economic Area (EEA) agreement).

Notifications and risk assessments
Figures on notifications and risk assessments provided by the European Commission (ECB) over the last three years (given in chapter 4 of this report) show that the system belonging to the Directive is being followed. During the time period November 1993 - December 1996, the Commission registered 1.047 notifications (referring to 752 substances) and 370 risk assessments.
Two essential new elements introduced by the 7th Amendment appear to have an important impact:
- The distinction between full and reduced notifications (resulting in 55% full notifications and 45% reduced notifications over the last three years);
- The sole representative system (see chapter 2, paragraph 2.1 for explanation), resulting in a sharp decrease in the difference between the number of notifications and the number of notified substances. This is clearly illustrated by a comparison with the figures over the time period 1983-1993 (6th Amendment), when the number of notifications was generally more than twice the number of notified substances. The sole representative system also leads to a concentration of notifications in the UK: 57% of the notifications were covered by sole representatives in this Member State.

Other conclusions that can be drawn from the data of the Commission (ECB) are:
- There are more notifications done by non EU manufacturers than by EU manufacturers. These figures do not support the criticism of chemical industry that the Directive is imposing too many restrictions on EU manufacturers compared to manufacturers in other continents (USA, Japan).
- The distinction between use categories and desired effect categories (as used in the New Chemicals Database: see appendix 4 for an explanation), makes clear that there is, as under the 6th Amendment (time period 1983-1993), a concentration of notifications in the chemical industry, polymers industry, pulp, paper and board industry and textile processing industry. Related to that, the most important desired effect categories are colouring agents, cosmetics, intermediates, photochemicals, process regulators and reprographic agents.

- The number of notifications of substances increases, whereas the ratio between classified (as dangerous) and non classified substances remains more or less the same (70% classified substances, 30% non classified substances).
- The number of polymer notifications is very low (39 of 1.047 notifications : 3,7%).
- More than half (53%) of the 370 risk assessments that were carried out under the Directive lead to the conclusion that the assessed substance is of no immediate concern and need not be considered again until further information is available (conclusion i; see chapter 4, paragraph 4.3 for a full explanation).

PORD exemptions

There is a steady increase in the amount of substances for which PORD (process orientated research and development) was actually carried out by companies, in most cases (90%) leading to actual PORD exemptions accepted by the Competent Authorities (mainly in chemical industry, polymer industry and pharmaceutical industry). The number of actual exemptions is substantially higher than under the 6th amendment (475 cases over three years against 199 cases over 10 years). Most of the exemptions refer to larger quantities of substances (weight categories 100-1000 kg/year and >1000 kg/year).

The procedures in practice

Conclusions that can be drawn from the Commission (ECB) data and from the data provided by the Member States, are:

- The average time period between the date of notification to the Competent Authority and the reception of the notification dossier by the Commission (ECB) is between 2 and 4 months.
- Most Member States let the time period between receiving a notification dossier from a notifier and placing the substance on the market (as defined in article 10 of the Directive) start when the notification dossier is accepted as being complete. This gives Competent Authorities enough time to judge the complete dossier.
- Most Member States (9) send their notification dossiers to the Commission (ECB) *after* the notified substance may legally be placed on the market. This implies that a new, notified substance can be marketed without the Commission (ECB) being able to register and to inform the other Member States.
- The delay in sending the notification dossiers to the Commission (ECB) is probably often caused by time consuming risk assessments. Some Member States (4) send in their risk assessment reports *after* the notification dossier.
- In case of notifications of dangerous substances, agreement on a proposal for classification and labelling is often reached with a notifier *before* sending the notification dossier to the Commission (ECB).

Issues arising out of the implementation

Most of the Member States have the opinion that the 7th Amendment to Directive 67/548/EEC (Directive 92/32/EEC) is a clear improvement over the 6th Amendment (Directive 79/831/EEC). Elements of improvement mentioned are:

- a clearer definition of substances;
- the introduction of risk assessments, as a further step towards the reduction of risks of new substances for men and the environment;
- the sole representative system (reducing the administrative burden);
- harmonisation with regard to substances marketed in small amounts (introduction of reduced notifications).

However, several issues of concern were identified by Member States. They are extensively described in chapter 6. The most important issues, mentioned by a number of Member States are:

- Data sharing could be improved, thus resulting in less animal testing, by making data sharing obligatory in all Member States and by informing prospective and previous notifiers.
- The one year period for PORD exemptions is felt to be too short (even with the possibility of extension to a second year), especially for pharmaceutical and agrochemical industries and for the production of polymers. Moreover, the PORD procedures should be further harmonised, to prevent a different approach in Member States.
- Risk assessments are too time consuming and require an increase in staffing levels. Moreover, the risk assessments in the different Member States differ in report format and interpretation. A common approach is needed.
- The current procedures for circulation of notifications are not very efficient and too time consuming.
- The procedure for updating Annex I is too slow.
- Member States indicate that industry has problems with the requirement to notify intermediates. It is difficult to motivate full testing when a substance is consumed completely during the production process.

Suggestions of Member States for improvement of the Directive

The response to the questionnaire has resulted in a number of suggestions for improvement of the Directive by the Member States. The ones that were suggested by several Member States are listed in this paragraph.

Several Member States feel that consideration could be given to certain Directive requirements that are already practice in a number of Member States:

- the obligation to notify substances marketed in quantities less than 10 kg per year;
- the obligation for previous and prospective notifiers to share data, in order to avoid duplicating testing on vertebrate animals;
- a requirement for legal charges for notifications;
- the obligation to inform the authorities each year on the marketed quantities of new, notified substances.

In addition, Member States suggest that the Directive could clarify the need for an information requirement for companies (companies should provide the data necessary to identify chemical substances) in national legislation.
They also feel that possibilities for improvement of the procedure for notifications and risk assessments could be investigated, such as:

- electronic transmission of the summary notification dossiers and risk assessments between Member States and the Commission (ECB), by establishing a central electronic database with 'read only' authorisation of the Member States;
- a more regular updating of Annex I, perhaps without the need for more ATP meetings;
- a more regular update of ELINCS;

Finally, several Member States suggest that the following amendments to the Directive could be considered:

- the maximum allowable period of two years for PORD exemptions could be extended for defined use categories;
- limit the substances for which a risk assessment has to be carried out;
- a reduced test package for intermediates could be considered;
- restrict the sole representative facility to importer only, to prevent notifications by companies without any chemical knowledge.

In view of the Member States' suggestions, the Commission will continue to strengthen the co-ordination of the implementation of the Directive within the Member States. The Commission will enhance the effective exchange of information between the Member States and between the Member States and the Commission in order to consolidate a harmonised system of notification in the European Union.

Three yearly report on the implementation of Directive 67/548/EEC as amended by Directive 92/32/EEC

Appendices

1. List of Competent Authorities
2. Questionnaire
3. Description of use categories and desired effect categories

Appendix 1
List of Competent Authorities

LISTE DES AUTORITES COMPETENTES
LIST OF COMPETENT AUTHORITIES

ETAT MEMBRE/MEMBER STATE	**AUSTRIA**
AUTORITE COMPETENTE COMPETENT AUTHORITY	BUNDESMINISTERIUM FÜR UMWELT JUGEND UND FAMILIE Chemikalienanmeldestelle Spittelauer Laende 5 A-1090 WIEN **Dr. H. WITZANI**
TELEPHONE: FAX: E-MAIL:	43-1-313 04 663 43-1-313 04 655 witzani@ubavie.gv.at
ETAT MEMBRE/MEMBER STATE	**BELGIQUE/BELGIE**
AUTORITE COMPETENTE	MINISTERE DES AFFAIRES SOCIALES, DE LA SANTE PUBLIQUE ET DE L'ENVIRONNEMENT / MINISTERIE VAN SOCIALE ZAKEN, VOLKSGEZONDHEID EN LEEFMILIEU Commission des Produits Dangereux / Commissie Gevaarlijke Producten Cité Administrative de l'Etat / Rijksadministratief Centrum Quartier Vésale / Vesaliusgebouw B-1010 BRUXELLES / BRUSSEL **Dr. DE CONINCK / Ms E. BOEL**
TELEPHONE FAX E-MAIL:	32-2-210 48 32 (E. Boel) 32-2-210 47 04 g.jacobs@iph.fgov.be els.boel@health.fgov.be

ETAT MEMBRE/MEMBER STATE	**DANEMARK**
AUTORITE COMPETENTE COMPETENT AUTHORITY	MILJOEMINISTERIET MILJOESTYRELSEN 29, Strandgade DK-1401 KØBENHAVN K **Ms L. SEEDORFF**
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TELEX	31 209 MILJOE DK
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E-MAIL	lo@mst.dk

ETAT MEMBRE/MEMBER STATE	**DEUTSCHLAND**
I. AUTORITE COMPETENTE COMPETENT AUTHORITY	BUNDESMINISTERIUM FÜR UMWELT, NATURSCHUTZ & REAKTORSICHERHEIT Bernkasteler Str. 8 D-53175 BONN **Dr. U. SCHLOTTMANN** Referat IG II 3
TELEPHONE	49-228-305 27 40
TELEX	88 57 90 BMU D
FAX	49-228-305 35 24
E-MAIL:	ig232002@wp-gate.bmu.de (BBU Hildebrand)
II. AUTORITE COMPETENTE COMPETENT AUTHORITY	BUNDESANSTALT FÜR ARBEITSSCHUTZ Anmeldestelle Chemikaliengesetz Friedrich-Henkel Weg 1-25 D-44149 DORTMUND **Dr. R. ARNDT**
TELEPHONE	49-231/907 12 79
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E-MAIL	amst@baua.do.shuttle.de

ETAT MEMBRE/MEMBER STATE	ELLAS/GREECE
AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTRY OF FINANCE State General Chemical Laboratory Division of Dangerous Substances and Preparations A. Tsocha Street, 16 EL-ATHENS 115 21 **Ms A. TSATSOU-DRITSA**
TELEPHONE	30-1-642 82 11/19
TELEX	21 83 11 GCSL GR
FAX	30-1-646 51 23

ETAT MEMBRE/MEMBER STATE	ESPAÑA/SPAIN
I. AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERIO DE SANIDAD Y CONSUMO Pº Prado, 18/20 E-28071 MADRID **Dr. F. VARGAS MARCOS**
TELEPHONE	34-91-596 20 84 / 34-91-596 20 85
TELEX	279 28 UNISE E
FAX	34-91-596 44 09
E-MAIL	fvargas@msc.es
II. AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERIO DE MEDIO AMBIENTE Direccion General de Calidad y Evaluacion Ambiental Plaza de San Juan de la Cruz s/n E-28071 - MADRID **Ms. A. FRESNO RUIZ**
TELEPHONE	34-91-597 6423
FAX	34-91-597 58 16
E-MAIL	ana.fresno@sgeaas.mma.es

ETAT MEMBRE/MEMBER STATE	**FINLAND**
AUTORITE COMPETENTE COMPETENT AUTHORITY	THE NATIONAL PRODUCT CONTROL AGENCY FOR WELFARE & HEALTH Chemicals Department P.O. Box 210 FIN-00531 HELSINKI **Ms K. RUUTH-RAUTALAHTI** **Ms A. EKMAN**
TELEPHONE	358-9 3967 2771 (Ms Ekman) 358-9 3967 2770 (Ms Ruuth-Rautalahti)
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ETAT MEMBRE/MEMBER STATE	**FRANCE**
I. AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERE DE L'ENVIRONNEMENT Direction de la Prévention des Pollutions et des Risques Sous-direction des produits et des déchets Bureau des substances et préparations chimiques 20, avenue de Ségur F-75007 PARIS 07 SP **Ms L. MUSSET**
TELEPHONE	33-1-42 19 20 21 / 33-1-42 19 15 85 (direct)
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II. AUTORITE COMPETENTE COMPETENT AUTHORITY	INSTITUT NATIONAL DE RECHERCHE ET DE SECURITE Service Contrôle des Produits 30, rue Olivier Noyer F-75014 PARIS **Ms J. CHERON**
TELEPHONE	33-1-40 44 30 57 (direct) / 33-1-40 44 30 00
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ETAT MEMBRE/MEMBER STATE	**IRELAND**
AUTORITE COMPETENTE COMPETENT AUTHORITY	HEALTH AND SAFETY AUTHORITY Hazardous Substances Assessment Unit Temple Court Hogan Place IRL-DUBLIN 2 **Dr. I. PRATT/** **Ms R. Mc ENEANY**
TELEPHONE	353-1-614 71 09 (Dr. Pratt) 353-1-614 70 60 (Ms Mc Eneany)
TELEX	917 92 HSAU EI
FAX	353-1-614 70 21 (Dr. Pratt) 353-1-614 70 20 (Ms Mc Eneany)
E-MAIL	iona@hsa.ie roisin@hsa.ie

ETAT MEMBRE/MEMBER STATE	**ITALIA**
I. AUTORITE COMPETENTE COMPETENT AUTHORITY	ISTITUTO SUPERIORE DI SANITA' Laboratorio di Tossicologia Applicata Viale Regina Elena, 299 I-00161 ROMA **Dr R. BINETTI**
TELEPHONE	39-06-49902593
TELEX	62 04 57 ISSTOA
FAX	39-06-49387170
E-MAIL:	binetti@iss.it
II. AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERO DELLA SANITA' - DIPARTIMENTO PREVENZIONE Via della Sierra Nevada, 60 I-00144 ROMA **Mr G. BATTAGLINO**
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ETAT MEMBRE/MEMBER STATE	**LUXEMBOURG**
AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERE DE L'ENVIRONNEMENT 18, Montée de la Pétrusse L-2327 LUXEMBOURG **Mr H. HAINE**
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E-MAIL:	henri.haine@mev.etat.lu

ETAT MEMBRE/MEMBER STATE	**THE NETHERLANDS**
I. AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERIE VAN VOLKSHUISVESTING, RUIMTELIJKE ORDENING EN MILIEUBEHEER Bureau Milieugevaarlijke Stoffen (DGMH/BWS) Directoraat-Generaal voor de Milieuhygiëne Rijnstraat 8 Postbus 30945 NL-2500 GX DEN HAAG **Dr. A. W. VAN DER WIELEN/Dr. K. A. GIJSBERTSEN**
TELEPHONE	31-70-339 48 96
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E-MAIL:	vanderwielen@dgvs.dgm.minvrom.nl
II. AUTORITE COMPETENTE COMPETENT AUTHORITY	MINISTERIE VAN SOCIALE ZAKEN EN WERKGELEGENHEID Directie Arbeidsomstandigheden Afdeling Arbeidsmilieu Anna van Hannoverstraat 4 P.O. Box 90801 NL-2509 LV DEN HAAG **Dr. P.C. NOORDAM**
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ETAT MEMBRE/MEMBER STATE	**PORTUGAL**
AUTORITE COMPETENTE COMPETENT AUTHORITY	DIRECÇÃO-GERAL DO AMBIENTE DRQ - Divisão de Riscos Industriais e Compostos Químicos Rua da Murgueira – Zambujal Apartado 7585 - Alfragide P-2720 AMADORA **Mr R. M. F. SIMÕES**
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ETAT MEMBRE/MEMBER STATE	**SWEDEN**
AUTORITE COMPETENTE COMPETENT AUTHORITY	NATIONAL CHEMICALS INSPECTORATE P.O. Box 1384 (Postal Address) Sundbybergsvägen 9 (Visiting Address) S-171 27 SOLNA **Mr Bengt MELSÄTER**
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ETAT MEMBRE/MEMBER STATE	**UNITED KINGDOM**
I. AUTORITE COMPETENTE COMPETENT AUTHORITY	HEALTH AND SAFETY EXECUTIVE Data Appraisal Unit Magdalen House Stanley Precinct Bootle, Merseyside UK-L20 3QZ **Dr. R. TURNER**
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II. AUTORITE COMPETENTE COMPETENT AUTHORITY	**HEALTH AND SAFETY EXECUTIVE** **Health Policy Division C2** **Room 629** **Rose Court** **2 Southwark Bridge** **UK-LONDON SE1 9HS** **Mr R. WARNER**
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III. AUTORITE COMPETENTE COMPETENT AUTHORITY	THE ENVIRONMENT AGENCY Ecotoxicology and Hazardous Substances National Centre Chemicals Assessment Unit Isis House Howbery Park Wallingford UK-OXON OX10 8BD **Dr. S. ROBERTSON**
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IV. AUTORITE COMPETENTE COMPETENT AUTHORITY	DEPARTMENT OF ENVIRONMENT, TRANSPORT AND THE REGIONS Floor 3/E4, Ashdown House 123 Victoria Street UK-LONDON SW1E 6DE **Mr R. TREGUNNO**
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EFTA	**NORWAY**
AUTORITE COMPETENTE COMPETENT AUTHORITY	NORWEGIAN POLLUTION CONTROL AUTHORITY P.O. Box 8100 Dep N-0032 OSLO **Mr Rolf BIÖRNSTAD**
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Appendix 2
Questionnaire

78.

Questionnaire
EU Directive 92/32/EEC

European Commission
DG XI

January 1997

Contents

1 Description of the administrative system in member states

When answering the questions in this section, you can make use of the enclosed information on the administrative system in your member state (if available), gathered within the framework of the European inspection project 'Notification of New Substances' (NONS)
If using this information, please confirm if it is accurate.

1.1 Which authority is appointed as 'competent authority' in your legislation (article 16) and how is the work of this authority organised (e.g. duties, division of responsibilities)?

1.2 Are there are other authorities or institutes involved in "running the system" (scientific institutes, advisory committees, etc.)?

1.3 Which authorities are in charge of the enforcement (control actions) of Directive 92/32/EEC?

Could you please provide us with relevant information, additional to the answers in this section, such as:
- *organisation schemes*
- *relevant articles, pressletters, brochures, etc.*
- *relevant legislation*

2 Implementation of Directive 92/32/EEC

A. Legal aspects

2.1 How is Directive 92/32/EEC implemented in your national legislation?
Please include in your answer a short description of the implementation of Directive 93/67/EEC (laying down the principles of risk assessment) and Directive 93\105\EEC (laying down the information requirements on polymers).

2.2 When was Directive 92/32/EEC incorporated in national legislation and when did the relevant legislation came into force?

2.3 The European Commission (i.e. through the Committee for adaption to technical progress) regularly updates the technical and scientific aspects of the Directive.
How are updates of Annex I (list of dangerous chemicals) and Annex V (methods for the determination of physico-chemical

properties, toxicity and ecotoxicity) implemented in national legislation?

2.4 Are there elements in your national legislation in addition to what is specifically required by the Directive? For example with regard to research and development exemptions (article 13), requirements on substances marketed in quantities less than 10 kg per year, data sharing (article 15), any other relevant issues.

2.5 Dy you impose any legal charges for a notification (if so: how much do you charge)?;

2.6 What penalties can be imposed on those that do not comply with your national legislation implementing Directive 92/32/EEC?

B. Classification of dangerous substances

2.7 In case of notification of a dangerous substance, in how many cases (per year, time period November 1993 - December 1996) did the proposal for classification and labelling of the substance put forward by the notifier differ from the one recommended by the competent authority?

C. Research and development exemptions

2.8 How many requests for *process-orientated research and development* (PORD) exemptions have been received under the 7th amendment (per year, time period November 1993 - December 1996).
Whilst the exemptions for research and development under the 6th amendment were different from the 7th amendment, could you please give the number of requests for the "equivalent" of PORD exemptions under the 6th amendment, if available?

2.9 How many of the requests for PORD exemptions, mentioned under 2.8, were granted under the 7th amendment (per year, time period November 1993 - December 1996). Please distinguish between use categories (e.g. pharmaceutical intermediates) and ranges of quantities:
- less than 100 kg per year;
- between 100 and 1.000 kg per year;
- more than 1.000 kg per year.

Could you please also give the number of granted requests for the "equivalent" of PORD exemptions under the 6th amendment, if available?

2.10 How many of the exemptions granted, mentioned under 2.9, actually resulted in a notification? Please distinguish between use categories and level of notification (Annex VII.A, VII.B, VII.C, VII.D, VIII level 1 and 2).
Could you please also give the number of the "equivalent" of PORD exemptions resulting in a notification under the 6th amendment, if available?

2.11 How many PORD exemptions were extended up to a further year (maximum two years in total) under the 7th amendment (per year, time period November 1993 - December 1996). Please distinguish between use categories/ranges of quantities, as in 2.9.

2.12 How many announcements of the use of substances for *scientific research and development* purposes (not exceeding 100 kg) were received under the 7th amendment (per year, time period November 1993 - December 1996). Please distinguish between use categories (e.g. pharmaceutical intermediates).
Could you please also give the number of announcements under the 6th amendment, if available?

D. Circulation of notifications

2.13 Could you indicate how you interpret the time period between receiving a notification dossier from a notifier and placing the substance on the market (article 10 of the Directive)?
Options are:

a. Time period of 60 days starts immediately after receiving a dossier of information from a notifier;
b. Time period of 60 days starts immediately after receiving a dossier of information from a notifier but "the clock stops" when a notifier is asked to provide your competent authority with missing information in case of an incomplete notification dossier;
c. Time period of 60 days starts when the notification dossier is accepted as being complete;
d. Otherwise, namely: ..

2.14 With reference to the date on which a notified substance may first be legally placed on the market (according to your national legislation), please indicate the number of substances (per year, time period November 1993 - December 1996) for which the summary of the notification dossier is sent to ECB:

a. more than 20 days *before* that reference date;
b. less than 20 days *before* that reference date;
c. less than 20 days *after* that reference date;
d. more than 20 days *after* that reference date.

2.15 For how many of the notified substances, mentioned under 2.14, was the report of the risk assessment circulated to ECB *after* the summary of the notification dossier?

2.16 If the summary of the notification dossier and the report of the risk assessment are circulated to ECB separately, could you indicate the average number of days between sending both documents?

E. Data sharing

2.17 Is data sharing obligatory in your national legislation?

2.18 If data sharing is not obligatory, how many "bonafide" inquiries for data sharing (actually referring to the same substance, previously notified) did you receive (per year, time period November 1993 - December 1996).
How many of these inquiries resulted in the prospective and the previous notifier sharing data (per year, time period November 1993 - December 1996).

2.19 If data sharing is obligatory, in how many cases were a prospective and a previous notifier obliged to share data (per year, time period November 1993 - December 1996).

F. Requests for non-confidential information

2.20 How many requests for the release of non-confidential information (as defined in article 19 of the Directive) did you receive from the public and from non-governmental organisations under the 7th amendment (per year, time period November 1993 - December 1996).
Could you please also give the number of requests under the 6th amendment, if available?

G. Guidance to trade and industry

2.21 In what way are trade and industry in your country informed on the requirements of Directive 92/32/EEC (please enclose relevant brochures, leaflets, information letters, etc.)

3 Cooperation and information exchange

3.1 How in your country is the cooperation and information exchange organised between parts of the competent authority, controlling authorities, other involved authorities/institutes, customs and trade organisations/individual companies?

3.2 Do you have direct contacts with other member states? If so, please give an indication of the frequency of such contacts and the issues you discuss.

4 Issues arising out of the implementation of Directive 92/32/EEC

4.1 In general: do you think that your national legislation is sufficient to fully enforce all aspects of Directive 92/32/EEC? If not, could you identify the main problems and indicate the solutions you are envisaging?

4.2 We would like to know your view with regard to a number of specific issues which have all been identified as being issues of concern. Please formulate your answers in terms of problems and suggested solutions as much as possible.
The list below is meant as a checklist: feel free to skip items if you have no specific thoughts on these or to add items if necessary:

- data sharing;
- research and development exemptions;
- confidentiality of data;
- risk assessments;
- notification procedure (circulation of notification dossiers);
- classification of dangerous substances/updating of Annex I;
- notification of intermediates;
- packaging and labelling;
- safety data sheets;
- guidance to trade and industry;
- cooperation with other member states;
- any other relevant issues.

4.3 We finally would like to know if you have any other general thoughts or comments on the operation of Directive 92/32/EEC.

Appendix 3

Description of use categories and desired effect categories

Description of use categories

1 Agricultural industry
e.g. Plant protection products; fertilisers.

2 Chemical industry: basic chemicals
e.g. Solvents; pH-regulating agents (acids, alkalis).

3 Chemical industry: chemicals used in synthesis
e.g. Intermediates (including monomers); process regulators.

4 Electrical/electronic engineering industry
e.g. Electrolytes; semiconductors.
Not: galvanics; electroplating agents.

5 Personal/domestic
e.g. Consumer products such as detergents (including additives); cosmetics; agricultural pesticides for domestic use.

6 Public domain
e.g. Professional products used in public areas as non-agricultural pesticides, cleaning agents, products used in offices such as correction fluids, printing inks.

7 Leather processing industry
e.g. Dyestuffs; tanning auxiliaries.

8 Metal extraction industry, refining and processing industry
e.g. Heat transferring agents.

9 Mineral oil and fuel industry
e.g. Gasoline; motor oil; gear oil; hydraulic fluid; colouring agents; fuel additives; antiknock agents; waste oil detoxification agents.

10 Photographic industry
e.g. Antifogging agents; sensitisers.

11 Polymers industry
e.g. Stabilisers; softeners; antistatic agents; dyestuffs.

12 Pulp, paper and board industry
e.g. Dyestuffs; toners.

13 Textile processing industry
e.g. Dyestuffs; flame retardants.

14 Paints, lacquers and varnishes industry
e.g. Solvents; viscosity adjusters; dyestuffs; pigments.

15/0 Others
NOTE: The industrial category number 15 is no longer used for new substances. For new substances industrial category "Others" is now numbered 0 (Zero).

Description of desired effect categories

1 Absorbents and adsorbents

Materials used to absorb or adsorb gases or liquids: filter material/media; molecular sieves; silica gel etc..

2 Adhesives, binding agents

Materials which are applied to two surfaces causing them to adhere: dispersion-based adhesives, hotmelt, resins for polymer-based hardening adhesives, solvent based adhesives.

3 Aerosol propellants

Compressed or liquefied gases within which substances are dissolved or suspended and expelled from a container upon discharge of the internal pressure through expansion of the gas.

4 Anti-condensation agents

Substances used to avoid condensation on surfaces and in the atmosphere: anti-dim agents, condensation removers.

5 Anti-freezing agents

Substances used to prevent and remove ice formation: antifreeze liquids, de-icing agents.

6 Anti-set-off and anti-adhesive agents

Substances used to prevent set-off and adhesion: spraying powder and anti-set-off additives for printing; oils and waxes for laths and shuttering; casting slip etc..

7 Anti-static agents

Substances used to prevent or reduce the tendency to accumulate electrostatic charges: anti-static additives; substances for surface treatment against static electricity.

8 Bleaching agents

Substances used to whiten or decolourise materials.

Not : cosmetics; photographic bleaches; optical brighteners.

9 Cleaning/washing agents and additives

Substances used to remove dirt or impurities from surfaces.

Sub-categories : detergents; soaps; dry cleaning solvents; optical brighteners in detergents.

10 Colouring agents

Substances used to impart their colour to other materials.

Sub-categories : dyestuffs; pigments (including toners); colour forming agents; fluorescent brighteners (but see below re detergents).

Not : cosmetics; food colours; photo-chemicals; optical brighteners used exclusively in detergents; reprographic agents.

11 Complexing agents
Substances used to combine with other substances (mainly metal ions) to form complexes.

12 Conductive agents
Materials used to conduct electrical current.

Sub-categories : electrolytes; electrode materials.

13 Construction materials additives
Substances used in building materials and constructional articles: wall construction materials; road surface materials, ceramic, metal, plastic and wooden construction materials.

14 Corrosion inhibitors
Substances used to prevent corrosion: corrosion inhibiting additives; rust preventives

15 Cosmetics
Substances used as components of cosmetic and toiletry formulations.

16 Dust binding agents
Substances used to control finely divided solid particles of powdered or ground materials to reduce their discharge into the air.

17 Electroplating agents
Substances used as a source for a layer of metal deposited on another surface; or that aid such a deposition.

18 Explosives
Substances or mixtures that are characterised by chemical stability but that may be made to undergo chemical change, rapidly producing a large quantity of energy and gas accompanied by bursting or expansion.

Sub-categories : blasting agents; detonators; incendiaries.

19 Fertilisers
Substances used to supply chemical elements needed for plant nutrition.

20 Fillers
Relatively inert, and normally non-fibrous, finely divided substances added to elastomers, plastics, paints, ceramics etc., usually to extend volume which may improve desired properties such as whiteness, lubricity, density or tensile strength.

21 Fixing agents
Substances used to interact with a dye on fibres to improve fastness.

22 Flame retardants and fire preventing agents
Substances incorporated into, or applied to the surface of, materials to slow down or prevent combustion.

23 Flotation agents
Substances used to concentrate and obtain minerals from ores: flotation oil; flotation depressants.

24 Flux agents for casting
Substances used to promote the fusing of minerals or prevent oxide formation.

25 Foaming agents
Substances used to form a foam or cellular structure in a plastic or rubber material : physically by expansion of compressed gases or vaporisation of liquid, or chemically by decomposition evolving a gas.

Sub-categories : chemical or physical blowing agents; frothers.

26 Food/feedstuff additives
Substances used in food or animal feedstuffs to produce or enhance taste, odour or colour or to improve conservation.

27 Fuels
Substances used to evolve energy in a controlled combustion reaction.

Sub-categories : gasoline; kerosine; gas oil; fuel oil; petroleum gas; non-mineral oil.

28 Fuel additives
Substances added to fuels.

Sub-categories : anti-fouling agents; antiknock agents; deposit modifiers; fuel oxidisers.

29 Heat transferring agents
Substances used to transmit or to remove heat from a material.

Sub-categories : cooling agents; heating agents.

30 Hydraulic fluids and additives
Fluids used for transmitting pressure.

31 Impregnation agents
Substances used to admix with solid materials, which retain their original form : impregnating agents for leather, paper, textile and wood.

Not : flame retardants; conserving agents; biocides.

32 Insulating agents
Agents used to prevent or inhibit the flow of electrical current, heat or light or the transmission of sound.

33 Intermediates
Substances used for synthesis of other chemicals.

Sub-categories : monomers; pre-polymers.

34 Laboratory chemicals
Substances used in laboratories for analytical purposes.

35 Lubricants and additives
Substances entrained between two surfaces and thereby used to reduce friction: oils; fats; waxes; friction reducing additives.

36 Odour agents

Substances used to produce, enhance or mask odour.

Not : food additives; cosmetics.

37 Oxidising agents

Substances that give up oxygen easily, remove hydrogen from other substances, or accept electrons in chemical reactions, and are used for such purposes.

38 Pesticides

Active ingredients and preparations containing one or more active ingredients, intended to protect plants or plant products against harmful organisms or prevent the action of such organisms, influence the life processes of plants, preserve plant products, destroy undesirable plants or destroy parts of plants.

Not : nutrients; fertilisers.

39 Pesticides, non-agricultural

Active substances and preparations containing one or more active substances, intended to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any organism which has an unwanted presence for man, or a detrimental effect for man, his activities or the products he uses or produces; or for animals or for the environment.

Sub-categories : disinfectants, preservative products, pest control products, specialist biocides.

Not : plant protection products; veterinary products.

40 pH-regulating agents

Substances used to alter or stabilise the hydrogen ion concentration (pH): acids; alkalis; buffers.

41 Pharmaceuticals

Substances used as active ingredients in medicinal preparations.

Sub-categories : veterinary medicines

49 Stabilisers

Substances used to prevent or slow down spontaneous changes in, and ageing of, materials.

Sub-categories : antioxidants; heat stabilisers; light stabilisers; scavengers; charge stabilisers.

50 Surface-active agents

Substances used to lower the surface and/or interfacial tension of liquids and promote cleaning, wetting, dispersion etc..

51 Tanning agents

Substances used for treating hides and skins.

52 Viscosity adjusters

Substances used to modify the flow characteristics of other substances, or mixtures, to which they are added.

Sub-categories : pour point depressants; thickeners; thixotropic agents; turbulence suppressors; viscosity index improvers.

53 Vulcanising agents

Substances added to rubber to aid and hasten vulcanisation: vulcanising accelerators and vulcanising assistants.

54 Welding and soldering agents

Materials used for welding and soldering; electrodes; flux; powdered metal; wire etc..

55/0 Others

Substances whose technical functions are not described elsewhere.

NOTE : The function category 55 is no longer used for new substances. For new substances function category "Others" is now numbered 0 (Zero).

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ISSN 0254-1475

COM(1999) 178 final

DOCUMENTS

EN **05 14 15 10**

Catalogue number : CB-CO-99-419-EN-C

Office for Official Publications of the European Communities
L-2985 Luxembourg