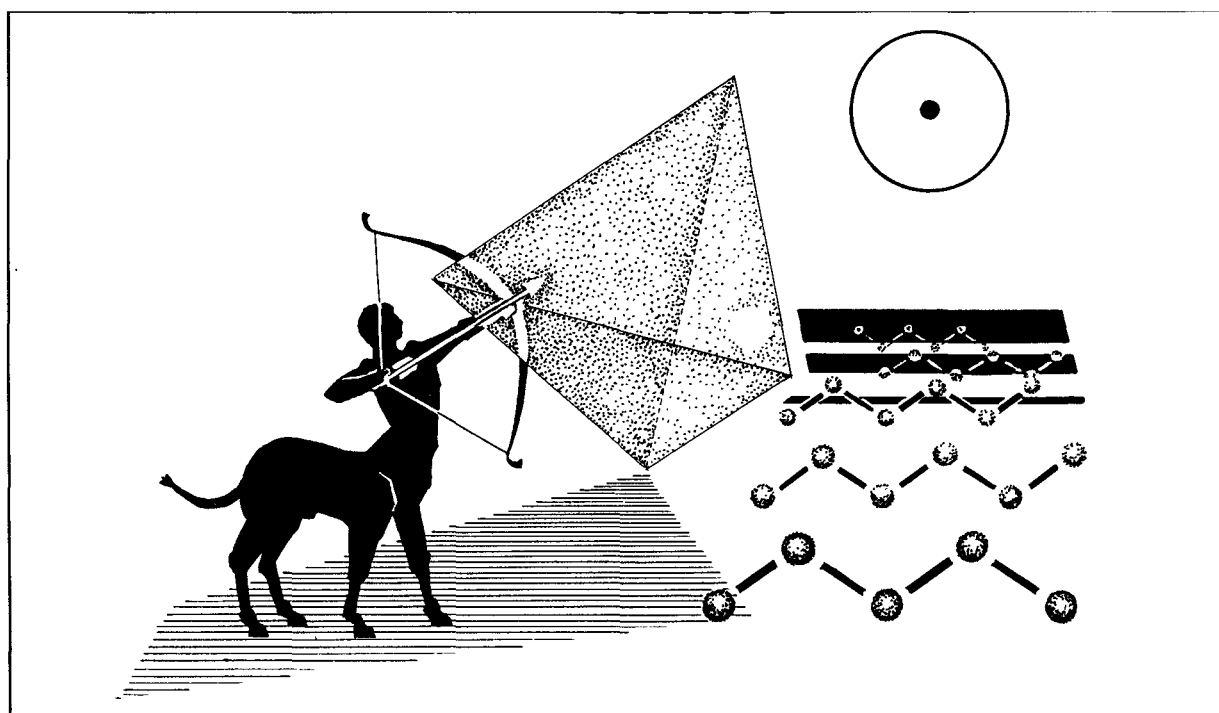


# EUROPEAN COMMUNITY ENVIRONMENTAL LEGISLATION 1967 – 1987

Vol. 3

## CHEMICALS & WASTE



Commission of the European Communities  
Directorate-General for Environment,  
Consumer Protection and  
Nuclear Safety  
Brussels

**EUROPEAN YEAR  
OF THE ENVIRONMENT**

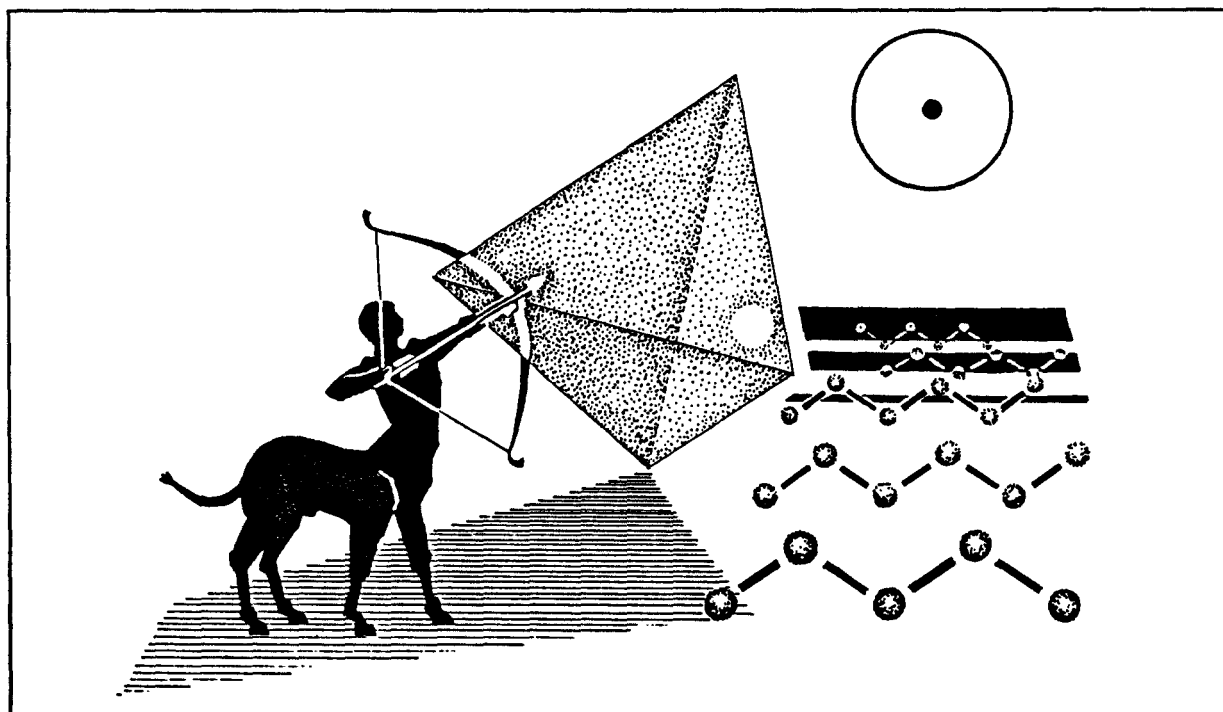




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# **European Community Environmental Legislation 1967 – 1987**

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## **Volume 3: Chemicals & Waste**

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Document No. XI/989/87

Commission of the European Communities  
Directorate-General for Environment,  
Consumer Protection and Nuclear Safety

Brussels

## **European Community Environmental Legislation**

### **Volume 3: Chemicals & Waste**

Series Editor: Cynthia Whitehead

The editor is grateful for the support of Nigel Haigh in the preparation of the introductions to these volumes. His book *EEC Environmental Policy & Britain, 2nd edition* (Longman: London, December 1987) offers fuller summaries and detailed analyses of the EC environment directives presented here.

The cover illustration, by Pierre Nagant, uses components of different symbolic systems to represent the element *Fire*:

Platonic – the tetrahedron; Astrological – Sagittarius; Planetary – Sun; Pythagorean – the top row of the Tetractys.

These volumes are also available in Danish, Dutch, French, German, Greek, Italian, Portuguese and Spanish.

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# Preface

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The Fourth Programme of Action for the Environment 1987-1992 sets out as one of its top priorities the correct application of the European directives for the protection of the environment by all member states. This goal is to be pursued with increased vigour by the Commission of the European Communities and it is to this end that this legislation is collected together in four volumes – in the nine languages of the Community.

The responsible authorities in each member state will have in this way a handy reference on the correct version of a particular directive.

The organisations for the protection of the environment and the public in general can find in these volumes what has been achieved until now for the European environment.

The various economic sectors can find here the directives that affect the organisation of their work.

In addition, there are included here multilateral conventions signed by the Community along with its neighbour countries – as well as many countries of the rest of the world – for the preservation of our planet.

These texts are the result of the collaboration of the member states within the Council of Ministers along with the Commission, under the scrutinizing eyes of the European Parliament and the Economic and Social Committee. All in all they represent an impressive part of the growing domain of European law.

They have been achieved in a rather short time since the beginning of the active pursuit of a European environmental policy in 1973.

Finally these texts owe their existence not in a small measure to the efforts of all those who have been working in the Directorate-General XI for the Environment, Consumer Protection and Nuclear Safety.

They, along with me, proudly dedicate these four volumes to the people of Europe as our contribution to their well-being.

**L. J. Brinkhorst**

Director General



# Introduction

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## 1. The nature of the European Community

The European Community is a unique political entity. It is neither a national government nor just an international organisation. The EC member states are not subnational entities (like the 50 states of the USA or the German Länder) but sovereign states. Still, these states have given the Community law-making and law-enforcing powers that go far beyond those of international organisations such as the United Nations, the Organisation for Economic Co-operation and Development (OECD), or the secretariats set up under numerous international treaties whose primary functions are to gather information and propose actions.

The European Community has institutions which can propose and adopt legislation that is binding on citizens and the member states without further national review or ratification. Further, it can monitor, coordinate and enforce the implementation of its laws.

## 2. The Institutions of the European Community

The European Community was established by the 1957 Treaty of Rome, the Euratom Treaty, and the Treaty on Coal and Steel; it was strengthened by a series of amendments to the Treaties which are contained in the Single European Act of 1987.

At present, the EC has 12 member states – Belgium, Denmark, the Federal Republic of Germany, France, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain and the United Kingdom.

The EC has an elected Parliament, a Council of Ministers with legislative powers, a Commission to propose and administer laws and regulations, and a Court of Justice to interpret and enforce its laws and the founding Treaties. The Economic and Social Committee advises the Council and Commission on current issues of law and policy.

### 2.1 The Council

The Council is composed of one minister from each of the member states; in practice the Council is composed of the minister responsible for the subject under discussion. Thus, it has become usual to refer to the 'Agriculture Council' or the 'Environment' or 'Consumer Affairs' Council. The 'European Council', composed of the prime ministers or heads of state, meets at least twice a year to discuss broad policy issues, including environment.

The Presidency of the Council passes from one member state to the next every 6 months (in alphabetical order in the language of each country). It decides the agenda for and presides over the Council meetings.

The Council is the main legislative institution of the Community. It can only act upon a proposal from the Commission. It may request the Commission to make a proposal on a particular subject, but this request is not mandatory.

Each member state maintains a Permanent Representation in Brussels to maintain relations with the EC institutions. The Committee of Permanent Representations (COREPER) and its working groups prepare issues for the Council. The working group is chaired by an official of the member state that holds the Presidency of the Council. Hence, the priorities set during each Presidency affect not only the decisions of the Council during that Presidency but also the agendas for the following 12-18 months.

Most environment legislation falls under the competency of the Environment Council, but some issues might fall under the competency of the Council that deals with the Internal Market or Industrial Affairs, Agriculture or others. Occasionally, as in the case of dangerous chemicals, a special, combined Council will be convened to consider proposed legislation or issues that cut across several areas of competence.

## **2.2 The Commission**

The Commission has the sole, formal power to propose legislation. It is composed of 17 Commissioners, proposed by the member states, who serve for a collective 4-year term of office and must take an oath that they are free from influence by their national government.

The Commissioners meet one day each week, normally Wednesdays, and must agree on all legislation proposed to the Council.

The Commission is supported by a number of administrative units: 'Directorates-General' and 'Services'. The Directorate-General XI (DG XI) is responsible for Environment, Consumer Protection and Nuclear Safety. The DG V – Employment, Social Affairs and Education – is responsible for worker safety and the DG III – Internal Markets and Industrial Affairs – is responsible for much product safety legislation, including pharmaceuticals, veterinary medicines, foodstuffs and food additives, and some dangerous chemical products. The DG VI – Agriculture – is responsible for pesticide regulation.

The Commissioners' responsibilities may cut across the competencies of or be divided among 2 or more Directorates-General.

In addition to its power to propose legislation, the Commission may adopt legislation in certain limited areas. This power, for example, is often used to adapt environmental laws to scientific or technical progress by amending requirements set out in annexes to the legislation; in such cases member states participate in the legislative process through a special committee.

The Commission is also responsible for monitoring the implementation of EC legislation by the member states. It is the 'Guardian of the Treaty' and can bring a member state before the Court of Justice for failure to carry out the obligations laid down in the EC Treaties or legislation.

## 2.3 The European Parliament

If the Council of Ministers may be said to represent the national interests of the member states, and the Commission to represent the 'Community interest', then the Parliament can be said to represent the voice of the people.

As the legislative role is filled by the Commission and the Council, the European Parliament is left with a largely advisory role. Its opinion must be obtained before certain types of legislation can be adopted by the Council and it has used this power quite frequently to delay legislation to achieve concessions from the Commission and the Council. It can raise new issues in parliamentary inquiries, debates and resolutions. The Parliament's consultative role has been strengthened by the Single European Act.

Members of the European Parliament (MEPs) are elected every 4 years and have divided themselves into political groupings cutting across nationalities.

Most of the work is carried out in the committees.

The Parliament meets once a month for about a week in Strasbourg, and the plenary sessions are open to the public. The committees meet once a month, usually in Brussels. The deliberations of the Environment Committee are open to the public, but this is not the case for many of the other committees.

## 2.4 The Court of Justice

The Court is composed of judges appointed by agreement with the member states. The judges are assisted by advocates general who analyse and propose decisions on the cases brought before it.

Cases may be brought by:

- the EC institutions against one another
- the Commission against member states
- the member states against the Commission
- natural or legal persons against the member states or the Commission.

National courts have retained the power to review actions taken by national institutions for implementation and enforcement of environmental legislation. They may apply to the Court of Justice for a preliminary ruling on an issue of EC law before reaching a decision.

The Court of Justice does not normally have the power to apply sanctions, but under the Treaty member states are required to comply with its rulings and have generally done so. National courts, of course, do have the power to enforce their decisions, including those concerning Community law.

## **2.5 The Economic and Social Committee (ESC)**

The members of this Committee are nominated by the member states to represent employers, employees, and other public interest organisations, including local government, consumer and environmental organisations. Often, it too must deliver its opinion before EC legislation may be adopted.

## **3. Competence for Environmental Law**

### **3.1 The Treaties of Rome**

The Treaty establishing the European Economic Community did not provide for environment protection as such, but for the need to achieve 'the constant improvement of the living and working conditions'. The first environmental laws – those concerning products – were based on Art. 100 of the Treaty, which empowers the Council to issue directives for the approximation of the laws, regulations or administrative actions in member states that directly affect the establishment or functioning of the common market. Later laws were based on Arts. 100 and 235. The latter empowers the Council to take appropriate measures to attain, in the course of the operation of the common market, one of the objectives of the Community where the Treaty has not provided the necessary powers.

### **3.2 The Single European Act**

A new Title VII 'Environment' (Articles 130 R, S & T) has been added to Part Three of the EEC Treaty covering the 'foundations and the policy of the Community', covering also human health and natural resource management. Environmental protection requirements must become a component of other Community policies. Art. 130 S empowers the Council to decide to take certain decisions by qualified majority. The text discusses the relationship between the Community and the member states at length and explicitly empowers the member states to maintain or adopt more stringent protective measures.

The new Article 100 A on the internal market cuts across environmental protection interests by introducing decision-making by a qualified majority, the Council being required to take a 'high level of protection' as its starting point. This clearly applies to product legislation, but is qualified by an escape clause permitting member states, for reasons of worker or environment protection, to continue to apply existing, more stringent legislation, provided it is not protectionist.

The meaning of this overlap between the protection of the common market and the protection of the environment where decisions are taken by qualified majority will before long probably have to be decided by the Court of Justice.



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## 4. Forms of European Community Legislation

The Council can adopt:

- **non-binding recommendations and resolutions**
- **regulations** that are binding and directly applicable in all member states
- **decisions** that are directly binding on the persons to whom it is addressed, including member states, individuals and legal persons
- **directives** that must be implemented by the laws or regulations of the member states within a designated time limit.

Regulations are usually used for very specific purposes such as trade in products and financial matters; they have not often been used for environmental legislation, except for controls on trade in endangered species.

Decisions have been primarily used in environmental legislation to authorise the Community to become a party to international conventions, but also for other purposes, e.g. to set up a system of information exchange on water quality.

The directive is the main tool of Community environmental policy. It empowers the Community to define objectives, standards and procedures but allows the member states some flexibility in that implementation must take place through national legislation and regulation.

In fact, environmental directives have sometimes been similar to regulations by laying down precise limits, controls, or technical, testing or labelling requirements, particularly regarding industrial products.

Some directives have set environmental quality standards combined with implementation plans or monitoring systems. This system allows the member states greater latitude in setting controls on actual emissions of individual polluters while meeting overall goals set by the Community.

Other directives have set broad environmental policy goals and encouraged cooperation among the member states without going so far as to define actual limits to pollution. This can be a useful tool when agreement on precise controls cannot be achieved in the Council.

The legislative process of the European Community is usually very thorough. It involves numerous close consultations with the member states, the European Parliament, the Economic and Social Committee, as well as private organisations, at both national and EC levels. During the process of developing their national positions on proposed EC legislation the member states must often formally consult their national parliaments and carry out informal consultations with national interest groups.

This painstaking process of consultation is a necessary part of the development of laws that must:

- serve the common interests of the European Community
- be integrated into the different legal systems of the member states, and
- be implemented by their different and varied administrations and levels of government.

## 5. Environmental Action Programmes

Although not legislation, the European Community has adopted three 5-year Action Programmes to guide its activities. The Action Programmes set out the Commission's priorities for the coming period.

### The Fourth Environmental Action Programme

On 24 October 1987 the Council formally adopted the Fourth Environmental Action Programme.

The Fourth Programme will mark an important new phase in EC environmental policy. It reflects the fundamental improvement in the status of environmental policy under the Single European Act by calling for protection of the environment to become an integral part of EC and national economic and social policies, in particular the Common Agriculture Policy, and Regional, Social, and Development policies.

Four areas are given top priority:

- **Implementation of EC legislation:** The Commission intends to step up efforts to ensure that member states apply directives fully, controlling both formal legal compliance and practical implementation. It is examining the possibility of appointing Community environment inspectors, and plans to encourage individuals and NGOs to monitor and report implementation problems, and organize workshops where national authorities can discuss their experiences.
- **'Substance'- and 'Source'- oriented pollution control:** The Programme reinforces the Community's commitment to preventive environmental policies by adopting a 'substance-oriented' approach to the regulation of existing problem chemicals such as asbestos, cadmium and lead. This approach is based on the analysis of all emissions of the substance to the environment and its movement and distribution through air, water and soil. It also seeks to revive the 'source-oriented' approach (all emissions from an installation to whatever environmental medium).
- **Information:** In 1987, the Commission has promised to draft a proposal that would expand the rights of citizens to obtain information from government about environmental policies and problems. It will also publish a report on the state of the environment every three years, beginning in 1987.
- **Job creation:** The Commission has proposed a five-year programme of demonstration projects in all member states to examine the job-creation potential of environmental investment.

**Cynthia Whitehead**

Brussels, 1987

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# Summaries of the legislation

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## Council Directive 67/548/EEC – Testing of chemicals

This Directive has been amended 16 times since its adoption, 11 of the amendments are currently in effect. The purpose of the principle Directive was to harmonize the laws of the Member States on the the testing, classification, packaging and labelling of chemicals that are dangerous to people or the environment. In 1979, the '6th Amendment' to the Directive (Council Directive 79/831/EEC) introduced a pre-market testing and notification system for new chemicals placed on the Community market.

The Directive distinguishes between 'new' and 'existing' chemicals. Existing chemicals are those which were placed on the Community market before 18 September 1981 and are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

Every producer or importer who places a new chemical substance on the market for the first time in the European Community after 18 September 1981 must submit a notification dossier about the chemical to a national competent authority at least 45 days in advance. Existing chemicals are exempt from notification.

The notification must contain 4 items:

- a technical dossier supplying the information necessary for evaluating foreseeable risks, whether immediate or delayed, that the substance may entail for people or the environment
- a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged (i.e. a risk assessment)
- proposed classification and labelling if the chemical is hazardous
- proposals for precautions for safe use and disposal.

The contents of the technical dossier are set out in Annex VII. This 'base set' of information is intended to be a screen for health and environmental hazards. It includes physicochemical data, toxicological and ecotoxicological tests, production quantities, uses, safety measures, and ways of rendering the substance harmless.

A summary of the notification is sent by the national competent authority to the Commission, which circulates it to the other competent authorities during the 45-day waiting period. Unless there is an objection, the substance may be placed on the market at the expiration of the waiting period. A properly notified substance may be marketed throughout the entire Community; it may not be subjected to further, prior national controls.

Substances which are already subject to Community controls, such as pharmaceuticals, narcotics, and radioactive substances, are excluded from the scope of the Directive.

Low-volume (under 1 tonne/year) and research chemicals, and polymers containing less than 2 % of a new monomer are considered as having been notified. A limited 'announcement' must

still be submitted to the national competent authority of each member state where the substance is marketed.

More thorough toxicological and ecotoxicological testing is required at certain threshold levels of marketing – 100 tonnes/year of 500 tonnes total, 1,000 tonnes/year or 5,000 tonnes total. These tests are set out in Annex VIII.

Follow-up information also may be required before these production levels are reached, for example in the event of:

- new knowledge of the effects of the substance
- new uses and exposure
- changes in the properties caused by a modification of the substance
- changes in annual or total marketing levels at 1 tonne, 10 tonnes or 50 tonnes.

The Directive requires that the test methods respect efforts at international harmonisation. They are set out in Annex V and are based on the test methods adopted by the OECD Council in 1981.

The Directive lists 14 categories for the classification of dangerous substances according to their physicochemical or toxicological properties. They are: explosive, oxidizing, extremely flammable, highly flammable and flammable, and very toxic, toxic, harmful, corrosive, irritant, carcinogenic, mutagenic, teratogenic, and dangerous for the environment. The classification criteria are given in Annex VI.

Corresponding symbols (except for flammable and dangerous for the environment) for the labelling according to the substance's most dangerous properties are given in Annex II.

Standard risk phrases (R-phrases) to be used for describing the substance's dangerous properties on the label are given in Annex III. Standard safety phrases (S-phrases) describing the necessary precautions in handling the substance are given in Annex IV. All of the chemicals which have been classified under the Directive are listed in Annex I, which is updated regularly. The Commission publishes in the Official Journal a list of all of the new chemicals which have been notified under the Directive.

The Directive also contains basic requirements for the packaging of dangerous substances.

Furthermore, the member states may also prescribe certain requirements such as child-resistant fastenings or tactile warnings of danger. The technical details of these safeguards will be given in Annex IX, which is still in preparation.

The Council directives made amendments to the text of the articles of the principle Directive. The Commission directives are known as the first through seventh adaptations to technical progress. They concern the addition of chemicals to Annex I and amendments to the Annexes which the Commission is empowered to make. Other adaptations have been made in consequence of the accessions of Greece, Spain and Portugal to the Community.

The legislative acts which are no longer in force are listed in the table of contents in italics.

## **Council Directive 82/501/EEC – Industrial accidents & emergency response**

The so-called 'Seveso Directive', named after the accident in the Italian town in 1976 which released clouds of dioxin, establishes a procedure whereby industrial plant operators, local and national authorities and the European Commission cooperate in identifying and controlling the risks of major accidents from industrial installations.

A major accident is defined to be: an occurrence such as a major emission, fire or explosion resulting from uncontrolled developments in the course of an industrial activity, leading to a serious danger to man, immediate or delayed, inside or outside the establishment, and/or to the environment, involving one or more dangerous substances.

The plant operator must take 'all measures necessary' to prevent major accidents and to limit their consequences for people and the environment.

The Directive is divided into 2 parts. Under the first part, for general hazards, the manufacturer must be able to prove to the national competent authority at any time that it has identified existing major-accident hazards, adopted the necessary safety measures, and provided the persons working on the site with information, training and equipment in order to ensure their safety.

Under the second part, certain industrial activities are subject to a notification procedure if one of the 180 chemicals on the list in Annex III are or may be present in the designated quantities, or if the chemicals listed in Annex II are stored in the designated quantities. The notification is to be submitted by the manufacturer to the competent authority. It must contain detailed information about:

- substances and manufacturing processes, hazards and risks, safety precautions and emergency procedures
- the industrial plant, including siting, exposed groups and environment, sources of danger from the location of the plant, preventive measures and technical controls
- possible major-accident situations, including emergency plans, safety equipment, alarms and resources.

In the case of an accident, the manufacturer must immediately inform the competent authority about all aspects of it and the emergency response measures taken. The member state must immediately inform the Commission and prepare a complete report on the causes of the accident, emergency procedures, the nature and extent of the damage and medium and long-term measures to alleviate the damage.

The Commission is keeping a register of information about major accidents.

Citizens liable to be affected by a major accident, and also those living in neighbouring member states, must be informed and their governments must be consulted about emergency planning measures.

The member states may impose more stringent requirements on their industries if they wish.

## **Council Directive 87/217/EEC – Asbestos**

This is the first 'substance oriented' directive announced under the Fourth Environmental Action Programme which links controls on emissions to air, water and land. It is intended to supplement restrictions on asbestos laid down by Directive 76/769/EEC on marketing and use, and by other directives dealing with worker protection, discharges to air, and waste.

A general duty is placed on the member states to ensure that asbestos emissions into the air, into water, and solid asbestos wastes are, as far as reasonably practicable, prevented by means of reductions at the source.

It covers crocidolite, actinolite, antophyllite, chrysolite, amosite, and tremolite. A limit value for air emissions of 0.1 milligrams per cubic metre (mg/m<sup>3</sup>) is set, with an exemption for plants

emitting less than 5,000 m<sup>3</sup>/hour of gaseous discharges if they do not emit more than 0.5 grams per hour.

Liquid effluents from asbestos cement and paper and board manufacture must be recycled. If recycling from the manufacture of asbestos cement is not 'economically feasible', the asbestos content of the wastes must not exceed 30 g/m<sup>3</sup>. The Directive applies to new plants, those which are built after 1 January 1989, and to existing plants (those built before this date) from 1 July 1991.

Work with asbestos products and the demolition of buildings may not cause significant environmental pollution by asbestos fibres or dust.

In the course of transport and landfill, no asbestos fibres or dust are to be released and no liquids containing asbestos fibres are to be spilled. Waste is to be treated, packaged or covered so that no release from landfill will occur.

Monitoring methods for discharges to air and water are laid down. The Commission is to review the methods used and make recommendations for a harmonized system in March 1992.

### **Council Directive 76/769/EEC – Marketing and use of dangerous substances (*not included*)**

The Directive created a framework for bans or restrictions on specific dangerous chemicals or preparations by means of an Annex. Member states must take all necessary measures to ensure that these dangerous substances and preparations are only placed on the market or used subject to the conditions specified. These restrictions do not apply to marketing or use for the purposes of research and development.

The Directive does not apply to transport, exports to non-EC member countries or substances in transit and subject to customs inspection.

The Directive first listed polychlorinated biphenyls and terphenyls (PCBs and PCTs) and monomer vinyl chloride. PCBs and PCTs may only be used in closed system electrical equipment, large condensers and for certain other applications. Monomer vinyl chloride may not be used as an aerosol propellant.

Council Directive 79/663/EEC added trichloroethylene, tetrachloroethylene and carbon tetrachloride to the Annex. These substances may not be used in ornamental objects intended to produce light or colour effects by means of different phases, e.g. lamps and ashtrays. A flame retardant that had been used on childrens' sleepwear – Tris (2,3 dibromopromyl) phosphate may not be used in textiles intended to come into contact with the skin.

Council Directive 82/806/EEC added benzene to the Annex and bans its use in toys where the benzene concentration is greater than 5 milligram/kilogram of the weight of the toy.

Council Directive 82/828/EEC relaxed the principle Directive by allowing PCTs to be used until 31 December 1984 in re-useable thermoplastic tooling compounds in the manufacture or maintenance of specified products, including gas turbines, nuclear reactors, ship and aircraft frames, semiconductor devices, and high-precision lenses.

Council Directive 83/264/EEC added to the Annex two flame retardants and three substances used in sneezing powders and novelties.

Council Directive 83/478/EEC added asbestos to the Annex. The marketing and use of crocidolite fibres and products containing them is banned, but the member states may allow products manufactured before 1 January 1986 to be marketed until 30 June 1988, or if they are

manufactured, placed on the market or used before 1 January 1986. Member states may also exempt fibres and semifinished products essential to the manufacture of asbestos-cement pipes, various types of seals and gaskets, and torque converters. All asbestos products, including crocidolite, must be labelled in accordance with the new Annex II of the Directive (the original Annex becoming Annex I).

Council Directive 85/467/EEC bans all new uses of PCBs and PCTs and terminates, as of 30 June 1986, the exemptions allowed under Directive 76/769/EEC. The second-hand sale of equipment containing PCBs or PCTs and fluids is also banned as of the same date.

The Directive increases the scope of the definition by a factor of 10; it now applies to any material containing more than 0.01 % by weight of PCB or PCT. The member states may withdraw existing equipment and their labelling. Topping up liquid levels in existing equipment is allowed where no substitute products exist. PCBs and PCTs may continue to be used as primary and intermediate products, provided that the Commission is informed and no deleterious effects result.

Council Directive 85/610/EEC revises and tightens the restrictions on asbestos. It adds toys, items for smoking, catalytic filters, and paints and varnishes to the list of products that may not contain asbestos fibres other than crocidolite.

## **Council Directive 75/442/EEC – Framework for waste**

The Directive seeks to provide the framework whereby the member states could control the disposal of wastes nationally, instead of locally as in the past.

Member states must take the necessary measures to ensure that waste is disposed of without endangering human health or harming the environment.

The Directive does not apply to radioactive wastes, mining waste, some agricultural wastes, waste waters and gaseous effluents.

Four general obligations are laid down. Member states must:

- designate national competent authorities to be responsible for waste management under the Directive
- see that the competent authorities draw up waste disposal plans
- subject installations which treat, store or dispose of wastes for third parties to a prior permit requirement
- apply the 'polluter pays principle'.

In addition, they must encourage recycling, and submit situation reports to the Commission every three years.

The plans to be drawn up by the competent authorities must cover the type and quantity of wastes to be disposed of; technical requirements; suitable disposal sites; and special arrangements for particular wastes.

The permits must cover the type and quantity of waste involved; technical requirements and precautions; and information to be made available on request of the competent authority concerning the origin, destination and treatment, and type and quantity of the waste.

The competent authorities must carry out periodic inspections to ensure that the conditions of the permits are being complied with.

Under the polluter pays principle, the cost of disposing of the waste must be borne by the originator of the waste or by the holder who has the waste disposed of by another party.

## **Council Directive 78/319/EEC – Toxic and dangerous waste**

This Directive falls within the framework of Directive 75/442/EEC and focuses on laying down a broad framework for the control of household and toxic wastes.

Member states must ensure that toxic and dangerous waste may only be stored, treated and/or deposited by authorized undertakings and that producers and holders of such wastes may only have it stored, treated or deposited by an authorized undertaking.

Toxic and dangerous waste is defined as any waste containing or contaminated by the substances or materials listed in the Annex to the Directive of such a nature, in such quantities or in such concentrations as to constitute a risk to health or the environment.

The Directive does not cover radioactive wastes, specific agricultural wastes, explosives or hospital wastes.

The member states must appoint competent authorities to authorize waste disposal and draw up management plans. These plans must be updated- and made available to the public. They must be sent to the Commission, which will arrange for regular comparisons and consultations.

The Directive defines the contents of the plans and permits. Permits may only be granted for a limited period of time.

Undertakings which produce, hold and/or dispose of these wastes must keep records and make them available to the competent authority on request.

A form, defined in the Directive, must accompany any shipment of these wastes. In particular, the form must give the name and address of the producer, previous holder, and final disposer of the wastes.

These wastes must be kept separate from other matter and residues when being collected, transported, stored or deposited.

The costs are to be borne by the holder who has waste handled by a waste collector, and/or by the previous holders or the producer of the product from which the waste came. Member states may impose levies on the costs of disposal, but the income must be used for financing control measures related to toxic and dangerous waste disposal or for financing research for their elimination.

Every 3 years, the member states must send a situation report on the disposal of toxic and dangerous waste to the Commission.

## **Council Directive 84/631/EEC – Transfrontier shipment**

This Directive supplements Directive 78/319/EEC on toxic and dangerous wastes by regulating their shipment across national frontiers from collection to disposal, both within and outside the Community.

It has been adapted to technical progress by Commission directive twice and amended by Council directive once.

It requires the member states to take the necessary measures to ensure the use of a detailed consignment note when the holder of a dangerous or toxic waste (as defined in Directive 78/319/EEC, except for chlorinated solvents, organic solvents, and PCBs) intends to move it across a national frontier.



The consignment note gives details about the source and composition of the waste, routes, insurance against damage to third parties, measures for safe transport and compliance with conditions imposed by member states, and the existence of a contractual agreement with the consignee of the waste.

If the waste is being shipped to a country outside the Community, the holder of the waste must obtain the agreement of that country before starting the notification procedure. The shipment may not take place until the competent authorities of the member state(s) concerned have acknowledged receipt of the notification. Such acknowledgement or objection must be sent within one month of receipt of notification to the holder of the waste, with copies to the consignee and any other states concerned.

Objections must be based on Community law or international agreements on the subject.

The Directive also sets out conditions governing packaging, labelling and instructions in the event of danger or accident. The cost of the procedure must be borne by the holder and/or the producer of the waste, in accordance with the polluter pays principle.

The issue of civil liability was left open for the Commission to make a proposal before 30 September 1988.

The member states must send a report to the Commission on the operation of the scheme every 2 years.

The Directive allows non-ferrous metals destined for recycling to be exempted from its requirements. The exemption can be claimed through the use of a form set out in an Annex to the Directive.

The Directive was intended to come into effect on 1 October 1985, but the date was extended to 1 January 1987 by Council Directive 86/279/EEC, which also amended the text of the original Directive to extend its requirements to non-EC countries.

Council Directive 86/121/EEC added the Spanish and Portuguese translations of the descriptions of the particular wastes set out in Box 36, Annex I.

Commission Directive 87/112/EEC amended and updated Annexes II – Declaration concerning waste from non-ferrous metals for re-use, regeneration or recycling, and IV – concerning the consignment note to be prepared by the holders of waste destined to be shipped to non-EC countries for disposal.

## **Council Directive 75/439/EEC – Waste oils**

The Directive is designed to prevent damage to the environment from the uncontrolled disposal of waste oils and also seeks to ensure that different financial arrangements adopted to promote safe disposal and recycling do not create barriers to the common market.

Member states must ensure the safe collection and disposal of waste oils, and ensure that they are 'as far as possible' recycled. 'Waste oils' include lubricating oils but not wastes from, e.g. oil refineries.

The Directive prohibits:

- the discharge of waste oils to water and drainage systems
- any deposit and/or discharge harmful to the soil
- any uncontrolled discharge of residues from processing
- any processing of waste oils causing air pollution exceeding the level prescribed by existing provisions.

Any undertaking disposing of waste oil must obtain a permit from the competent authority, and any undertaking collecting waste oils must be registered and adequately supervised. Undertakings which regenerate or burn waste oils may be granted a permit only when the competent authority is satisfied that all appropriate preventive measures have been taken.

Furnaces with a thermal capacity of above 3 megawatts are subject to the emission limits laid down in the Directive for heavy metals, chlorine and fluorine. Sulphur dioxide and particulate emission limits may be set by the member states. PCBs and PCTs must not be present in amounts greater than 50 ppm in regenerated waste oil.

Every 3 years the member states must submit a report to the Commission. The Commission must report to the Council by January 1992 on the measures taken by the member states concerning the operation of regeneration and combustion plants.

### **Council Directive 86/278/EEC – Sewage sludge**

The Directive aims to control the use of sewage sludge in agriculture by fixing limit values for concentrations of heavy metals in the soil and in sludge, and the maximum quantities of heavy metals (cadmium, copper, nickel, lead, zinc and mercury) which may be added to the soil. These limit values are to some extent alternatives.

The Directive defines conditions for the use of sludge: Member states must ensure that the limit values set out in Annexes I.A, I.B and I.C are not exceeded. Minimum time limits are set for the use of sludge on certain types of agricultural lands. Sludge and the soil on which it is applied must be analyzed according to the procedures set out in Annexes II.A and II.B. Reference methods for sampling and analysis are given in Annexe II.C.

The member states must keep records on the application of the Directive. They must report to the Commission on the implementation of the Directive for the first time in 1991, and every 4 years thereafter. The Commission may publish these reports.

Within one year, the Commission must propose limit values for chromium sludge in the soil.

### **Council Directive 85/339/EEC – Beverage containers (*not included*)**

The Directive requires the member states to draw up programmes for reducing the tonnage and/or volume of beverage containers (cans and bottles) in waste for disposal. It covers sealed containers of all types (except barrels and casks) containing liquids for human consumption listed in the Annex.

The first programmes were to start 1 January 1987; they must be revised and updated every 4 years. The measures to be taken include consumer education; facilitating refilling and recycling; selective collection and recovery of nonrefillable containers; technical development of new containers; and maintaining and increasing the proportion of refilled and recycled containers used. These measures may be taken by legislative or administrative action, or even by voluntary agreements with industry. Existing glass bottle systems are exempt for 10 years from the programmes. The draft programmes must be sent in advance to the Commission for review and national reports must be submitted to the Commission every 4 years.

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# Chemicals

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**COUNCIL DIRECTIVE**

of 27 June 1967

on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(67/548/EEC)

(as amended by Council Directive 71/144/EEC of 22 March 1971 (OJ L 74, 29.3.71, p. 15; OJ English Special Edn. 1971 (1) p. 15); Commission Directive 76/907/EEC of 14 July 1976 (OJ L 360, 30.12.76, p. 1; OJ L 28, 2.2.79, p. 32); Commission Directive 79/370/EEC of 30 January 1979 (OJ L 88, 7.4.79, p. 1); Council Directive 79/831/EEC of 18 September 1979 (OJ L 259, 15.10.79, p. 10); Council Directive 80/1189/EEC of 4 December 1980 (OJ L 366, 31.12.80, p. 1); Commission Directive 81/957/EEC of 23 October 1981 (OJ L 351, 7.12.81, p. 5); Commission Directive 82/232/EEC of 25 March 1982 (OJ L 106, 21.4.82, p. 18); Commission Directive 83/467/EEC of 29 July 1983, OJ L 257, 16.9.83, p. 1); Commission Directive 84/449/EEC of 25 April 1984 (OJ L 251, 19.9.84, p. 1); Act of Accession of Spain and Portugal of 12 June 1985 (OJ L 302, 15.11.85, p. 9); and Commission Directive 86/431/EEC of 24 June 1986 (OJ L 247, 1.9.86, p. 1; OJ L 271, 23.9.86, p. 31; OJ L 50, 19.2.87, p. 38))

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament<sup>1</sup>;

Having regard to the Opinion of the Economic and Social Committee<sup>2</sup>;

Whereas any rules concerning the placing on the market of dangerous substances and preparations must aim at protecting the public, and in particular workers using such substances and preparations;

Whereas the differences between the national provisions of the six Member States on the classification, packaging and labelling of dangerous substances and preparations hinder trade in these substances and preparations within the Community and hence affect the establishment and functioning of the common market;

Whereas it is therefore necessary to remove such hindrances; whereas this entails approximating the laws, regulations and administrative provisions on classification, packaging and labelling;

Whereas, in view of the preparatory work still to be carried out, the approximation of provisions relating to dangerous preparations will have to be dealt with in later directives; whereas therefore the present Directive must be restricted to the approximation of provisions relating to dangerous substances;

Whereas in view of the extent of this field and the many detailed measures which will be required for the approximation of all the provisions relating to dangerous substances, it would appear advisable to deal first with the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and to deal in later directives with the approximation of the provisions relating to the use of those dangerous substances and preparations if it is established that the differences between such provisions directly affect the establishment or functioning of the common market;

Whereas the approximation of national provisions which is laid down by this Directive does not prejudice application of the provisions of Articles 31 and 32 of the Treaty;

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States on:

<sup>1</sup> OJ No 209, 11.12.1965, p. 3133/65.

<sup>2</sup> OJ No 11, 20.1.1966, p. 143/66.

- (a) the notification of substances, and
- (b) the classification, packaging and labelling of substances dangerous to man and the environment,

which are placed on the market in the Member States.

2. This Directive does not apply to the provisions relating to:

- (a) medicinal products, narcotics and radioactive substances;
- (b) the carriage of dangerous substances by rail, road, inland waterway, sea or air;
- (c) foodstuffs or feedingstuffs;
- (d) substances in the form of waste which are covered by Council Directive 75/442/EEC of 15 July 1975 relating to waste <sup>(1)</sup> and Council Directive 78/319/EEC of 20 March 1978 relating to toxic and dangerous waste <sup>(2)</sup>;
- (e) substances in transit which are under customs supervision provided they do not undergo any treatment or processing.

3. Articles 15, 16 and 17 do not apply to the provisions governing:

- (a) containers which contain gases compressed, liquefied or dissolved under pressure, excluding aerosols which comply with the requirements of Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers <sup>(3)</sup>;
- (b) munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

4. Articles 5, 6 and 7, in so far as they are concerned with notification, do not apply:

- (a) — until six months after publication of the inventory referred to in Article 13 (1), to substances placed on the market before 18 September 1981;  
— six months after publication of the inventory referred to in Article 13 (1), to substances which appear in that inventory;
- (b) to pesticides and fertilizers, in as far as they are subject to approval procedures which are at

least equivalent or Community notification procedures or procedures which are not yet harmonized;

- (c) to substances which are already subject to similar testing and notification requirements under existing Directives.

#### Article 2

1. For the purpose of this Directive:

- (a) "substances" means chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the market;
- (b) "preparations" means mixtures or solutions composed of two or more substances;
- (c) "environment" means water, air and land and their inter-relationship as well as relationships between them and any living organisms;
- (d) "notification" means the documents whereby the manufacturer or any other person established in the Community who places a substance on its own or in a preparation on the market presents the requisite information to the competent authority of a Member State. The person so doing shall hereinafter be referred to as "the notifier";
- (e) "placing on the market" means supplying or making available to third parties.

Importation into Community customs territory shall be deemed to be placing on the market for the purposes of this Directive.

2. The following substances and preparations are "dangerous" within the meaning of this Directive:

- (a) explosive:  
substances and preparations which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene;
- (b) oxidizing:  
substances and preparations which give rise to highly exothermic reaction when in contact with other substances, particularly flammable substances;
- (c) extremely flammable:  
liquid substances and preparations having a flash point lower than 0 °C and a boiling point lower than or equal to 35 °C;

<sup>(1)</sup> OJ No L 194, 15. 7. 1975, p. 39.

<sup>(2)</sup> OJ No L 84, 31. 3. 1978, p. 43.

<sup>(3)</sup> OJ No L 147, 9. 6. 1975, p. 40.

- (d) highly flammable:
- substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
  - solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
  - liquid substances and preparations having a flash point below 21 °C, or
  - gaseous substances and preparations which are flammable in air at normal pressure, or
  - substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;
- (e) flammable:
- liquid substances and preparations having a flash point equal to or greater than 21 °C and less than or equal to 55 °C;
- (f) very toxic:
- substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve extremely serious, acute or chronic health risks and even death;
- (g) toxic:
- substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks and even death;
- (h) harmful:
- substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve limited health risks;
- (i) corrosive:
- substances and preparations which may, on contact with living tissues, destroy them;
- (j) irritant:
- non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation;
- (k) dangerous for the environment:
- substances and preparations the use of which presents or may present immediate or delayed risks for the environment;
- (l) carcinogenic:
- substances or preparations which, if they are inhaled or ingested or if they penetrate the skin,

may induce cancer in man or increase its incidence;

(m) teratogenic;

(n) mutagenic.

#### Article 3

1. The physico-chemical properties of the substances and preparations shall be determined according to the methods specified in Annex V (A); their toxicity shall be determined according to the methods specified in Annex V (B) and their ecotoxicity according to those specified in Annex V (C).

2. The real or potential environmental hazard shall be assessed according to the characteristics set out in Annexes VII and VIII, on the basis of any existing internationally recognized parameters.

3. The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI, save where contrary requirements for dangerous preparations are specified in separate Directives.

#### Article 4

1. The classification of dangerous substances according to the degree of hazard and to the specific nature of the risks involved shall be based on the categories laid down in Article 2 (2). For categories (a) to (j) the substances shall be classified according to the greatest degree of hazard, in accordance with Article 16 (4).

2. The dangerous substances listed in Annex I shall, where appropriate, be given a rating enabling the health hazard of preparations to be assessed. The ratings shall be determined in accordance with the criteria established by a subsequent Council Directive.

#### Article 5

1. The Member States shall take all the measures necessary to ensure that without prejudice to Article 8 substances cannot be placed on the market on their own or in preparations unless the substances have been:

- notified to the competent authority of one of the Member States in accordance with this Directive,

- packaged and labelled in accordance with Articles 15 to 18 and with the criteria in Annex VI, and in accordance with the results of the tests provided for in Article 6.

2. The measures referred to in the second indent of paragraph 1 shall apply until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 21.

Dangerous substances not yet appearing in Annex I but included in the list referred to in Article 13 (1) or already on the market before 18 September 1981 must, in so far as the manufacturer whether or not established in the Community may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria in Annex VI.

#### Article 6

1. Without prejudice to Articles 1 (4) and 8 (1), any manufacturer or importer into the Community of a substance within the meaning of this Directive shall be required to submit to the competent authority referred to in Article 7 of the Member State in which the substance is produced or into which it is imported into the Community, at the latest 45 days before the substance is placed on the market, a notification including:

- a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing at least the information and results of the studies referred to in Annex VII, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them,
- a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged,
- the proposed classification and labelling of the substance in accordance with this Directive,
- proposals for any recommended precautions relating to the safe use of the substance.

2. However, in the case of a substance which has already been notified, the competent authority may agree that the notifier of that substance may, for the purposes of the technical dossier, refer to the results of the studies carried out by one or more previous notifiers, provided the latter have given their agreement in writing.

3. If a substance is already listed in Annex I, the notifier need not present the declaration concerning its unfavourable effects, the proposed classification and the proposals for any recommended precautions

relating to safe use. Furthermore, the notifier need not supply the information required for the technical dossier in Annex VII, with the exception of points 1 and 2 of that Annex, if the substance was originally notified at least 10 years previously.

4. Any notifier of a substance already notified shall be required to inform the competent authority of:

- changes in the annual or total quantities placed on the market by him in accordance with the tonnage range laid down in Annex VII, point 2.2.1,
- new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware,
- new uses for which the substance is placed on the market (within the meaning of Annex VII, point 2.1.2) of which he may reasonably be expected to have become aware,
- any change in the properties resulting from a modification of the substance referred to in Annex VII, point 1.3.

5. The notifier shall also be required to inform the competent authority of the results of the studies carried out in accordance with Annex VIII.

#### Article 7

1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Article 6 and examining its conformity with the requirements of the Directive, and in particular:

- the notifier's proposed findings on any foreseeable risks which the substance may entail,
- classification and labelling,
- the proposals for any recommended precautions relating to safe use submitted by the notifier.

Moreover, if it can be shown to be necessary for the evaluation of the hazard which may be caused by a substance, the competent authorities may:

- ask for further information and/or verification tests concerning the substances of which they have been notified; this may also include requesting the information referred to in Annex VIII earlier than provided for therein,
- carry out such sampling as is necessary for control purposes,
- take appropriate measures relating to safe use of a substance pending the introduction of Community provisions.



2. The procedure laid down in Article 21 shall be followed in confirming or amending proposals for:

- classification,
- labelling, and
- the recommended precautionary measures provided for in Annex VII, points 2.3, 2.4 and 2.5.

3. Member States and the Commission shall ensure that any information concerning commercial exploitation or manufacturing is kept secret.

#### Article 8

1. The substances listed below, shall be considered as having been notified within the meaning of this Directive when the following conditions are fulfilled:

- polymerizates, polycondensates and polyadducts except those containing in combined form 2% or more of any monomer unmarketed before 18 September 1981,
- substances for research and analysis purposes, in so far as they are placed on the market for the purpose of determining their properties in accordance with this Directive;
- substances placed on the market for research or analysis purposes in quantities of less than one tonne per year per manufacturer or importer and intended solely for laboratories,
- substances placed on the market in quantities of less than one tonne per year per manufacturer provided that the manufacturer announces their identity, labelling data and quantity to the competent authorities of the Member States where the substances are placed on the market and complies with any conditions imposed by those authorities.

However, substances placed on the market at the research and development stage with a limited number of registered customers, in quantities which are limited to the purpose of the research and development but which amount to more than one tonne per year per manufacturer, shall qualify for exemption for a period of one year, provided that the manufacturer announces their identity, labelling data and quantity to the competent authorities of each Member State where the manufacture, research or development takes place and complies with any conditions imposed by those authorities on such research and development; after this period, these substances shall be subject to notification. The manufacturer shall also give an assurance that the

substance or the preparation in which it is incorporated will be handled by customers' staff only, under controlled conditions, and will not be made available to the public.

2. The substances referred to in paragraph 1 must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria imposed in Annex VI.

If labelling in accordance with the principles set out in Article 16 is not yet possible, the label should bear the warning: "Caution — substance not yet fully tested".

3. Where a substance as referred to in paragraph 1, labelled in accordance with the principles set out in Article 16, is very toxic or toxic, the manufacturer or importer of such a substance must transmit to the competent authority any appropriate information as regards Annex VII, points 2.3, 2.4 and 2.5.

#### Article 9

When a Member State has received the notification dossier or additional information referred to in Article 6 it shall forthwith send to the Commission a copy of the dossier or a summary thereof together with any relevant comments; in the case of the further information referred to in Article 7 (1) and the additional information or studies provided for in Annex VIII, the competent authority shall notify the Commission of the tests chosen, the reasons for their choice, and the assessment of their results.

#### Article 10

1. On receipt of the copy of the notification dossier, the summary thereof or the additional information sent by a Member State, the Commission shall forward:

- the notification dossier or the summary thereof to the other Member States,
- any other relevant information it has collected pursuant to this Directive to all Member States.

2. The competent authority of any Member State may consult direct the competent authority which received the original notification, or the Commission, on specific details of the data

contained in the dossier required under this Directive; it may also suggest that further tests or information be requested. If the competent authority which received the original notification fails to comply with the suggestions of other authorities regarding further information or amendments in the study programmes provided for in Annex VIII, it shall give its reasons to the other authorities concerned. Should it not be possible for the authorities concerned to reach agreement and should any one authority feel, on the basis of detailed reasons, that additional information or amendments in the study programmes are nevertheless really necessary to protect man and the environment, it may ask the Commission to take a decision in accordance with the procedure laid down in Article 21.

#### Article 11

1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Article 6 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission. Full justification must be given in such cases.

Industrial and commercial secrecy shall not apply to:

- the trade name of the substance,
- physico-chemical data concerning the substance in connection with Annex VII, point 3,
- the possible ways of rendering the substance harmless,
- the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests,
- the recommended methods and precautions referred to in Annex VII, point 2.3 and the emergency measures referred to in Annex VII, points 2.4 and 2.5.

If the notifier himself subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

2. The authority receiving the notification shall decide on its own responsibility which information is covered by industrial and commercial secrecy in accordance with paragraph 1.

3. The name of a substance appearing in the list provided for in Article 13 (2) may be included in encoded form where the competent authority to which the notification has been submitted so requests because of the confidentiality problems to which publication of the name of the substance would give rise, provided that the substance is not classified as dangerous.

A substance may be included in the list in encoded form for no longer than three years.

4. Confidential information brought to the attention either of the Commission or of a Member State shall be kept secret.

In all cases such information

- may be brought to the attention only of the authorities whose responsibilities are specified in Article 7 (1),
- may, however, when administrative or legal proceedings involving sanctions are undertaken for the purpose of controlling substances placed on the market, be divulged to persons directly involved in such proceedings.

This Article and Article 12 shall not oblige a Member State whose legislation or administrative practices impose stricter limits for the protection of industrial and commercial secrecy than those laid down in these Articles to supply information, where the State concerned does not take steps to comply with these stricter limits.

#### Article 12

The data supplied in accordance with Articles 9 and 10 (1) may be forwarded to the Commission and the Member States in summary form.

In such cases and in the context of Article 10 (2), the competent authorities of a Member State and the Commission shall have access to the notification dossier and the additional information at all times.

#### Article 13

1. The Commission shall, on the basis in particular of information provided by the Member States, draw up an inventory of substances on the Community market by 18 September 1981.

In so doing it shall have regard to Articles 1 (4) and 8.

The inventory shall give the chemical name under an internationally recognized chemical

nomenclature (preferably IUPAC), the CAS number and the common name or ISO abbreviation, if any.

2. The Commission shall keep a list of all substances notified under this Directive.

3. The information and the form in which it is recorded in the list and the inventory, together with the criteria covering the provision to the Commission by the Member States of information relating to the inventory, shall be determined in accordance with the procedure laid down in Article 21.

*Article 14*

Annex I contains the list of substances classified in accordance with Article 4 and any recommendations relating to safe use.

*Article 15*

1. Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless their packaging satisfies the following requirements:

- (a) it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;
- (b) the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form harmful or dangerous compounds with the contents;
- (c) packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
- (d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be repeatedly refastened without the contents escaping.

2. The Member States may also prescribe that:

- packages shall initially be closed with a seal in such a way that when the package is opened for the first time the seal is irreparably damaged,
- containers with a capacity not exceeding three litres which contain dangerous substances intended for domestic use shall have child-resistant fastenings,

- containers with a capacity not exceeding one litre which contain very toxic, toxic or corrosive liquids intended for domestic use shall carry a tactile warning of danger.

3. Any technical specifications which may be necessary with regard to the devices referred to in paragraph 2 shall be adopted by the procedure in Article 21 and shall be given in Annex IX, in particular:

- in Annex IX (A) relating to child-resistant fastenings,
- in Annex IX (B) relating to tactile warnings of danger.

*Article 16*

1. Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the following requirements.

2. Every package shall show clearly and indelibly the following:

- the name of the substance,
  - the origin of the substance,
  - the danger symbol, when laid down, and indication of danger involved in the use of the substance,
  - standard phrases indicating the special risks arising from such dangers,
  - standard phrases indicating the safety advice relating to the use of the substance.
- (a) The name of the substance shall be one of the terms listed in Annex I; if this is not the case the name must be given in accordance with internationally recognized nomenclature.
- (b) The indication of origin shall include the name and address of the manufacturer, the distributor or the importer.

(c) The following symbols and indications of danger are to be used:

- explosive:  
an exploding bomb (E)
- oxidizing:  
a flame over a circle (O)
- extremely flammable:  
a flame (F)
- highly flammable:  
a flame (F)

- very toxic:  
a skull and cross-bones (T)
- toxic:  
a skull and cross-bones (T)
- harmful:  
a St Andrew's cross (Xn)
- corrosive:  
the symbol showing the damaging effect of an acid (C)
- irritant:  
a St Andrew's cross (Xi)

The symbols must conform to those in Annex II; they shall be printed in black on an orange-yellow background.

(d) The special risks involved in using the substances shall be indicated by one or more of the standard phrases which, in accordance with the references contained in the list in Annex I, are set out in Annex III. In the case of a substance not listed in Annex I, the reference to the special risks attributed to the dangerous substances shall comply with appropriate indications given in Annex III.

The phrases "extremely flammable" or "highly flammable" need not be indicated where they repeat the wording of an indication of danger used in accordance with (c) above.

(e) The safety advice relating to the use of the substances shall be indicated by standard phrases which, in accordance with the references contained in the list in Annex I, are set out in Annex IV.

The packaging shall be accompanied by the safety advice required by the above paragraph where it is materially impossible for this to be given on the label or package itself.

In the case of a substance not listed in Annex I, the safety advice relating to the dangerous substances shall comply with appropriate indications given in Annex IV.

(f) Indications such as "non-toxic", "non-harmful" or any other similar indications must not appear on the label or packaging of substances subject to this Directive.

3. In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of special risks and safety advice need not be given where the package does not contain more than 125 ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

4. When more than one danger symbol is assigned to a substance:

- the obligation to indicate the symbol T makes the symbols X and C optional, unless Annex I includes provision to the contrary,
- the obligation to indicate the symbol C makes the symbol X optional,
- the obligation to indicate the symbol E makes the symbols F and O optional.

*Article 17*

1. Where the particulars required by Article 16 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

<i>Capacity of the package</i>	<i>Dimensions (in millimetres)</i>
— not exceeding three litres:	if possible at least 52 × 74
— greater than three litres but not exceeding 50 litres:	at least 74 × 105
— greater than 50 litres but not exceeding 500 litres:	at least 105 × 148
— greater than 500 litres:	at least 148 × 210

Each symbol shall cover at least one tenth of the surface area of the label but not be less than 1 cm<sup>2</sup>. The entire surface of the label shall adhere to the package immediately containing the substance.

These dimensions are intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety indications.

2. A label is not required where the particulars are clearly shown on the package itself, as specified in paragraph 1.

3. The colour and presentation of the label — or, in the case of paragraph 2, of the package, — shall be such that the danger symbol and its background stand out clearly from it.

4. Member States may make the placing on the market of dangerous substances in their territories subject to the use of the official language or languages in respect of the labelling thereof.

5. For the purpose of this Directive, labelling requirements shall be deemed to be satisfied:

- (a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in accordance with international rules on the transport of dangerous substances and the inner package or packages are labelled in accordance with this Directive;
- (b) in the case of a single package, if such a package is labelled in accordance with international rules on the transport of dangerous substances and with Article 16 (2) (a), (b), (d) and (e).

Where dangerous substances do not leave the territory of a Member State, labelling may be permitted which complies with national rules instead of with international rules on the transport of dangerous substances.

#### Article 18

1. Member States may:

- (a) permit the labelling required by Article 16 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 17 (1) and (2);
- (b) by way of derogation from Articles 16 and 17 permit the packaging of dangerous substances which are neither explosive, very toxic nor toxic to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no reason to fear any danger to persons handling such substances or other persons.

2. If a Member State makes use of the options provided for in paragraph 1, it shall forthwith inform the Commission thereof.

#### Article 19

The amendments necessary for adapting the Annexes, other than Annex VI, Part I and Annexes VII and VIII, to technical progress, shall be adopted in accordance with the procedure laid down in Article 21.

#### Article 20

1. A Committee (hereinafter called "the Committee") is hereby set up to adapt to technical progress the Directives concerning the elimination of technical barriers to trade in dangerous substances and preparations. It shall consist of representatives of the Member States, with a Commission representative as chairman.

2. The Committee shall adopt its own rules of procedure.

#### Article 21

1. Where reference is made to the procedure laid down in this Article, the matter shall be referred to the Committee by its chairman, either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit a draft of the measures to be adopted to the Committee. The Committee shall give its view of the draft within a time limit set by the chairman having regard to the urgency of the matter. Decisions shall be taken by a majority of 54 votes, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the proposed measures if they are in accordance with the opinion of the Committee;

(b) If the proposed measures are not in accordance with the opinion of the Committee, or if no opinion has been stated, the Commission shall without delay submit a proposal to the Council concerning the measures to be adopted. The Council shall act by a qualified majority;

(c) If the Council has not acted within three months of the proposal being submitted to it, the proposed measures shall be adopted by the Commission.

#### Article 22

The Member States may not, on grounds relating to notification, classification, packaging or labelling within the meaning of this Directive, prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this Directive and the Annexes thereto.

*Article 23*

1. Where a Member State has detailed evidence that a substance, although satisfying the requirements of this Directive, constitutes a hazard for man or the environment by reason of its classification, packaging or labelling, it may provisionally prohibit the sale of that substance or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. The Commission shall consult the Member States concerned within six weeks, then give its view without delay and take the appropriate measures.

3. If the Commission considers that technical adaptations to this Directive are necessary, such adaptations shall be adopted, either by the Commission or by the Council, in accordance with the procedure laid down in Article 21; in such case, the Member State which has adopted safeguard measures may maintain them until the adaptations enter into force.

*Article 24*

Member States shall inform the Commission of all laws, regulations and administrative provisions which they adopt in the field covered by this Directive.

*Article 25*

Member States shall adopt the measures needed in order to comply with this Directive and shall apply them by 1 January 1972 at the latest.

They shall forthwith inform the Commission thereof.

*Article 26*

This Directive is addressed to the Member States.

Done at Brussels, 27 June 1967.

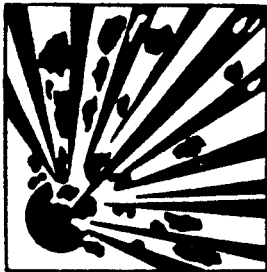
*For the Council*

*The President*

R. VAN ELSLANDE

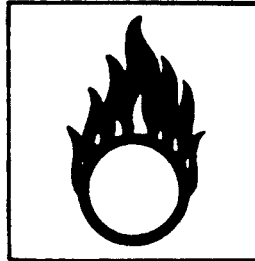
ANNEX II

E



- \* ES: Explosivo
- DA: Eksplosiv
- DE: Explosionsgefährlich
- EL: Εκρηκτικό
- EN: Explosive
- FR: Explosif
- IT: Esplosivo
- NL: Ontplofbaar
- \* PT: Explosivo

O



- \* ES: Comburente
- DA: Brandnærende (oxiderende)
- DE: Brandfördernd
- EL: Οξειδωτικό
- EN: Oxidizing
- FR: Comburant
- IT: Comburente
- NL: Oxyderend
- \* PT: Comburente

F



- \* ES: Fácilmente inflamable
- DA: Let antændelig
- DE: Leichtentzündlich
- EL: Λίαν εύφλεκτο
- EN: Highly flammable
- FR: Facilement inflammable
- IT: Facilmente infiammabile
- NL: Licht ontvlambaar
- \* PT: Fácilmente inflamável

F +



- \* ES: Extremadamente inflamabl
- DA: Yderst let antændelig
- DE: Hochentzündlich
- EL: Εξόχως εύφλεκτο
- EN: Extremely flammable
- FR: Extrêmement inflammable
- IT: Estremamente infiammabili
- NL: Zeer licht ontvlambaar
- \* PT: Extremamente inflamável

T



- \* ES: Tóxico
- DA: Giftig
- DE: Giftig
- EL: Τοξικό
- EN: Toxic
- FR: Toxique
- IT: Tossico
- NL: Vergiftig
- \* PT: Tóxico

T +



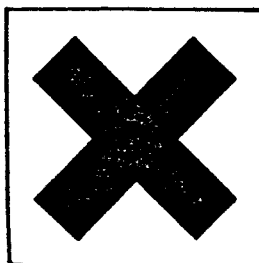
- \* ES: Muy tóxico
- DA: Meget giftig
- DE: Sehr giftig
- EL: Λίαν τοξικό
- EN: Very toxic
- FR: Très toxique
- IT: Molto tossico
- NL: Zeer vergiftig
- \* PT: Muito tóxico

C



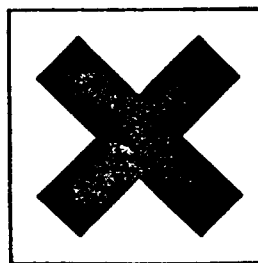
- \* ES: Corrosivo
- DA: Ætsende
- DE: Ätzend
- EL: Διαβρωτικό
- EN: Corrosive
- FR: Corrosif
- IT: Corrosivo
- NL: Corrosief
- \* PT: Corrosivo

Xn



- \* ES: Nocivo
- DA: Sundhedsskadelig
- DE: Mindergiftig (Gesundheitsschädlich)
- EL: Επιβλαβές
- EN: Harmful
- FR: Nocif
- IT: Nocivo
- NL: Schadelijk
- \* PT: Nocivo

Xi



- \* ES: Irritante
- DA: Lokalmiriterende
- DE: Reizend
- EL: Ερεθιστικό
- EN: Irritant
- FR: Irritant
- IT: Irritante
- NL: Irriterend
- \* PT: Irritante

## ANNEX VI

## GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES

## Part I

A. Save where otherwise provided in the separate Directives on dangerous preparations, the substances and preparations shall be classified as very toxic, toxic or harmful according to the following criteria:

- (a) classification as very toxic, toxic or harmful shall be effected by determining the acute toxicity of the commercial substance or preparation in animals, expressed in LD<sub>50</sub> or LC<sub>50</sub> values with the following parameters being taken as reference values:

Category	LD <sub>50</sub> absorbed orally in rat mg/kg	LD <sub>50</sub> percutaneous absorption in rat or rabbit mg/kg	LC <sub>50</sub> absorbed by inhalation in rat mg/litre/four hours
Very toxic	≤ 25	≤ 50	≤ 0.5
Toxic	25 to 200	50 to 400	0.5 to 2
Harmful	200 to 2 000	400 to 2 000	2 to 20

- (b) if facts show that for the purposes of classification it is inadvisable to use the LD<sub>50</sub> or LC<sub>50</sub> values as a principal basis because the substances or preparations produce other effects, the substances or preparations shall be classified according to the magnitude of these effects.

## Part II

B. Save where otherwise provided in separate Directives on dangerous preparations, substances and preparations shall be classified as corrosive or as irritant according to the following criteria:

## (a) Corrosion criteria

A substance or a preparation is considered to be corrosive if, when it is applied to healthy intact animal skin, it produces full thickness destruction of skin tissue on at least one animal during the test for skin irritation cited in Annex V or during an equivalent method or if the result can be predicted, for example from strongly acid or alkaline reactions.



**(b) Irritation criteria**

A substance or a preparation is considered to be irritant if it causes inflammation of the skin or ocular lesions corresponding to the evaluation of the parameters given below:

**1. Inflammation of the skin**

(i) Inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours and corresponds to the following values determined on the rabbit according to the cutaneous irritation test method cited in Annex V:

- the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is two or more,
- or, in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of two or more calculated for each animal separately has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values.

(ii) If practical experience shows the substances and preparations to be capable of inducing a sensitization reaction in a substantial number of persons by skin contact, or on the basis of a positive response in experimental animals.

In the case of the test method for skin sensitization detailed in Annex V or in the case of other adjuvant-type test methods a response in at least 30 % of the animals is considered positive. For any other test method a response in at least 15 % of the animals is considered positive.

**2. Ocular lesion**

Ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours and correspond to the following values determined on the rabbit according to the eye irritation test method cited in Annex V:

- the mean value of the scores for each type of lesion, calculated over all the animals tested, is one of the following:
 

— cornea opacity	two or more
— iris lesion	one or more
— redness of conjunctivae	2,5 or more
— oedema of conjunctivae (chemosis)	two or more
- or, in the case where the Annex V test has been completed using three animals, either cornea opacity, iris lesion, redness of conjunctive or oedema of conjunctive (chemosis) equivalent to a mean value such as is quoted above, but calculated for each animal separately, has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hours) and for an effect should be used in calculating the respective means values.

**C.** If the facts show the existence of effects other than the acute effects indicated by experiments with animals, e.g. carcinogenic, mutagenic, allergenic, sub-acute or chronic effects, the substances or preparations shall be classified according to the magnitude of these effects.

**D. Guide to the classification and labelling of dangerous substances and preparations; criteria for the choice of phrases indicating special risks (R phrases) and safety advice (S phrases)**

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- 1. General introduction**
- 2. Classification as dangerous and choice of risk phrases**
  - 2.1. Introduction**
  - 2.2. Physico-chemical properties**
  - 2.5. Toxicological properties**
  - 2.4. Criteria for classification, choice of symbols, indication of danger and choice of risk phrases**
    - 2.4.1. Explosive**
    - 2.4.2. Oxidizing**
    - 2.4.3. Extremely flammable**
    - 2.4.4. Highly flammable**
    - 2.4.5. Flammable**
    - 2.4.6. Very toxic**
    - 2.4.7. Toxic**
    - 2.4.8. Harmful**
    - 2.4.9. Corrosive**
    - 2.4.10. Irritant**
    - 2.4.11. Other properties**
- 3. Additional criteria concerning specific effects of substances on health**
  - 3.1. Procedure for the classification of substances which may possibly have the effects mentioned in this chapter**
  - 3.2. Carcinogenic substances**
  - 3.3. Mutagenic substances**
  - 3.4. Teratogenic substances**
- 4. Choice of safety advice phrases**
- 5. Labelling proposal**

1. GENERAL INTRODUCTION

1.1. The information provided in this document is intended as a guide for all those concerned (manufacturers, importers, national authorities) with methods of classifying and labelling dangerous substances and preparations. It sets out the general principles governing the classification and labelling of substances and preparations referred to in Article 3 (3) of Directive 67/548/EEC, bearing in mind the exceptions mentioned in Article 3 (3) — 'save where contrary requirements for dangerous preparations are specified in separate Directives'.

1.2. The labelling requirements of this Directive and the separate Directives on dangerous preparations are intended to provide a primary means by which the general public and persons at work are given essential information about dangerous substances and preparations. The label draws the attention of persons handling or using substances and preparations to the inherent danger of certain such materials.

The label may also serve to draw attention to more comprehensive product information on safety and use available in other forms.

1.3. The label takes account of all potential hazards which are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, e.g. diluted. The most severe hazards are highlighted by symbols, such hazards and those arising from other dangerous properties are specified in standard risk phrases, and safety phrases give advice on necessary precautions.

The information is completed by the name of the substance under an internationally recognized chemical nomenclature, and the name and address of the manufacturer, or the distributor or the importer.

1.4. With respect to substances referred to in the second subparagraph of Article 5 (2) of Directive 67/548/EEC, the labelling applied by the manufacturer or his representative remains valid until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 21.

2. CLASSIFICATION AS DANGEROUS AND CHOICE OF RISK PHRASES

2.1. Introduction

The object of classification is to identify all the toxicological and physico-chemical properties of substances and preparations which may constitute a risk during normal handling or use.

— As regards substances for which the information specified in Annex VII is required, most of the necessary data for classification and labelling appear in the 'base set'. This classification and labelling must be reviewed, if necessary, when further information is available (Annex VIII).

— As regards other substances (e.g. those referred to in Article 5 (2)), the data required for classification and labelling may if necessary be obtained from a number of different sources, for example the results of previous tests, information required by international rules on the transport of dangerous substances, information taken from reference works and the literature or information derived from practical experience.

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V. In other cases, the available

data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling criteria.

## 2.2 Physico-chemical properties

2.2.1. The test methods relating to explosive, oxidizing and flammable properties included in Annex V to this Directive serve to give specific meaning to the general definitions given in Article 2 (2) (a) to (e). Criteria follow directly from the test methods in Annex V as far as they are mentioned.

2.2.2. If adequate information is available to demonstrate in practice that the physico-chemical properties of substances and preparations (apart from organic peroxides) are different from those revealed by the test methods given in Annex V, then such substances and preparations should be classified according to the hazard they present, if any, to those handling the substances and preparations or to other persons.

2.2.3. Organic peroxides are classified as dangerous on the basis of their structure (e.g. R-O-O-H; R<sub>1</sub>-O-O-R<sub>2</sub>). In general terms, organic peroxides shall be classified as oxidizing, and labelled as under 2.4.2, unless:

- tests carried out in accordance with the methods given in Annex V show the organic peroxide, in the form in which it is placed on the market, to have explosive properties, as under 2.4.1, or
- the organic peroxide is so diluted or phlegmatized that it has neither explosive, oxidizing nor flammable properties.

## 2.3 Toxicological properties

2.3.1. Classification is concerned with both the acute and long-term effects of these substances and preparations, whether resulting from a single instance of exposure or repeated or prolonged exposure.

2.3.2. Substances and preparations should generally be classified in accordance with the acute toxicity of the marketed product, expressed as LD<sub>50</sub> or LC<sub>50</sub> as determined by tests on experimental animals. Reference values are given in part I of Annex VI.

If the facts show the existence of effects other than the acute effects indicated by experiments with animals, e.g. carcinogenic, mutagenic, allergenic, sub-acute or chronic effects, the substances or preparations shall be classified according to the magnitude of these effects.

If adequate evidence is available to demonstrate in practice that the toxic effect of substances and preparations on man is, or is likely to be different from that suggested by the experimental results obtained in animal tests then such substances and preparations should be classified according to their toxicity in man.

2.3.3. When the classification is to be established from experimental results obtained in animal tests, the results should have validity for man in that the tests reflect, in an appropriate way, the risks to man.

## 2.4 Criteria for classification, choice of symbols, indication of danger and choice of risk phrases

Classification must cover both the toxicological and the physico-chemical properties of substances and preparations. The object of choosing risk phrases is to ensure that the specific nature of the potential dangers identified in classification are expressed on the label. For this purpose it is necessary to consider the criteria given for the choice of symbol(s) and risk phrases in each of the sections 2.4.1 to 2.4.11 and chapter 3, for example classification under 2.4.6 does not imply that the sections such as 2.4.7 or 2.4.9 can be ignored.

The criteria are applicable to gaseous substances and preparations but only in so far as they may be subject to the packaging and labelling provisions of this Directive or the separate Directive on preparations.

Notwithstanding the criteria given under 2.4.3, 2.4.4 and 2.4.5, substances and preparations in the form of aerosols shall be subject to the flammability criteria set out in paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC.

**2.4.1. Explosive**

Substances and preparations shall be classified as explosive and assigned the symbol 'E' and the indication of danger 'explosive' in accordance with the results of the tests given in Annex V and in so far as the substances and preparations are explosive as placed on the market. One risk phrase is obligatory, it is to be specified on the basis of the following:

- R 2     **Risk of explosion by shock, friction, fire or other sources of ignition**
  - substances and preparations including certain organic peroxides but excepting those set out below.
  
- R 3     **Extreme risk of explosion by shock, friction, fire or other sources of ignition**
  - substances and preparations which are particularly sensitive such as picric acid salts, PETN and certain undiluted organic peroxides such as dibenzoyl peroxide.

**2.4.2. Oxidizing**

Substances and preparations shall be classified as oxidizing and assigned the symbol 'O' and the indication of danger 'oxidizing' in accordance with the results of the tests given in Annex V (see also 2.2.3). One risk phrase is obligatory, it is to be specified on the basis of the test results but subject to the following:

- R 11    **Highly flammable**
  - organic peroxides which have flammable properties even when not in contact with other combustible material.
  
- R 8     **Contact with combustible material may cause fire**
  - other oxidizing substances and preparations which may cause fire or enhance the risk of fire when in contact with combustible material.
  
- R 9     **Explosive when mixed with combustible material**
  - other substances and preparations which become explosive when mixed with combustible materials, e.g. certain chlorates.

**2.4.3. Extremely flammable**

Substances and preparations shall be classified as extremely flammable and assigned the symbol 'F+' and the indication of danger 'extremely flammable' in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the following criteria:

- R 12    **Extremely flammable**
  - Liquid substances and preparations which have a flash point lower than 0 °C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 °C.

**2.4.4. Highly flammable**

Substances and preparations shall be classified as highly flammable and assigned the symbol 'F' and the indication of danger 'highly flammable' in accordance with the results of the tests given in Annex V. Risk phrases shall be assigned in accordance with the following criteria:

- R 17 **Spontaneously flammable in air**  
 — substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy.
- R 11 **Highly flammable**  
 — solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition;  
 — liquid substances and preparations having a flash point below 21 °C but are not extremely flammable.
- R 12 **Extremely flammable**  
 — gaseous substances and preparations which are flammable in air at normal pressure.
- R 13 **Extremely flammable liquefied gas**  
 — gaseous substances and preparations which are flammable in air at normal pressure when put on the market in liquefied form.
- R 15 **Contact with water liberates highly flammable gases**  
 — substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities, at a minimum rate of 1 litre/kg/h.

#### 2.4.5. *Flammable*

Substances and preparations shall be classified as flammable in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the criteria mentioned below.

- R 10 **Flammable**  
 — liquid substances and preparations having a flash point equal to or greater than 21 °C, and less than or equal to 55 °C.

However, in practice it has been shown that a preparation having a flash point equal to or greater than 21 °C and less than or equal to 55 °C need not be classified as flammable if the preparation could not in any way support combustion and only so long as there is no reason to fear risks to those handling these preparations or to other persons.

#### 2.4.6. *Very toxic*

Substances and preparations shall be classified as very toxic and assigned the symbol 'T+' and the indication of danger 'very toxic' in accordance with the criteria given in part I of Annex VI, as specified below.

Risk phrases shall be assigned in accordance with the following criteria:

- R 28 **Very toxic if swallowed**  
 — acute toxicity results:  
 LD<sub>50</sub> oral, rat: < 25 mg/kg
- R 27 **Very toxic in contact with skin**  
 — acute toxicity results:  
 LD<sub>50</sub> dermal, rat or rabbit: < 50 mg/kg
- R 26 **Very toxic by inhalation**  
 — acute toxicity results:  
 LC<sub>50</sub> inhalation, rat: < 0,5 mg/litre/4 h
- R 39 (\*) **Danger of very serious irreversible effects**  
 — Strong evidence that irreversible damage other than the effects referred to in chapter 3 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 2.3.2 and 2.3.3).

(\*) R 26, R 27 or R 28 is also to be assigned to indicate route of administration/exposure.

2.4.7. *Toxic*

Substances and preparations shall be classified as toxic and assigned the symbol 'T' and the indication of danger 'toxic' in accordance with the criteria given in part I of Annex VI, as specified below. Risk phrases shall also be assigned in accordance with the following criteria:

- R 25 **Toxic if swallowed**  
 — acute toxicity results:  
 $LD_{50}$  oral, rat:  $25 < LD_{50} \leq 200$  mg/kg
- R 24 **Toxic in contact with skin**  
 — acute toxicity results:  
 $LD_{50}$  dermal, rat or rabbit:  $50 < LD_{50} \leq 400$  mg/kg
- R 23 **Toxic by inhalation**  
 — acute toxicity results:  
 $LC_{50}$  inhalation, rat:  $0,5 < LC_{50} \leq 2$  mg/litre/4 h
- R 39 (\*) **Danger of very serious irreversible effects**  
 — strong evidence that irreversible damage other than the effects referred to in chapter 3 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 2.3.2 and 2.3.3).
- R 48 (\*) **Danger of serious damage to health by prolonged exposure**  
 — serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure, by an appropriate route, at levels significantly lower than those quoted in section 2.4.8 (see also 2.3.2 and 2.3.3).

2.4.8. *Harmful*

Substances and preparations shall be classified as harmful and assigned the symbol 'Xn' and the indication of danger 'harmful' in accordance with the criteria given in part I of Annex VI as specified below. Risk phrases shall also be assigned in accordance with the following criteria:

- R 22 **Harmful if swallowed**  
 — acute toxicity results:  
 $LD_{50}$  oral, rat:  $200 < LD_{50} \leq 2\ 000$  mg/kg
- R 21 **Harmful in contact with skin**  
 — acute toxicity results:  
 $LD_{50}$  dermal, rat or rabbit:  $400 < LD_{50} \leq 2\ 000$  mg/kg
- R 20 **Harmful by inhalation**  
 — acute toxicity results:  
 $LC_{50}$  inhalation, rat:  $2 < LC_{50} \leq 20$  mg/litre/4 h
- R 40 (\*\*) **Possible risk of irreversible effects**  
 — strong evidence that irreversible damage other than the effects referred to in chapter 3 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 2.3.2 and 2.3.3).

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(\*) R 23, R 24 or R 25 is also to be assigned to indicate route of administration/exposure.

(\*\*) R 20, R 21 or R 22 is also to be assigned to indicate route of administration/exposure.

**R 48 (\*) Danger of serious damage to health by prolonged exposure**

— serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route, at levels of the order of (see also 2.3.2 and 2.3.3):

- oral, rat  $\leq 50$  mg/kg (body weight)/day (\*\*),
- dermal, rat or rabbit  $\leq 100$  mg/kg (body weight)/day (\*\*),
- inhalation, rat  $\leq 0,5$  mg/litre 6 h/day (\*\*),

These guide values can apply directly when severe lesions have been observed in a sub-chronic (90 days) toxicity study, but also serve as a guide when interpreting the results of sub-acute (28 days) or chronic (two years) toxicity tests.

**R 42 May cause sensitization by inhalation**

— if practical evidence is available which shows the substances and preparations to be capable of inducing a sensitization reaction in humans by inhalation, at a greater frequency than would be expected from the response of a normal population.

**2.4.9. Corrosive**

Substances and preparations shall be classified as corrosive and assigned the symbol 'C' and the indication of danger 'corrosive' in accordance with the criteria given in Annex VI (B). Risk phrases shall be assigned in accordance with the following criteria:

**R 35 Causes severe burns**

— if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to three minutes exposure, or if this result can be predicted.

**R 34 Causes burns**

— if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to four hours exposure, or if this result can be predicted.

**2.4.10. Irritant**

Non-corrosive substances and preparations shall be classified as irritant and assigned the symbol 'Xi' and the indication of danger 'irritant' in accordance with the criteria given in Annex VI (B) and as specified below. Risk phrases shall also be assigned in accordance with the following criteria:

**R 38 Irritating to skin**

— if, when applied to healthy intact animal skin for up to four hours, significant inflammation is caused and which is present 24 hours or more after the end of the exposure period.

Inflammation is significant, if the mean value of the scores is two or more for either erythema and eschar formation or oedema formation. The same shall be the case where the test has been completed using three animals if the score for either erythema and eschar formation or oedema formation observed in two or more animals is equivalent to the value of two or more.

**R 36 Irritating to eyes**

— if, when applied to the eye of the animal, significant ocular lesions are caused and which are present 24 hours or more after instillation of the test material.

Ocular lesions are significant, if the means of the scores have any of the values: cornea opacity equal to or greater than two but less than three; iris lesion equal to or greater than one but not greater than 1,5; redness of the conjunctivae equal to or greater than 2,5; oedema of the conjunctivae (chemosis) equal to or greater than 2. The same shall be the case where the test has been completed using three animals if the lesions, on two or more animals, are equivalent to any of the above values except that for iris lesion the value should be equal to or greater than one but less than two and for redness of conjunctivae the value should be 2,5 or more.

(\*) R 20, R 21 or R 22 is also to be assigned to indicate route of administration/exposure.

(\*\*) These values are not intended to influence in any way the choice of dose levels in carrying out the tests of Annex V.



- R 41 (\*) Risk of serious damage to eyes**  
 — if when applied to the eye of the animal severe ocular lesions are caused and which are present 24 hours or more after instillation of the test material.  
 Ocular lesions are severe if the means of the scores have any of the values:  
 cornea opacity equal to or greater than three; iris lesion greater than 1,5. The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values:  
 cornea opacity equal to or greater than three; iris lesion equal to two.
- R 43 May cause sensitization by skin contact**  
 — if practical experience shows the substances and preparations to be capable of inducing a sensitization reaction in a substantial number of persons by skin contact, or on the basis of a positive response in experimental animals.  
 In the case of the test method for skin sensitization detailed in Annex V or in the case of other adjuvant-type test methods, a response of at least 30 % of the animals is considered positive. For any other test method a response of at least 15 % of the animals is considered positive.
- R 37 Irritating to respiratory system**  
 — substances and preparations which cause serious irritation to the respiratory system, based normally on practical observation

**2.4.11. Other properties**

Additional risk phrases shall be assigned to substances and preparations, classified by virtue of 2.4.1 to 2.4.10 above, in accordance with the following criteria (based on experience obtained during compilation of Annex I):

- R 1 Explosive when dry**  
 For explosive substances and preparations put on the market in solution or in a wetted form; e.g. nitrocellulose with more than 12,6 % nitrogen.
- R 4 Forms very sensitive explosive metallic compounds**  
 For substances and preparations which may form sensitive explosive metallic derivatives, e.g. picric acid, styphnic acid.
- R 5 Heating may cause an explosion**  
 For thermally unstable substances and preparations not classified as explosive, e.g. perchloric acid > 50 %.
- R 6 Explosive with or without contact with air**  
 For substances and preparations which are unstable at ambient temperatures, e.g. acetylene.
- R 7 May cause fire**  
 For reactive substances and preparations: e.g. fluorine, sodium hydrosulphite.
- R 14 Reacts violently with water**  
 For substances and preparations which react violently with water, e.g. acetyl chloride, alkali metals, titanium tetrachloride.
- R 16 Explosive when mixed with oxidizing substances**  
 For substances and preparations which react explosively with an oxidizing agent, e.g. red phosphorus.
- R 18 In use, may form flammable/explosive vapour-air mixture**  
 For preparations not in themselves classified as flammable, which contain volatile components which are flammable in air.

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(\*) The use of R 34 or R 35 precludes the use of R 41.

- R 19**    **May form explosive peroxides**  
For substances and preparations which may form explosive peroxides during storage, e.g. diethyl ether, 1,4-dioxan.
- R 29**    **Contact with water liberates toxic gas**  
For substances and preparations which in contact with water or damp air, evolve very toxic/toxic gases in potentially dangerous amounts, e.g. aluminium phosphide, phosphorus pentasulphide.
- R 30**    **Can become highly flammable in use**  
For preparations not in themselves classified as flammable, which may become flammable due to the loss of non-flammable volatile components.
- R 31**    **Contact with acids liberates toxic gas**  
For substances and preparations which react with acids to evolve toxic gases in dangerous amounts; e.g. sodium hypochlorite, barium polysulphides. For substances used by members of the general public, the use of S 50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.
- R 32**    **Contact with acids liberates very toxic gas**  
For substances and preparations which react with acids to evolve very toxic gases in dangerous amounts; e.g. salts of hydrogen cyanide, sodium azide. For substances used by members of the general public, the use of S 50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.
- R 33**    **Danger of cumulative effects**  
For substances and preparations when accumulation in the human body is likely and may cause some concern which, however, is not sufficient to justify the use of R 48.  
Previously assigned to substances of Annex I and preparations which were likely to cause damage to health by prolonged exposure or which were likely to be retained and then accumulated within the human body. Now to be progressively replaced when appropriate by R 48.
- R 44**    **Risk of explosion if heated under confinement**  
For substances and preparations not in themselves classified as explosive in accordance with 2.4.1 above but which may nevertheless display explosive properties in practice if heated under sufficient confinement. For example, certain substances which would decompose explosively if heated in a steel drum do not show this effect if heated in less-strong containers.

### 3.    **ADDITIONAL CRITERIA CONCERNING SPECIFIC EFFECTS OF SUBSTANCES ON HEALTH**

For the record: further guidance applicable to preparations will be published later.

- 3.1.**    **Procedure for the classification of substances which may possibly have the effects mentioned in this chapter**
- 3.1.1.**    If a manufacturer or his representative has information available which indicates that a substance should be classified and labelled in accordance with the criteria given in section 3.2, 3.3 or 3.4, he or his representative shall provisionally label the substance with R 40 and assign at least the symbol 'Xn' unless the conclusions reached by the application of the criteria mentioned in 2.4.6 to 2.4.10 indicate the need for a more severe classification.
- 3.1.2.**    Furthermore, the manufacturer or his representative is requested to submit as soon as possible a document summarizing all relevant information to one Member State in which the substance is placed on the market. This summary document should include a bibliography containing all relevant references and may include any relevant unpublished data.

- 3.1.3. In order to obtain as quickly as possible a harmonized classification for the Community by the procedure defined in Article 21, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information together with suggestions for classification and labelling, to the Commission as soon as possible.

The Commission will forward to the other Member States the classification and labelling proposal that it receives. Any Member State may ask the Commission for the information it has received.

Any Member State which has good reason to believe that the suggested classification and labelling is inappropriate as far as the carcinogenic, mutagenic or teratogenic effects are concerned shall notify the Commission thereof.

- 3.1.4. The provisional labelling applied by a manufacturer or his representative shall remain valid until the entry into force of a decision on the inclusion or non-inclusion of the substance concerned in Annex I.

### 3.2. Carcinogenic substances

- 3.2.1. For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

#### *Category 1*

Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

#### *Category 2*

Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

- appropriate long-term animal studies,
- other relevant information.

#### *Category 3*

Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

- 3.2.2. The following specific risk phrases apply:

Categories 1 and 2:

R 45 May cause cancer

Category 3:

R 40 Possible risk of irreversible effects

- 3.2.3. The following classifications and symbols apply:

Categories 1 and 2: at least: Toxic

Category 3: Harmful

The conclusions reached by application of the criteria mentioned in 2.4.6 to 2.4.10 may indicate the need of a more severe classification.

### 3.3. Mutagenic substances

- 3.3.1. For the purposes of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

*Category 1*

Substances known to be mutagenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

*Category 2*

Substances which should be regarded as if they are mutagenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:

- appropriate animal studies,
- other relevant information.

*Category 3*

Substances which cause concern for man owing to possible mutagenic effects but in respect of which the available information does not satisfactorily demonstrate heritable genetic damage. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in category 2.

- 3.3.2. The following specific risk phrases apply:

Categories 1 and 2:

R 46 May cause heritable genetic damage

Category 3:

R 40 Possible risk of irreversible effects

- 3.3.3. The following classifications and symbols apply:

Category 1: at least: Toxic

Categories 2 and 3: Harmful

The conclusions reached by the application of the criteria mentioned in 2.4.6 to 2.4.10 may indicate the need for a more severe classification.

- 3.4. Teratogenic substances

- 3.4.1. For the purposes of classification and labelling, and having regard to the current state of knowledge, such substances are divided into two categories:

*Category 1*

Substances known to be teratogenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and subsequent non-heritable birth defects in offspring.

*Category 2*

Substances which should be regarded as if they are teratogenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in non-heritable birth defects in offspring, generally on the basis of:

- appropriate animal studies,
- other relevant information.

- 3.4.2. The following specific risk phrases apply:

Categories 1 and 2

R 47 May cause birth defects

3.4.3. The following classifications and symbols apply:

Category 1: at least: Toxic

Category 2: Harmful

The conclusions reached by the application of the criteria mentioned in 2.4.6 to 2.4.10 may indicate the need for a more severe classification.

#### 4. CHOICE OF SAFETY ADVICE PHRASES

Safety advice phrases (S phrases) shall be assigned to substances and preparations in accordance with the following general criteria:

##### S 1 Keep locked up

- Applicability
  - Very toxic and toxic substances and preparations.
- Criteria for use
  - Recommended for very toxic and toxic substances and preparations likely to be used by members of the general public.

##### S 2 Keep out of reach of children

- Applicability
  - All dangerous substances and preparations.
- Criteria for use
  - *Obligatory* only for all dangerous substances and preparations likely to be used by members of the general public or likely to be used in places to which the general public have access unless there is no reason to fear any danger particularly to children.

##### S 3 Keep in a cool place

- Applicability
  - Organic peroxides.
  - Other dangerous substances and preparations having a boiling point  $\leq 40$  °C.
- Criteria for use
  - *Obligatory* for organic peroxides unless S 47 is used.
  - Recommended for other dangerous substances and preparations having a boiling point  $\leq 40$  °C.

##### S 4 Keep away from living quarters

- Applicability
  - Very toxic and toxic substances and preparations.
- Criteria for use
  - Normally limited to very toxic and toxic substances and preparations when desirable to supplement S 13; for example when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters.

##### S 5 Keep contents under . . . (appropriate liquid to be specified by the manufacturer)

- Applicability
  - Spontaneously flammable solid substances and preparations.
- Criteria for use
  - Normally limited to special cases, e.g. sodium, potassium or white phosphorous.

- S 6 **Keep under . . . (inert gas to be specified by the manufacturer)**
- Applicability
    - Dangerous substances and preparations which must be kept under an inert atmosphere.
  - Criteria for use
    - Normally limited to special cases, e.g. certain organo metallic compounds.
- S 7 **Keep container tightly closed**
- Applicability
    - Organic peroxides.
    - Substances and preparations which can give off very toxic, toxic, harmful, extremely flammable or highly flammable vapours.
    - Substances and preparations which on contact with moisture give off highly flammable gases.
    - Highly flammable solids.
  - Criteria for use
    - *Obligatory* for organic peroxides in the combination of S 3/7/9.
    - Recommended for the other fields of application mentioned above.
- S 8 **Keep container dry**
- Applicability
    - Substances and preparations which may react violently with water.
    - Substances and preparations which on contact with water liberate highly flammable gases.
    - Substances and preparations which on contact with water liberate very toxic or toxic gases.
  - Criteria for use
    - Normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R 14, R 15 in particular, and R 29.
- S 9 **Keep container in a well-ventilated place**
- Applicability
    - Organic peroxides.
    - Volatile substances and preparations which may give off very toxic, toxic or harmful vapours.
    - Extremely flammable or highly flammable liquids and gases.
  - Criteria for use
    - *Obligatory* for organic peroxides in the combination S 3/7/9.
    - Recommended for volatile substances and preparations which may give off very toxic, toxic or harmful vapours.
    - Recommended for extremely flammable or highly flammable liquids or gases.
- S 12 **Do not keep the container sealed**
- Applicability
    - Substances and preparations which will by giving off gases or vapours be liable to burst the container.
  - Criteria for use
    - Normally limited to the special cases mentioned above.

- S 13 Keep away from food, drink and animal feedingstuffs**
- **Applicability**
    - Very toxic, toxic and harmful substances and preparations.
  - **Criteria for use**
    - Recommended when such substances and preparations are likely to be used by members of the general public.
- S 14 Keep away from . . . (incompatible materials to be indicated by the manufacturer)**
- **Applicability**
    - Organic peroxides.
  - **Criteria for use**
    - *Obligatory* for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to produce a particular risk.
- S 15 Keep away from heat**
- **Applicability**
    - Substances and preparations which may decompose or which may react spontaneously under the effect of heat.
  - **Criteria for use**
    - Normally limited to special cases, e.g. monomers but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.
- S 16 Keep away from sources of ignition — No smoking**
- **Applicability**
    - Extremely flammable or highly flammable liquids and gases.
  - **Criteria for use**
    - Recommended for the substances and preparations mentioned above but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.
- S 17 Keep away from combustible material**
- **Applicability**
    - Substances and preparations which may form explosive or spontaneously flammable mixtures with combustible material.
  - **Criteria for use**
    - Available for use in special cases; e.g. to emphasize R 8 and R 9.
- S 18 Handle and open container with care**
- **Applicability**
    - Substances and preparations liable to produce an overpressure in the container.
    - Substances and preparations which may form explosive peroxides.
  - **Criteria for use**
    - Normally limited to the abovementioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely to be used by members of the general public.

**S 20 When using do not eat or drink**

- Applicability
  - Very toxic, toxic and corrosive substances and preparations.
- Criteria for use
  - Normally limited to special cases (e.g. arsenic and arsenic compounds; fluoracetates) in particular when any of these are likely to be used by members of the general public.

**S 21 When using do not smoke**

- Applicability
  - Substances and preparations which produce toxic products on combustion.
- Criteria for use
  - Normally limited to special cases (e.g. halogenated compounds).

**S 22 Do not breathe dust**

- Applicability
  - All solid dangerous substances and preparations.
- Criteria for use
  - Recommended for those substances and preparations mentioned above which are liable to form inhalable dusts, and when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have been ascribed. However may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 42.

**S 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)**

- Applicability
  - All liquid or gaseous dangerous substances and preparations.
- Criteria for use
  - Recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have to be ascribed. However, may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 42.
  - Recommended for substances and preparations in the form of aerosols which are likely to be used by members of the general public.

**S 24 Avoid contact with skin**

- Applicability
  - All dangerous substances and preparations.
- Criteria for use
  - Recommended when it is necessary to draw the attention of the user to skin contact risks, not mentioned in the risk phrases which have to be ascribed. However, may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 43.

**S 25 Avoid contact with eyes**

- Applicability
  - Corrosive or irritant substances and preparations.
- Criteria for use
  - Normally limited to special cases, i.e. when it is considered essential to emphasize the risk to eyes denoted by use of R 34, R 35, R 36 or R 41. Thus important if these substances and preparations are likely to be used by members of the general public and eye or face protection may not be available.



**S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice**

- Applicability
  - Corrosive or irritant substances and preparations.
- Criteria for use
  - *Obligatory* for corrosive substance and preparations and those to which R 41 has already been ascribed.
  - Recommended for irritant substances to which the risk phrase R 36 has already been ascribed.

**S 27 Take off immediately all contaminated clothing**

- Applicability
  - Organic peroxides.
  - Very toxic, toxic or corrosive substances and preparations.
- Criteria for use
  - *Obligatory* for organic peroxides.
  - Recommended for very toxic and toxic substances and preparations which are easily absorbed by the skin and for corrosive substances and preparations unless safety phrase S 36 can be considered sufficient by itself.

**S 28 After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer)**

- Applicability
  - Very toxic, toxic or corrosive substances and preparations.
- Criteria for use
  - Recommended for the substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid.

**S 29 Do not empty into drains**

- Applicability
  - Extremely or highly flammable liquids.
- Criteria for use
  - Recommended for those extremely or highly flammable liquids which are immiscible with water. The intention is to avoid accidents (e.g. fire, explosion) and not to emphasize general pollution problems.

**S 30 Never add water to this product**

- Applicability
  - Substances and preparations which react violently with water.
- Criteria for use
  - Normally limited to special cases (e.g. sulphuric acid) and may be used, as appropriate to give the clearest possible information, either to emphasize R 14 or as an alternative to R 14.

**S 33 Take precautionary measures against static discharges**

- Applicability
  - Extremely or highly flammable substances and preparations.
- Criteria for use
  - Recommended for substances and preparations used in industry which do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by members of the general public.

**S 34 Avoid shock and friction**

- Applicability
  - Explosive substances and preparations.
- Criteria for use
  - *Obligatory* for and normally limited to explosive organic peroxides.

**S 35 This material and its container must be disposed of in a safe way**

- Applicability
  - Explosive substances and preparations.
  - *Very toxic and toxic* substances and preparations.
- Criteria for use
  - *Obligatory* for explosive substances and preparations other than organic peroxides.
  - Recommended for very toxic and toxic substances and preparations, particularly when such substances and preparations are likely to be used by members of the general public.

**S 36 Wear suitable protective clothing**

- Applicability
  - *Very toxic, toxic or harmful* substances and preparations.
  - Corrosive substances and preparations.
- Criteria for use
  - Recommended for substances and preparations used in industry which are:
    - very toxic, toxic or corrosive, and/or
    - harmful and easily absorbed by the skin and/or
    - liable to damage health by prolonged exposure.

**S 37 Wear suitable gloves**

- Applicability
  - *Very toxic, toxic, harmful or corrosive* substances and preparations.
  - Organic peroxides.
  - Substances and preparations irritating to the skin.
- Criteria for use
  - Recommended for very toxic, toxic and corrosive substances and preparations, when S 36 is not used (e.g. viz general public).
  - Recommended for organic peroxides as combination S 37/39.
  - Recommended for substances and preparations irritating to the skin particularly when R 38 is not shown on the label.

**S 38 In case of insufficient ventilation wear suitable respiratory equipment**

- Applicability
  - *Very toxic or toxic* substances and preparations.
- Criteria for use
  - Normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture.

- S 39 Wear eye/face protection**
- Applicability
    - Organic peroxides.
    - Corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes.
    - Very toxic and toxic substances and preparations.
  - Criteria for use
    - Recommended for organic peroxides as the combination S 37/39.
    - Recommended for the corrosive substances and preparations mentioned above, in particular when there is a risk of splashing.
    - Normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin.
- S 40 To clean the floor and all objects contaminated by this material use . . . (to be specified by the manufacturer)**
- Applicability
    - All dangerous substances and preparations.
  - Criteria for use
    - Normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (e.g. where absorption by powdered material, dissolution by solvent etc. is necessary) and where it is important for health and or safety reasons to provide a warning on the label.
- S 41 In case of fire and/or explosion do not breathe fumes**
- Applicability
    - Dangerous substances and preparations which on combustion give off very toxic or toxic gases.
  - Criteria for use
    - Normally limited to special cases.
- S 42 During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)**
- Applicability
    - Substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken.
  - Criteria for use
    - Normally limited to special cases.
- S 43 In case of fire use . . . (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add: Never use water)**
- Applicability
    - Extremely flammable, highly flammable and flammable substances and preparations.
  - Criteria for use
    - *Obligatory* for substances and preparations which in contact with water or damp air, evolve highly flammable gases.
    - Recommended for extremely flammable, highly flammable and flammable substances and preparations, particularly when they are immiscible with water.
- S 44 If you feel unwell seek medical advice (show the label where possible)**
- Applicability
    - Toxic substances and preparations.
  - Criteria for use
    - *Obligatory* for the substances and preparations mentioned above when used in industry and not likely to be used by members of the general public.

- S 45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
- Applicability
    - Very toxic substances and preparations.
    - Toxic substances and preparations.
  - Criteria for use
    - *Obligatory* for the very toxic substances and preparations mentioned above.
    - *Obligatory* for toxic substances and preparations mentioned above when likely to be used by members of the general public.
- S 46 If swallowed, seek medical advice immediately and show this container or label
- Applicability
    - All dangerous substances and preparations other than those which are toxic or very toxic.
  - Criteria for use
    - *Obligatory* for all dangerous substances and preparations mentioned above which are likely to be used by members of the general public, unless there is no reason to fear any danger from swallowing, particularly by children.
- S 47 Keep at temperature not exceeding ... °C (to be specified by the manufacturer)
- Applicability
    - Substances and preparations which become unstable at a certain temperature.
  - Criteria for use
    - Normally limited to special cases (e.g. certain organic peroxides).
- S 48 Keep wetted with ... (appropriate material to be specified by the manufacturer)
- Applicability
    - Substances and preparations which may become very sensitive to sparks, friction or impact if allowed to dry out.
  - Criteria for use
    - Normally limited to special cases, e.g. nitrocelluloses.
- S 49 Keep only in the original container
- Applicability
    - Substances and preparations sensitive to catalytic decomposition.
  - Criteria for use
    - Normally limited to substances and preparations sensitive to catalytic decomposition; e.g. certain organic peroxides.
- S 50 Do not mix with ... (to be specified by the manufacturer)
- Applicability
    - Substances and preparations which may react with the specified product to evolve very toxic or toxic gases.
    - Organic peroxides.
  - Criteria for use
    - Recommended for substances and preparations mentioned above which are likely to be used by members of the general public, when it is a better alternative to R 31 or R 32.
    - *Obligatory* with certain peroxides which may give violent reaction with accelerators or promoters.

- S 51 Use only in well-ventilated areas**
- Applicability
    - Substances and preparations likely to or intended to produce vapours, dusts, sprays, fumes, mists, etc. which give rise to inhalation risks or to a fire or explosion risk.
  - Criteria for use
    - Recommended when use of S 38 would not be appropriate. Thus important when such substances and preparations are likely to be used by members of the general public.
- S 52 Not recommended for interior use on large surface areas**
- Applicability
    - Volatile, very toxic, toxic and harmful substances and preparations containing them.
  - Criteria for use
    - Recommended when damage to health is likely to be caused by prolonged exposure to these substances by reason of its volatilization from large treated surfaces in the home or other enclosed places where persons congregate.
- S 53 Avoid exposure — obtain special instructions before use**
- Applicability
    - Carcinogenic, mutagenic and/or teratogenic substances and preparations
  - Criteria for use
    - Obligatory for substances and preparations mentioned above to which R 45, R 46 and/or R 47 have been ascribed.

## 5. LABELLING PROPOSAL

- 5.1. The labelling proposal for a substance should be derived from the total number of symbols, risk phrases and safety phrases assigned**
- 5.2. The labelling proposal for a preparation should be derived in a way analogous to that for a substance and in particular be based on:**
- (a) determination of the risk categories according to the specific criteria laid down in each particular directive (on preparations);
  - (b) choice of the most relevant R and S phrases; whereas some risk phrases follow directly from the risk categories, other risk and safety phrases which are applicable shall be derived mainly from the R and S phrases assigned in accordance with sections 2 and 4 above to the constituent which most contributes to the dangerous properties of the preparation;
  - (c) in certain cases, particular directives give obligatory phrases for certain preparations (e.g. cyanoacrylate glues, paints intended for spraying). In these cases, these phrases shall always be mentioned.
- 5.3. Although the final choice of the most appropriate risk and safety phrases is primarily governed by the need to give all necessary information, consideration should also be given to the clarity and impact of the label. With clarity in mind, the necessary information should be expressed in a minimum number of phrases. Generally, up to four risk phrases and up to four safety phrases will be sufficient; for this purpose the combination phrases listed in Annexes III and IV are considered as single phrases. Whilst it may be possible to reduce the total number of phrases for substances and preparations classified for example as harmful, irritant or flammable, more than four risk and four safety phrases should only be specified in very particular cases.**

- 5.4. When more than four risk phrases are assigned to a substance or preparation, it is generally possible to eliminate phrases which refer to the lowest degree of hazard providing that the overall effectiveness of the special warning is not thereby reduced. It is frequently found that certain such risk phrases are rendered superfluous by a suitable choice of safety phrase.

The risk phrases which correspond to the symbols indicated on the label are obligatory except that the risk phrases 'extremely flammable' or 'highly flammable' need not be indicated where they repeat the wording of the indication of danger used with a symbol.

- 5.5. The final choice of safety phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation:

- safety phrases which give obvious advice in relation to risk phrases are generally omitted from the label unless used to give particular emphasis to a specific warning;
- certain safety phrases, e.g. S 2, have particular relevance to substances and preparations intended to be used by the public, other phrases have particular relevance to persons at work. Phrases should be chosen with the intended use in view;
- particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations, e.g. spraying or other aerosol effects.

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#### Commission statement

With regard to 3.1.3, and in particular to the last paragraph of 3.1.3, the Commission states that, should it envisage making use of the procedure of Article 21, it is prepared to consult in advance appropriate experts designated by Member States and having special qualifications with respect to either carcinogenicity, mutagenicity or teratogenicity.

This consultation will take place in the framework of the normal consultation procedure with national experts and/or in the framework of existing committees. The same will be the case when substances already included in Annex I must be reclassified in respect of their carcinogenic, mutagenic or teratogenic effects.

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ANNEX VII

**INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ('BASE SET') REFERRED TO IN ARTICLE 6 (1)**

When giving notification the manufacturer or any other person placing a substance on the market shall provide the information set out below.

If it is not technically possible or if it does not appear necessary to give information, the reasons shall be stated.

Tests must be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The bodies carrying out the tests shall comply with the principles of good current laboratory practice.

When complete studies and the results obtained are submitted, it shall be stated that the tests were conducted using the substance to be marketed. The composition of the sample shall be indicated.

In addition, the description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the technical dossier, together with the name of the body or bodies responsible for carrying out the studies.

**1. IDENTITY OF THE SUBSTANCE**

**1.1 Name**

1.1.1. Names in the IUPAC nomenclature

1.1.2. Other names (usual name, trade name, abbreviation)

1.1.3. CAS number (if available)

**1.2. Empirical and structural formula**

**1.3 Composition of the substance**

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including isomers and by-products

1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm; ...%

1.3.5. Spectral data (UV, IR, NMR)

**1.4. Methods of detection and determination**

A full description of the methods used or the appropriate bibliographical references

**2. INFORMATION ON THE SUBSTANCE**

**2.1. Proposed uses**

**2.1.1. Types of use**

Describe: the function of the substance .....  
the desired effects .....

- 2.1.2. Fields or application with approximate breakdown
  - (a) closed system
    - industries .....
    - farmers and skilled trades .....
    - use by the public at large .....
  - (b) open system
    - industries .....
    - farmers and skilled trades .....
    - use by the public at large .....
  
- 2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
  - 2.2.1. Overall production and/or imports in order of tonnes per year 1; 10; 50; 100; 500; 1 000 and 5 000
    - first 12 months .....tonnes/year
    - thereafter .....tonnes/year
  - 2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2, expressed as a percentage
    - first 12 months .....
    - thereafter .....
  
- 2.3. Recommended methods and precautions concerning:
  - 2.3.1. handling .....
  - 2.3.2. storage .....
  - 2.3.3. transport .....
  - 2.3.4. fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
  - 2.3.5. other dangers, particularly chemical reaction with water
  
- 2.4. Emergency measures in the case of accidental spillage
  
- 2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
  
- 3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE
  - 3.1. Melting point  
.....°C
  - 3.2. Boiling point  
..... °C ..... Pa
  - 3.3. Relative density  
..... (D<sub>4</sub><sup>20</sup>)
  - 3.4. Vapour pressure  
..... Pa at ..... °C  
..... Pa at ..... °C
  - 3.5. Surface tension  
..... M/m (..... °C)



- 3.6. **Water solubility**  
 ..... mg/litre (..... °C)
- 3.7. **Fat solubility**  
 Solvent — oil (to be specified)  
 ..... mg/100 g solvent (..... °C)
- 3.8. **Partition coefficient**  
 n-octanol/water
- 3.9. **Flash point**  
 ..... °C  open cup  closed cup
- 3.10. **Flammability** (within the meaning of the definition given in Article 2 (2) (c), (d) and (e))
- 3.11. **Explosive properties** (within the meaning of the definition given in Article 2 (2) (a))
- 3.12. **Auto-flammability**  
 ..... °C
- 3.13. **Oxidizing properties** (within the meaning of the definition given in Article 2 (2) (b))
  
- 4. **TOXICOLOGICAL STUDIES**
- 4.1. **Acute toxicity**
- 4.1.1. **Administered orally**  
 LD<sub>50</sub>..... mg/kg  
 Effects observed, including in the organs .....
- 4.1.2. **Administered by inhalation**  
 LC<sub>50</sub>..... (ppm) Duration of exposure .....hours  
 Effects observed, including in the organs .....
- 4.1.3. **Administered cutaneously (percutaneous absorption)**  
 LD<sub>50</sub>..... mg/kg  
 Effects observed, including in the organs .....
- 4.1.4. **Substances other than gases shall be administered via two routes at least, one of which should be the oral route. The other route will depend on the intended use and on the physical properties of the substance.**  
 Gases and volatile liquids should be administered by inhalation (a minimum period of administration of four hours).  
 In all cases, observation of the animals should be carried out for at least 14 days.  
 Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.  
 The experiments in 4.1.1, 4.1.2 and 4.1.3 shall be carried out on both male and female subjects.
- 4.1.5. **Skin irritation**  
 The substance should be applied to the shaved skin of an animal, preferably an albino rabbit.  
 Duration of exposure ..... hours

- 4.1.6. Eye irritation
  - The rabbit is the preferred animal.
  - Duration of exposure ..... hours
- 4.1.7. Skin sensitization
  - To be determined by a recognized method using a guinea-pig.
- 4.2. Sub-acute toxicity
  - 4.2.1. Sub-acute toxicity (28 days)
    - Effects observed on the animal and organs according to the concentrations used, including clinical and laboratory investigations .....
    - Dose for which no toxic effect is observed .....
  - 4.2.2. A period of daily administration (five to seven days per week) for at least four weeks should be chosen. The route of administration should be the most appropriate having regard to the intended use, the acute toxicity and the physical and chemical properties of the substance.
    - Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.
- 4.3. Other effects
  - 4.3.1. Mutagenicity (including carcinogenic pre-screening test)
  - 4.3.2. The substance should be examined during a series of two tests, one of which should be bacteriological, with and without metabolic activation, and one non-bacteriological.
- 5. ECOTOXICOLOGICAL STUDIES
  - 5.1. Effects on organisms
    - 5.1.1. Acute toxicity for fish
      - LC<sub>50</sub>..... (ppm) Duration of exposure determined in accordance with Annex V (C)
      - Species selected (one or more) .....
    - 5.1.2. Acute toxicity for daphnia
      - LC<sub>50</sub>..... (ppm) Duration of exposure determined in accordance with Annex V (C)
  - 5.2. Degradation
    - biotic
    - abiotic
    - The BOD and the BOD/COD ratio should be determined as a minimum
- 6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS
  - 6.1. For industry/skilled trades
    - 6.1.1. Possibility of recovery .....
    - 6.1.2. Possibility of neutralization .....
    - 6.1.3. Possibility of destruction:
      - controlled discharge .....
      - incineration .....

- water purification station .....
- others .....

**6.2. For the public at large**

**6.2.1. Possibility of recovery .....**

**6.2.2. Possibility of neutralization .....**

**6.2.3. Possibility of destruction:**

- controlled discharge .....
- incineration .....
- water purification station .....
- others .....

—

## ANNEX VIII

## ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER ARTICLE 6 (5)

Any person who has notified a substance to a competent authority in accordance with the requirements of Article 6 of this Directive shall provide at the request of the authority further information and carry out additional tests as provided for in this Annex.

If it is not technically possible or if it does not appear necessary to give information, the reasons shall be stated.

Tests shall be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The bodies carrying out the tests shall comply with the principles of good current laboratory practice.

When complete studies and the results obtained are submitted, it shall be stated that the tests were conducted using the substance marketed. The composition of the sample shall be indicated.

In addition the description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the technical dossier, together with the name of the body or bodies responsible for carrying out the studies.

## LEVEL 1

Taking into account:

- current knowledge of the substance,
- known and planned uses,
- the results of the tests carried out in the context of the base set,

the competent authority may require the following additional studies where the quantity of a substance placed on the market by a notifier reaches a level of 10 tonnes per year or a total of 50 tonnes and if the conditions specified after each of the tests are fulfilled in the case of that substance.

## Toxicological studies

- Fertility study (one species, one generation, male and female, most appropriate route of administration)

If there are equivocal findings in the first generation, study of a second generation is required.

It is also possible in this study to obtain evidence on teratogenicity.

If there are indications of teratogenicity, full evaluation of teratogenic potential may require a study in a second species.

- Teratology study (one species, most appropriate route of administration)

This study is required if teratogenicity has not been examined or evaluated in the preceding fertility study.

- Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration)

If the results of the sub-acute study in Annex VII or other relevant information demonstrate the need for further investigation, this may take the form of a more detailed examination of certain effects, or more prolonged exposure, e.g. 90 days or longer (even up to two years).

The effects which would indicate the need for such a study could include for example:

- (a) serious or irreversible lesions;
- (b) a very low or absence of a 'no effect' level;
- (c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.

— Additional mutagenesis studies (including screening for carcinogenesis)

A. If results of the mutagenesis tests are negative, a test to verify mutagenesis and a test to verify carcinogenesis screening are obligatory.

If the results of the mutagenesis verification test are also negative, further mutagenesis tests are not necessary at this level; if the results are positive, further mutagenesis tests are to be carried out (see B).

If the results of the carcinogenesis screening verification test are also negative, further carcinogenesis screening verification tests are not necessary at this level; if the results are positive further carcinogenesis screening verification tests are to be carried out (see B).

B. If the results of the mutagenesis tests are positive (a single positive test means positive), at least two verification tests are necessary at this level. Both mutagenesis tests and carcinogenesis screening tests should be considered here. A positive result of a carcinogenesis screening test should lead to a carcinogenesis study at this level.

Ecotoxicology studies

— An algal test: one species, growth inhibition test.

— Prolonged toxicity study with *Daphnia magna* (21 days, thus study should also include determination of the 'no-effect level' for reproduction and the 'no-effect level' for lethality).

The conditions under which this test is carried out shall be determined in accordance with the procedure described in Article 21 in the light of the methods laid down in Annex V (C) for acute toxicity tests with *Daphnia*.

— Test on a higher plant.

— Test on an earthworm.

— Prolonged toxicity study with fish (e.g. *Oryzias*, *Jordanella*, etc.; at least a period of 14 days; this study should also include determination of the 'threshold level').

The conditions under which this test is carried out shall be determined in accordance with the procedure described in Article 21 in the light of the methods adopted under Annex V (C) for acute toxicity tests with fish.

— Tests for species accumulation; one species, preferably fish (e.g. *Poecilia reticulata*).

— Prolonged biodegradation study, if sufficient (bio)degradation has not been proved by the studies laid down in Annex VII, another test (dynamic) shall be chosen with lower concentrations and with a different inoculum (e.g. flow-through system).

In any case, the notifier shall inform the competent authority if the quantity of a substance placed on the market reaches a level of 100 tonnes per year or a total of 500 tonnes.

On receipt of such notification and if the requisite conditions are fulfilled, the competent authority, within a time limit it will determine, shall require the above tests to be carried out unless in any particular case an alternative scientific study would be preferable.

LEVEL 2

If the quantity of a substance placed on the market by a notifier reaches 1 000 tonnes per year or a total of 5 000 tonnes, the notifier shall inform the competent authority. The latter shall then draw up a programme of tests to be carried out by the notifier in order to enable the competent authority to evaluate the risks of the substance for man and the environment.

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:

- chronic toxicity study,
- carcinogenicity study,
- fertility study (e.g. three-generation study); only if an effect on fertility has been established at level 1,
- teratology study (non-rodent species) study to verify teratology study at level 1 and experiment additional to the level 1 study, if effects on embryos/foetuses have been established,
- acute and sub-acute toxicity study on second species: only if results of level 1 studies indicate a need for this. Also results of biotransformation studies and studies on pharmacokinetics may lead to such studies,
- additional toxicokinetic studies.

#### Ecotoxicology

- Additional tests for accumulation, degradation and mobility.

The purpose of this study should be to determine any accumulation in the food chain.

For further bioaccumulation studies special attention should be paid to the solubility of the substance in water and to its n-octanol/water partition coefficient.

The results of the level 1 accumulation study and the physicochemical properties may lead to a large-scale flow-through test.

- Prolonged toxicity study with fish (including reproduction).
  - Additional toxicity study (acute and sub-acute) with birds (e.g. quails): if accumulation factor is greater than 100.
  - Additional toxicity study with other organisms (if this proves necessary).
  - Absorption — desorption study where the substance is not particularly degradable.
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ANNEX IX

- A. PROVISIONS RELATING TO CHILD-RESISTANT FASTENINGS: for the record
  - B. PROVISIONS RELATING TO TACTILE WARNINGS OF DANGER: for the record
-

*not included:*

**ANNEX I**

List of dangerous substances classified in the order of the atomic number of the element most characteristic of their properties

**ANNEX III**

Nature of the special risks attaching to dangerous substances

**ANNEX IV**

Safety advice concerning dangerous chemical substances

**ANNEX V**

Test methods for the determination of physicochemical, toxicological and ecotoxicological properties listed in Annexes VII and VIII

**Indications of danger in Spanish (ES) and Portuguese (PT)**

No Council or Commission Directive has yet been promulgated directly to amend Annex II by the addition of Spanish and Portuguese language equivalents of these words and phrases. However, such equivalents are indirectly to be found in the European Community legislation: see the Spanish and Portuguese versions of Annex VI, Part II D, para 2.4 enacted by Directive 79/831/EEC, Article 3 and Annex VI (Spanish and Portuguese Special Editions of the Secondary Legislation, Part 13, Volume 10, p. 228) and amended by Directive 83/467/EEC, Article 1.9 and Annex III (Ibid., Part 13, Volume 14, p. 168). These equivalents have been included in the text of Annex II printed in this volume, but to give notice of their special legislative status they are marked with asterisks in front of the language indicators, thus – \*ES or \*PT.



## COMMISSION DECISION

of 21 December 1984

concerning the list of chemical substances notified pursuant to Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(85/71/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>(1)</sup>, as last amended by Directive 79/831/EEC<sup>(2)</sup>, and in particular Article 13 thereof,

Whereas Article 13 (2) of Directive 67/548/EEC provides that the Commission shall keep a list of substances notified pursuant to the Directive;

Whereas Article 13 (3) of Directive 67/548/EEC providing that the form of the list and the information contained in it are to be decided by the procedure set out in Article 21;

Whereas the list should be published in accordance with the objectives of Directive 67/548/EEC, namely the protection of man and the environment against risks which could arise from the placing on the market of new substances;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Sector of Dangerous Substances and Preparations,

HAS DECIDED AS FOLLOWS:

*Article 1*

The list of chemical substances to be kept by the Commission pursuant to Article 13 (2) of Directive 67/548/EEC, hereinafter referred to as 'the list', shall be drawn up in accordance with the provisions set out in the Annex.

*Article 2*

The list of these chemical substances notified pursuant to Article 6 of Directive 67/548/EEC before 1 July of the year of the publication of the Eines Inventory shall be published in the *Official Journal of the European Communities* not later than 31 December of the same year. Supplements to the list shall be published in the *Official Journal of the European Communities* not later than 31 December of each year thereafter, covering the period 1 July of the previous year to 30 June of the year of publication.

Done at Brussels, 21 December 1984.

*For the Commission*

Karl-Heinz NARJES

*Member of the Commission*

<sup>(1)</sup> OJ No 196, 16. 8. 1967, p. 1.

<sup>(2)</sup> OJ No L 259, 15. 10. 1979, p. 10.

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**ANNEX****Procedure for the preparation of the list**

1. The list shall be prepared and maintained by the Commission on the basis of the information supplied to it by the competent authorities of the Member States pursuant to Article 9 of the Directive.
2. The list shall contain the following information in respect of each substance included :
  - the number of the notification,
  - the identity of the substance.

In addition, in respect of a dangerous substance, the list shall include its classification in accordance with Article 4 of the Directive, after it has been recorded in Annex I thereto, with its EEC number.

3. Subject to the provisions of paragraph 4, the identity of the substance shall be recorded under :
  - its trade name(s), and
  - its chemical name in the IUPAC Nomenclature.
4. Where the competent authority of a Member State has so requested pursuant to Article 11 of the Directive, the identity of a substance may be recorded under its trade name(s) alone as provided by the notifier pursuant to Article 6.1 of the Directive.

In the case of a dangerous substance, the identity of the substance may be so recorded until such time as the substance is added to Annex I of the Directive. After this addition to Annex I, the names contained therein will be added to the list.

In the case of a substance not classified as dangerous, the identity of the substance may be so recorded for a period of no longer than three years following its first inclusion in the list. However, for the purpose of ensuring observance of Article 7.3 of the Directive, where in the opinion of the competent authority concerned, the chemical name in the IUPAC Nomenclature itself reveals information concerning commercial exploitation or manufacturing, the substance shall be recorded under its trade name(s) alone for so long as this competent authority considers it necessary.

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**Declaration by the Commission**

The Commission undertakes the commitment to use systematically, each time it is possible, the IUPAC name for addition of new dangerous substances to Annex I of the Directive.

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**COUNCIL DIRECTIVE**  
**of 24 June 1982**  
**on the major-accident hazards of certain industrial activities**  
**(82/501/EEC)**

(as amended by Council Directive 87/216/EEC of 19 March 1987 (OJ L 85, 28.3.87, p. 36))

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas the objectives and principles of the Community environment policy were fixed by the action programmes of the European Communities on the environment of 22 November 1973 <sup>(4)</sup> and 17 May 1977 <sup>(5)</sup>, and having regard in particular to the principle that the best policy consists in preventing the creation of pollution or nuisances at source; whereas to this end technical progress should be conceived and directed so as to meet the concern for the protection of the environment;

Whereas the objectives of the Community policy of health and safety at work were fixed by the Council

resolution of 29 June 1978 on an action programme of the European Communities on safety and health at work <sup>(6)</sup>, and having regard in particular to the principle that the best policy consists in obviating possible accidents at source by the integration of safety at the various stages of design, construction and operation;

Whereas the Advisory Committee on Safety, Hygiene and Health Protection at Work, set up by Decision 74/325/EEC <sup>(7)</sup>, has been consulted;

Whereas the protection of the public and the environment and safety and health protection at work call for particular attention to be given to certain industrial activities capable of causing major accidents; whereas such accidents have already occurred in the Community and have had serious consequences for workers and, more generally, for the public and the environment;

Whereas, for every industrial activity which involves, or may involve, dangerous substances and which, in the event of a major accident, may have serious consequences for man and the environment, the manufacturer must take all necessary measures to prevent such accident and to limit the consequences thereof;

<sup>(1)</sup> OJ No C 212, 24. 8. 1979, p. 4.

<sup>(2)</sup> OJ No C 175, 14. 7. 1980, p. 48.

<sup>(3)</sup> OJ No C 182, 21. 7. 1980, p. 25.

<sup>(4)</sup> OJ No C 112, 20. 12. 1973, p. 1.

<sup>(5)</sup> OJ No C 139, 13. 6. 1977, p. 1.

<sup>(6)</sup> OJ No C 165, 11. 7. 1978, p. 1.

<sup>(7)</sup> OJ No L 185, 9. 7. 1974, p. 15.

Whereas the training and information of persons working on an industrial site can play a particularly important part in preventing major accidents and bringing the situation under control in the event of such accidents;

Whereas, in the case of industrial activities which involve or may involve substances that are particularly dangerous in certain quantities, it is necessary for the manufacturer to provide the competent authorities with information including details of the substances in question and high-risk installations and situations, with a view to reducing the hazards of major accidents and enabling the necessary steps to be taken to reduce their consequences;

Whereas it is necessary to lay down that any person outside the establishment liable to be affected by a major accident should be appropriately informed of the safety measures to be taken and of the correct behaviour to be adopted in the event of an accident;

Whereas, if a major accident occurs, the manufacturer must immediately inform the competent authorities and communicate the information necessary for assessing the impact of that accident;

Whereas Member States should forward information to the Commission regarding major accidents occurring on their territory, so that the Commission can analyze the hazards from major accidents;

Whereas this Directive does not preclude the conclusion by a Member State of agreements with third countries concerning the exchange of information to which it is privy at internal level other than that obtained through the Community arrangements for the exchange of information set up by this Directive;

Whereas disparity between provisions already applicable or being prepared in the various Member States on measures to prevent major accidents and limit their consequences for man and the environment may create unequal conditions of competition and hence directly affect the functioning of the common market; whereas the approximation of laws provided for in Article 100 of the Treaty should therefore be carried out in this field;

Whereas it seems necessary to combine this approximation of laws with action by the Community aimed at attaining one of the Community objectives in the field of environmental protection and health and safety at work; whereas, in pursuance of this aim, certain specific provisions should therefore be laid down; whereas, since the necessary powers have not

been provided by the Treaty, Article 235 of the Treaty should be invoked,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

1. This Directive is concerned with the prevention of major accidents which might result from certain industrial activities and with the limitation of their consequences for man and the environment. It is directed in particular towards the approximation of the measures taken by Member States in this field.

2. For the purposes of this Directive:

(a) *Industrial activity* means:

- any operation carried out in an industrial installation referred to in Annex I involving, or possibly involving, one or more dangerous substances and capable of presenting major-accident hazards, and also transport carried out within the establishment for internal reasons and the storage associated with this operation within the establishment,
- any other storage in accordance with the conditions specified in Annex II;

(b) *Manufacturer* means:

- any person in charge of an industrial activity;

(c) *Major accident* means:

- an occurrence such as a major emission, fire or explosion resulting from uncontrolled developments in the course of an industrial activity, leading to a serious danger to man, immediate or delayed, inside or outside the establishment, and/or to the environment, and involving one or more dangerous substances;

(d) *Dangerous substances* means:

- for the purposes of Articles 3 and 4, substances generally considered to fulfil the criteria laid down in Annex IV,
- for the purposes of Article 5, substances in the lists in Annex III and Annex II in the quantities referred to in the second column.

*Article 2*

This Directive does not apply to the following:

1. nuclear installations and plant for the processing of radioactive substances and material;
2. military installations;
3. the manufacture and separate storage of explosives, gunpowder and munitions;
4. extraction and other mining operations;
5. installations for the disposal of toxic and dangerous waste which are covered by Community Acts in so far as the purpose of those Acts is the prevention of major accidents.

*Article 3*

Member States shall adopt the provisions necessary to ensure that, in the case of any of the industrial activities specified in Article 1, the manufacturer is obliged to take all the measures necessary to prevent major accidents and to limit their consequences for man and the environment.

*Article 4*

Member States shall take the measures necessary to ensure that all manufacturers are required to prove to the competent authority at any time, for the purposes of the controls referred to in Article 7 (2), that they have identified existing major-accident hazards, adopted the appropriate safety measures, and provided the persons working on the site with information, training and equipment in order to ensure their safety.

*Article 5*

1. Without prejudice to Article 4, Member States shall introduce the necessary measures to require the manufacturer to notify the competent authorities specified in Article 7:

- if, in an industrial activity as defined in Article 1 (2) (a), first indent, one or more of the dangerous substances listed in Annex III are involved, or it is recognized that they may be involved, in the quantities laid down in the said Annex, such as:
  - substances stored or used in connection with the industrial activity concerned,
  - products of manufacture,
  - by-products, or
  - residues,

- or if, in an industrial activity as defined in Article 1 (2) (a), second indent, one or more of the dangerous substances listed in Annex II are stored in the quantities laid down in the second column of the same Annex.

The notification shall contain the following:

- (a) information relating to substances listed, respectively, in Annex II and Annex III, that is to say:
  - the data and information listed in Annex V,
  - the stage of the activity in which the substances are involved or may be involved,
  - the quantity (order of magnitude),
  - the chemical and/or physical behaviour under normal conditions of use during the process,
  - the forms in which the substances may occur or into which they may be transformed in the case of abnormal conditions which can be foreseen,
  - if necessary, other dangerous substances whose presence could have an effect on the potential hazard presented by the relevant industrial activity;
- (b) information relating to the installations, that is to say:
  - the geographical location of the installations and predominant meteorological conditions and sources of danger arising from the location of the site,
  - the maximum number of persons working on the site of the establishment and particularly of those persons exposed to the hazard,
  - a general description of the technological processes,
  - a description of the sections of the establishment which are important from the safety point of view, the sources of hazard and the conditions under which a major accident could occur, together with a description of the preventive measures planned,
  - the arrangements made to ensure that the technical means necessary for the safe operation of plant and to deal with any malfunctions that arise are available at all times;
- (c) information relating to possible major-accident situations, that is to say:
  - emergency plans, including safety equipment, alarm systems and resources available for use

inside the establishments in dealing with a major accident,

- any information necessary to the competent authorities to enable them to prepare emergency plans for use outside the establishment in accordance with Article 7 (1),
- the names of the person and his deputies or the qualified body responsible for safety and authorized to set the emergency plans in motion and to alert the competent authorities specified in Article 7.

2. In the case of new installations, the notification referred to in paragraph 1 must reach the competent authorities a reasonable length of time before the industrial activity commences.

3. The notification specified in paragraph 1 shall be updated periodically to take account of new technical knowledge relative to safety and of developments in knowledge concerning the assessment of hazards.

4. In the case of industrial activities for which the quantities, by substance, laid down in Annex II or III, as appropriate, are exceeded in a group of installations belonging to the same manufacturer which are less than 500 metres apart, the Member States shall take the necessary steps to ensure that the manufacturer supplies the amount of information required for the notification referred to in paragraph 1, without prejudice to Article 7, having regard to the fact that the installations are a short distance apart and that any major-accident hazards may therefore be aggravated.

#### Article 6

In the event of modification of an industrial activity which could have significant consequences as regards major-accident hazards, the Member States shall take appropriate measures to ensure that the manufacturer:

- revises the measures specified in Articles 3 and 4,
- informs the competent authorities referred to in Article 7 in advance, if necessary, of such modification in so far as it affects the information contained in the notification specified in Article 5.

#### Article 7

1. The Member States shall set up or appoint the competent authority or authorities who, account being taken of the responsibility of the manufacturer, are responsible for:

- receiving the notification referred to in Article 5 and the information referred to in the second indent of Article 6,
- examining the information provided,
- ensuring that an emergency plan is drawn up for action outside the establishment in respect of whose industrial activity notification has been given,

and, if necessary,

- requesting supplementary information,
- ascertaining that the manufacturer takes the most appropriate measures, in connection with the various operations involved in the industrial activity for which notification has been given, to prevent major accidents and to provide the means for limiting the consequences thereof.

2. The competent authorities shall organize inspections or other measures of control proper to the type of activity concerned, in accordance with national regulations.

#### Article 8

1. Member States shall ensure that persons liable to be affected by a major accident originating in a notified industrial activity within the meaning of Article 5 are informed in an appropriate manner of the safety measures and of the correct behaviour to adopt in the event of an accident.

2. The Member States concerned shall at the same time make available to the other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their own nationals.

#### Article 9

1. This Directive shall apply to both new and existing industrial activities.

2. 'New industrial activity' shall also include any modification to an existing industrial activity likely to have important implications for major-accident hazards.

3. In the case of existing industrial activities, this Directive shall apply at the latest on 8 January 1985.

However, as regards the application of Article 5 to an existing industrial activity, the Member States shall ensure that the manufacturer shall submit to the

competent authority, at the latest on 8 January 1985, a declaration comprising:

- name or trade name and complete address,
- registered place of business of the establishment and complete address,
- name of the director in charge,
- type of activity,
- type of production or storage,
- an indication of the substances or category of substances involved, as listed in Annexes II or III.

4. Moreover, Member States shall ensure that the manufacturer shall, at the latest on 8 July 1989, supplement the declaration provided for in paragraph 3, second subparagraph, with the data and information specified in Article 5. Manufacturers shall normally be obliged to forward such supplementary declaration to the competent authority; however, Member States may waive the obligation on manufacturers to submit the supplementary declaration; in that event such declaration shall be submitted to the competent authority at the explicit request of the latter.

#### Article 10

1. Member States shall take the necessary measures to ensure that, as soon as a major accident occurs, the manufacturer shall be required:

(a) to inform the competent authorities specified in Article 7 immediately;

(b) to provide them with the following information as soon as it becomes available:

- the circumstances of the accident,
- the dangerous substances involved within the meaning of Article 1 (2) (d),
- the data available for assessing the effects of the accident on man and the environment,
- the emergency measures taken;

(c) to inform them of the steps envisaged:

- to alleviate the medium and long-term effects of the accident,
- to prevent any recurrence of such an accident.

2. The Member States shall require the competent authorities:

(a) to ensure that any emergency and medium and long-term measures which may prove necessary are taken;

(b) to collect, where possible, the information necessary for a full analysis of the major accident and possibly to make recommendations.

#### Article 11

1. Member States shall inform the Commission as soon as possible of major accidents which have occurred within their territory and shall provide it with the information specified in Annex VI as soon as it becomes available.

2. Member States shall inform the Commission of the name of the organization which might have relevant information on major accidents and which is able to advise the competent authorities of the other Member States which have to intervene in the event of such an accident.

3. Member States may notify the Commission of any substance which in their view should be added to Annexes II and III and of any measures they may have taken concerning such substances. The Commission shall forward this information to the other Member States.

#### Article 12

The Commission shall set up and keep at the disposal of the Member States a register containing a summary of the major accidents which have occurred within the territory of the Member States, including an analysis of the causes of such accidents, experience gained and measures taken, to enable the Member States to use this information for prevention purposes.

#### Article 13

1. Information obtained by the competent authorities in pursuance of Articles 5, 6, 7, 9, 10 and 12 and by the Commission in pursuance of Article 11 may not be used for any purpose other than that for which it was requested.

2. However this Directive shall not preclude the conclusion by a Member State of agreements with third

countries concerning the exchange of information to which it is privy at internal level other than that obtained through the Community machinery for the exchange of information set up by the Directive.

3. The Commission and its officials and employees shall not divulge the information obtained in pursuance of this Directive. The same requirement shall apply to officials and employees of the competent authorities of the Member States as regards any information they obtain from the Commission.

Nevertheless, such information may be supplied:

- in the case of Articles 12 and 18,
- when a Member State carries out or authorizes the publication of information concerning that Member State itself.

4. Paragraphs 1, 2 and 3 shall not preclude the publication by the Commission of general statistical data or information on matters of safety containing no specific details regarding particular undertakings or groups of undertakings and not jeopardizing industrial secrecy.

#### Article 14

The amendments necessary for adapting Annex V to technical progress shall be adopted in accordance with the procedure specified in Article 16.

#### Article 15

1. For the purposes of applying Article 14, a Committee responsible for adapting this Directive to technical progress (hereinafter referred to as 'the Committee') is hereby set up. It shall consist of representatives of the Member States and be chaired by a representative of the Commission.

2. The Committee shall draw up its own rules of procedure.

#### Article 16

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which may be determined by the chairman according to the urgency of the matter. It shall decide by a majority of 45 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where these are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or in the absence of an opinion, the Commission shall forthwith submit a proposal to the Council on the measures to be adopted. The Council shall act by a qualified majority.

(c) If the Council does not act within three months of the proposal being submitted to it, the measures proposed shall be adopted by the Commission.

#### Article 17

This Directive shall not restrict the right of the Member States to apply or to adopt administrative or legislative measures ensuring greater protection of man and the environment than that which derives from the provisions of this Directive.

#### Article 18

Member States and the Commission shall exchange information on the experience acquired with regard to the prevention of major accidents and the limitation of their consequences; this information shall concern, in particular, the functioning of the measures provided for in this Directive. Five years after notification of this Directive, the Commission shall forward to the Council and the European Parliament a report on its application which it shall draw up on the basis of this exchange of information.

#### Article 19

At the latest on 8 January 1986 the Council shall, on a proposal from the Commission, review Annexes I, II and III.



*Article 20*

1. Member States shall take the measures necessary to comply with this Directive at the latest on 8 January 1984. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

*Article 21*

This Directive is addressed to the Member States.

Done at Luxembourg, 24 June 1982.

*For the Council*

*The President*

F. AERTS

## ANNEX I

## INDUSTRIAL INSTALLATIONS WITHIN THE MEANING OF ARTICLE 1'

1. — Installations for the production, processing or treatment of organic or inorganic chemicals using for this purpose, amongst others:
  - alkylation
  - amination by ammonolysis
  - carbonylation
  - condensation
  - dehydrogenation
  - esterification
  - halogenation and manufacture of halogens
  - hydrogenation
  - hydrolysis
  - oxidation
  - polymerization
  - sulphonation
  - desulphurization, manufacture and transformation of sulphur-containing compounds
  - nitration and manufacture of nitrogen-containing compounds
  - manufacture of phosphorus-containing compounds
  - formulation of pesticides and of pharmaceutical products.
  - distillation
  - extraction
  - solvation
  - mixing.
2. Installations for distillation, refining or other processing of petroleum or petroleum products.
3. Installations for the total or partial disposal of solid or liquid substances by incineration or chemical decomposition.
4. Installations for the production, processing or treatment of energy gases, for example, LPG, LNG, SNG.
5. Installations for the dry distillation of coal or lignite.
6. Installations for the production of metals or non-metals by the wet process or by means of electrical energy.

## ANNEX II

STORAGE AT INSTALLATIONS OTHER THAN THOSE COVERED BY ANNEX I  
(ISOLATED STORAGE)

The quantities set out below relate to each installation or group of installations belonging to the same manufacturer where the distance between the installations is not sufficient to avoid, in foreseeable circumstances, any aggravation of major-accident hazards. These quantities apply in any case to each group of installations belonging to the same manufacturer where the distance between the installations is less than approximately 500 m.

Substances or groups of substances	Quantities (tonnes) $\geq$	
	For application of Articles 3 and 4	For application of Article 5
1. Flammable gases as defined in Annex IV (c) (i)	50	300
2. Highly flammable liquids as defined in Annex IV (c) (ii)	10 000	100 000
3. Acrylonitrile	350	5 000
4. Ammonia	60	600
5. Chlorine	10	75
6. Sulphur dioxide	20	500
7. (a) Ammonium nitrate (*)	350	2 500
7. (b) Ammonium nitrate in the form of fertilizers (*)	1 250	10 000
8. Sodium chlorate	25	250
9. Liquid oxygen	200	2 000
10. Sulphur trioxide	15	100

(\*) This applies to ammonium nitrate and mixtures of ammonium nitrate where the nitrogen content derived from the ammonium nitrate is > 28 % by weight and to aqueous solutions of ammonium nitrate where the concentration of ammonium nitrate is > 90 % by weight.

(\*) This applies to straight ammonium nitrate fertilizers which comply with Directive 80/876/EEC and to compound fertilizers where the nitrogen content derived from the ammonium nitrate is > 28 % by weight (a compound fertilizer contains ammonium nitrate together with phosphate and/or potash).

## ANNEX III

## LIST OF SUBSTANCES FOR THE APPLICATION OF ARTICLE 5

The quantities set out below relate to each installation or group of installations belonging to the same manufacturer where the distance between the installations is not sufficient to avoid, in foreseeable circumstances, any aggravation of major-accident hazards. These quantities apply in any case to each group of installations belonging to the same manufacturer where the distance between the installations is less than approximately 500 m.

Name	Quantity ( $\geq$ )	CAS No	EEC No
1. 4-Aminodiphenyl	1 kg	92-67-1	
2. Benzidine	1 kg	92-87-5	612-042-00-2
3. Benzidine salts	1 kg		
4. Dimethylnitrosamine	1 kg	62-75-9	
5. 2-Naphthylamine	1 kg	91-59-8	612-022-00-3
6. Beryllium (powders, compounds)	10 kg		
7. Bis(chloromethyl)ether	1 kg	542-88-1	603-046-00-5
8. 1,3-Propanesultone	1 kg	1120-71-4	
9. 2,3,7,8-Tetra chlorodibenzo-p-dioxin (TCDD)	1 kg	1746-01-6	
10. Arsenic pentoxide, Arsenic (V) acid and salts	500 kg		
11. Arsenic trioxide, Arsenious (III) acid and salts	100 kg		
12. Arsenic hydride (Arsine)	10 kg	7784-42-1	
13. Dimethylcarbamoyl chloride	1 kg	79-44-7	
14. 4-(Chloroformyl) morpholine	1 kg	15159-40-7	
15. Carbonyl chloride (Phosgene)	750 kilograms	75-44-5	006-002-00-8
16. Chlorine	25 tonnes	7782-50-5	017-001-00-7
17. Hydrogen sulphide	50 t	7783-06-04	016-001-00-4
18. Acrylonitrile	200 t	107-13-1	608-003-00-4
19. Hydrogen cyanide	20 t	74-90-8	006-006-00-X
20. Carbon disulphide	200 t	75-15-0	006-003-00-3
21. Bromine	500 t	7726-95-6	035-001-00-5
22. Ammonia	500 t	7664-41-7	007-001-00-5
23. Acetylene (Ethyne)	50 t	74-86-2	601-015-00-0
24. Hydrogen	50 t	1333-74-0	001-001-00-9
25. Ethylene oxide	50 t	75-21-8	603-023-00-X
26. Propylene oxide	50 t	75-56-9	603-055-00-4
27. 2-Cyanopropan-2-ol (Acetone cyanohydrin)	200 t	75-86-5	608-004-00-X
28. 2-Propenal (Acrolein)	200 t	107-02-8	605-008-00-3
29. 2-Propen-1-ol (Allyl alcohol)	200 t	107-18-6	603-015-00-6
30. Allylamine	200 t	107-11-9	612-046-00-4
31. Antimony hydride (Stibine)	100 kg	7803-52-3	
32. Ethyleneimine	50 t	151-56-4	613-001-00-1

Name	Quantity ( $\geq$ )	CAS No	EEC No
33. Formaldehyde (concentration $\geq$ 90 %)	50 t	50-00-0	605-001-01-2
34. Hydrogen phosphide (Phosphine)	100 kg	7803-51-2	
35. Bromomethane (Methyl bromide)	200 t	74-83-9	602-002-00-3
36. Methyl isocyanate	150 kilograms	624-83-9	615-001-00-7
37. Nitrogen oxides	50 t	11104-93-1	
38. Sodium selenite	100 kg	10102-18-8	
39. Bis(2-chloroethyl) sulphide	1 kg	505-60-2	
40. Phosacetim	100 kg	4104-14-7	015-092-00-8
41. Tetraethyl lead	50 t	78-00-2	
42. Tetramethyl lead	50 t	75-74-1	
43. Promurit (1-(3,4-Dichlorophenyl)-3-triazenethio-carboxamide)	100 kg	5836-73-7	
44. Chlorfenvinphos	100 kg	470-90-6	015-071-00-3
45. Crimidine	100 kg	535-89-7	613-004-00-8
46. Chloromethyl methyl ether	1 kg	107-30-2	
47. Dimethyl phosphoramidocyanidic acid	1 t	63917-41-9	
48. Carbophenothion	100 kg	786-19-6	015-044-00-6
49. Dialifos	100 kg	10311-84-9	015-088-00-6
50. Cyanthoate	100 kg	3734-95-0	015-070-00-8
51. Amiton	1 kg	78-53-5	
52. Oxydisulfoton	100 kg	2497-07-6	015-096-00-X
53. 00-Diethyl S-ethylsulphinylmethyl phosphorothioate	100 kg	2588-05-8	
54. 00-Diethyl S-ethylsulphonylmethyl phosphorothioate	100 kg	2588-06-9	
55. Disulfoton	100 kg	298-04-4	015-060-00-3
56. Demeton	100 kg	8065-48-3	
57. Phorate	100 kg	298-02-2	015-033-00-6
58. 00-Diethyl S-ethylthiomethyl phosphorothioate	100 kg	2600-69-3	
59. 00-Diethyl S-isopropylthiomethyl phosphorodithioate	100 kg	78-52-4	
60. Pyrazoxon	100 kg	108-34-9	015-023-00-1
61. Pensulfothion	100 kg	115-90-2	015-090-00-7
62. Paraoxon (Diethyl 4-nitrophenyl phosphate)	100 kg	311-45-5	
63. Parathion	100 kg	56-38-2	015-034-00-1
64. Azinphos-ethyl	100 kg	2642-71-9	015-056-00-1
65. 00-Diethyl S-propylthiomethyl phosphorodithioate	100 kg	3309-68-0	
66. Thionazin	100 kg	297-97-2	
67. Carbofuran	100 kg	1563-66-2	006-026-00-9
68. Phosphamidon	100 kg	13171-21-6	015-022-00-6
69. Tirpate (2,4-Dimethyl-1,3-dithiolane-2-carboxaldehyde O-methylcarbamoyloxime)	100 kg	26419-73-8	
70. Mevinphos	100 kg	7786-34-7	015-020-00-5
71. Parathion-methyl	100 kg	298-00-0	015-035-00-7

Name	Quantity (≥)	CAS No	EEC No
72. Azinphos-methyl	100 kg	86-50-0	015-039-00-9
73. Cyclobeximide	100 kg	66-81-9	
74. Diphacinone	100 kg	82-66-6	
75. Tetramethylenedisulphotetramine	1 kg	80-12-6	
76. EPN	100 kg	2104-64-5	015-036-00-2
77. 4-Fluorobutyric acid	1 kg	462-23-7	
78. 4-Fluorobutyric acid, salts	1 kg		
79. 4-Fluorobutyric acid, esters	1 kg		
80. 4-Fluorobutyric acid, amides	1 kg		
81. 4-Fluorocrotonic acid	1 kg	37759-72-1	
82. 4-Fluorocrotonic acid, salts	1 kg		
83. 4-Fluorocrotonic acid, esters	1 kg		
84. 4-Fluorocrotonic acid, amides	1 kg		
85. Fluoroacetic acid	1 kg	144-49-0	607-081-00-7
86. Fluoroacetic acid, salts	1 kg		
87. Fluoroacetic acid, esters	1 kg		
88. Fluoroacetic acid, amides	1 kg		
89. Flufenetil	100 kg	4301-50-2	607-078-00-0
90. 4-Fluoro-2-hydroxybutyric acid	1 kg		
91. 4-Fluoro-2-hydroxybutyric acid, salts	1 kg		
92. 4-Fluoro-2-hydroxybutyric acid, esters	1 kg		
93. 4-Fluoro-2-hydroxybutyric acid, amides	1 kg		
94. Hydrogen fluoride	50 t	7664-39-3	009-002-00-6
95. Hydroxyacetonitrile (Glycolonitrile)	100 kg	107-16-4	
96. 1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin	100 kg	19408-74-3	
97. Isodrin	100 kg	465-73-6	602-050-00-4
98. Hexamethylphosphoramide	1 kg	680-31-9	
99. Juglone (5-Hydroxynaphthalene-1,4-dione)	100 kg	481-39-0	
100. Warfarin	100 kg	81-81-2	607-056-00-0
101. 4,4'-Methylenebis (2-chloroaniline)	10 kg	101-14-4	
102. Ethion	100 kg	563-12-2	015-047-00-2
103. Aldicarb	100 kg	116-06-3	006-017-00-X
104. Nickel tetracarbonyl	10 kg	13463-39-3	028-001-00-1
105. Isobenzan	100 kg	297-78-9	602-053-00-0
106. Pentaborane	100 kg	19624-22-7	
107. 1-Propen-2-chloro-1,3-diol-diacetate	10 kg	10118-72-6	
108. Propyleneimine	50 t	75-55-8	
109. Oxygen difluoride	10 kg	7783-41-7	
110. Sulphur dichloride	1 t	10545-99-0	016-013-00-X
111. Selenium hexafluoride	10 kg	7783-79-1	

Name	Quantity (±)	CAS No	EEC No
112. Hydrogen selenide	10 kg	7783-07-5	
113. TEPP	100 kg	107-49-3	015-025-00-2
114. Sulfotep	100 kg	3689-24-5	015-027-00-3
115. Dimetop	100 kg	115-26-4	015-061-00-9
116. 1-Tri(cyclohexyl) stannyl-1H-1,2,4-triazole	100 kg	41083-11-8	
117. Triethylenemelamine	10 kg	51-18-3	
118. Cobalt metal, oxides, carbonates, sulphides, as powders	1 tonne		
119. Nickel metal, oxides, carbonates, sulphides, as powders	1 tonne		
120. Anabasine	100 kg	494-52-0	
121. Tellurium hexafluoride	100 kg	7783-80-4	
122. Trichloromethanesulphenyl chloride	100 kg	594-42-3	
123. 1,2-Dibromoethane (Ethylene dibromide)	50 t	106-93-4	602-010-00-6
124. Flammable substances as defined in Annex IV (c) (i)	200 t		
125. Flammable substances as defined in Annex IV (c) (ii)	50 000 t		
126. Diazodinitrophenol	10 t	7008-81-3	
127. Diethylene glycol dinitrate	10 t	693-21-0	603-033-00-4
128. Dinitrophenol, salts	50 t		609-017-00-3
129. 1-Guanyl-4-nitrosaminoguanyl-1-tetrazene	10 t	109-27-3	
130. Bis (2,4,6-trinitrophenyl)amine	50 t	131-73-7	612-018-00-1
131. Hydrazine nitrate	50 t	13464-97-6	
132. Nitroglycerine	10 t	55-63-0	603-034-00-X
133. Pentaerythritol tetranitrate	50 t	78-11-5	603-035-00-5
134. Cyclotrimethylene trinitramine	50 t	121-82-4	
135. Trinitroaniline	50 t	26952-42-1	
136. 2,4,6-Trinitroanisole	50 t	606-35-9	609-011-00-0
137. Trinitrobenzene	50 t	25377-32-6	609-005-00-8
138. Trinitrobenzoic acid	50 t	{ 35860-50-5 129-66-8	
139. Chlorotrinitrobenzene	50 t	28260-61-9	610-004-00-X
140. N-Methyl-N,2,4,6-N-tetranitroaniline	50 t	479-45-8	612-017-00-6
141. 2,4,6-Trinitrophenol (Picric acid)	50 t	88-89-1	609-009-00-X
142. Trinitroresorcinol	50 t	28905-71-7	609-012-00-6
143. 2,4,6-Trinitrophenetole	50 t	4732-14-3	
144. 2,4,6-Trinitroresorcinol (Styphnic acid)	50 t	82-71-3	609-018-00-9
145. 2,4,6-Trinitrotoluene	50 t	118-96-7	609-008-00-4
146. (a) Ammonium nitrate (?)	2 500 tonnes	6484-52-2	
146. (b) Ammonium nitrate in the form of fertilizers (?)	5 000 tonnes	9004-70-0	603-037-00-6
147. Cellulose nitrate (containing > 12.6 % nitrogen)	100 t	9004-70-0	603-037-00-6
148. Sulphur dioxide	250 tonnes	7446-09-05	016-011-00-9
149. Hydrogen chloride (liquefied gas)	250 t	7647-01-0	017-002-00-2
150. Flammable substances as defined in Annex IV (c) (iii)	200 t		

Name	Quantity (≥)	CAS No	EEC No
151. Sodium chlorate <sup>(1)</sup>	250 t	7775-09-9	017-005-00-9
152. tert-Butyl peroxyacetate (concentration ≥ 70 %)	50 t	107-71-1	
153. tert-Butyl peroxyisobutyrate (concentration ≥ 80 %)	50 t	109-13-7	
154. tert-Butyl peroxy maleate (concentration ≥ 80 %)	50 t	1931-62-0	
155. tert-Butyl peroxy isopropyl carbonate (concentration ≥ 80 %)	50 t	2372-21-6	
156. Dibenzyl peroxydicarbonate (concentration ≥ 90 %)	50 t	2144-45-8	
157. 2,2-Bis (tert-butylperoxy) butane (concentration ≥ 70 %)	50 t	2167-23-9	
158. 1,1-Bis (tert-butylperoxy) cyclohexane (concentration ≥ 80 %)	50 t	3006-86-8	
159. Di-sec-butyl peroxydicarbonate (concentration ≥ 80 %)	50 t	19910-65-7	
160. 2,2-Dihydroperoxypropane (concentration ≥ 30 %)	50 t	2614-76-8	
161. Di-n-propyl peroxydicarbonate (concentration ≥ 80 %)	50 t	16066-38-9	
162. 3,3,6,6,9,9-Hexamethyl-1,2,4,5-tetroxacyclononane (concentration ≥ 75 %)	50 t	22397-33-7	
163. Methyl ethyl ketone peroxide (concentration ≥ 60 %)	50 t	1338-23-4	
164. Methyl isobutyl ketone peroxide (concentration ≥ 60 %)	50 t	37206-20-5	
165. Peracetic acid (concentration ≥ 60 %)	50 t	79-21-0	607-094-00-8
166. Lead azide	50 t	13424-46-9	082-003-00-7
167. Lead 2,4,6-trinitroresorcinoxide (Lead styphnate)	50 t	15245-44-0	609-019-00-4
168. Mercury fulminate	10 t	{ 20820-45-5 628-86-4	080-005-00-2
169. Cyclotetramethylenetetranitramine	50 t	2691-41-0	
170. 2,2',4,4',6,6'-Hexanitrostilbene	50 t	20062-22-0	
171. 1,3,5-Triamino-2,4,6-trinitrobenzene	50 t	3058-38-6	
172. Ethylene glycol dinitrate	10 t	628-96-6	603-032-00-9
173. Ethyl nitrate	50 t	625-58-1	007-007-00-8
174. Sodium picramate	50 t	831-52-7	
175. Barium azide	50 t	18810-58-7	
176. Di-isobutyryl peroxide (concentration ≥ 50 %)	50 t	3437-84-1	
177. Diethyl peroxydicarbonate (concentration ≥ 30 %)	50 t	14666-78-5	
178. tert-Butyl peroxy pivalate (concentration ≥ 77 %)	50 t	927-07-1	
179. Liquid oxygen	2 000 tonnes	7 782-44-7	008-001-00-8
180. Sulphur trioxide	75 tonnes	7 446-11-9	

(<sup>1</sup>) This applies to ammonium nitrate and mixtures of ammonium nitrate where the nitrogen content derived from the ammonium nitrate is > 28 % by weight and aqueous solutions of ammonium nitrate where the concentration of ammonium nitrate is > 90 % by weight.

(<sup>2</sup>) This applies to straight ammonium nitrate fertilizers which comply with Directive 80/876/EEC and to compound fertilizers where the nitrogen content derived from the ammonium nitrate is > 28 % by weight (a compound fertilizer contains ammonium nitrate together with phosphate and/or potash).

NB: The EEC numbers correspond to those in Directive 67/548/EEC and its amendments.



## ANNEX IV

## INDICATIVE CRITERIA

## (a) Very toxic substances:

- substances which correspond to the first line of the table below,
- substances which correspond to the second line of the table below and which, owing to their physical and chemical properties, are capable of entailing major-accident hazards similar to those caused by the substance mentioned in the first line:

	LD 50 (oral) <sup>(1)</sup> mg/kg body weight	LD 50 (cutaneous) <sup>(2)</sup> mg/kg body weight	LC 50 <sup>(3)</sup> mg/l (inhalation)
1	LD 50 ≤ 5	LD 50 ≤ 10	LC 50 ≤ 0.1
2	5 < LD 50 ≤ 25	10 < LD 50 ≤ 50	0.1 < LC 50 ≤ 0.5

<sup>(1)</sup> LD 50 oral in rats.

<sup>(2)</sup> LD 50 cutaneous in rats or rabbits.

<sup>(3)</sup> LC 50 by inhalation (four hours) in rats.

## (b) Other toxic substances:

The substances showing the following values of acute toxicity and having physical and chemical properties capable of entailing major-accident hazards:

LD 50 (oral) <sup>(1)</sup> mg/kg body weight	LD 50 (cutaneous) <sup>(2)</sup> mg/kg body weight	LC 50 <sup>(3)</sup> mg/l (inhalation)
25 < LD 50 ≤ 200	50 < LD 50 ≤ 400	0.5 < LC 50 ≤ 2

<sup>(1)</sup> LD 50 oral in rats.

<sup>(2)</sup> LD 50 cutaneous in rats or rabbits.

<sup>(3)</sup> LC 50 by inhalation (four hours) in rats.

## (c) Flammable substances

## (i) flammable gases:

substances which in the gaseous state at normal pressure and mixed with air become flammable and the boiling point of which at normal pressure is 20 °C or below;

## (ii) highly flammable liquids:

substances which have a flash point lower than 21 °C and the boiling point of which at normal pressure is above 20 °C;

## (iii) flammable liquids:

substances which have a flash point lower than 55 °C and which remain liquid under pressure, where particular processing conditions, such as high pressure and high temperature, may create major-accident hazards.

## (d) Explosive substances:

Substances which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene.

ANNEX V

**DATA AND INFORMATION TO BE SUPPLIED IN CONNECTION WITH THE NOTIFICATION PROVIDED FOR IN ARTICLE 5**

If it is not possible or if it seems unnecessary to provide the following information, reasons must be given.

**1. IDENTITY OF THE SUBSTANCE**

**Chemical name**

**CAS number**

**Name according to the IUFAC nomenclature**

**Other names**

**Empirical formula**

**Composition of the substance**

**Degree of purity**

**Main impurities and relative percentages**

**Detection and determination methods available to the installation**

**Description of the methods used or references to scientific literature**

**Methods and precautions laid down by the manufacturer in connection with handling, storage and fire**

**Emergency measures laid down by the manufacturer in the event of accidental dispersion**

**Methods available to the manufacturer for rendering the substance harmless**

**2. BRIEF INDICATION OF HAZARDS**

— For man:                   — immediate .....

                                  — delayed .....

— For the environment: — immediate .....

                                  — delayed .....

ANNEX VI

INFORMATION TO BE SUPPLIED TO THE COMMISSION BY THE MEMBER STATES  
PURSUANT TO ARTICLE 11

REPORT OF MAJOR ACCIDENT

Member State:

Authority responsible for report:

Address:

1. General data

Date and time of the major accident:

Country, administrative region, etc.:

Address:

Type of industrial activity:

2. Type of major accident

Explosion  Fire  Emission of dangerous substances

Substance(s) emitted:

3. Description of the circumstances of the major accident

4. Emergency measures taken

5. Cause(s) of major accident

Known:

(to be specified)

Not known:

Information will be supplied as soon as possible

6. Nature and extent of damage

(a) *Within the establishment*

— casualties

..... killed

..... injured

..... poisoned

— persons exposed to the major accident

.....

— material damage

— the danger is still present

— the danger no longer exists

(b) *Outside the establishment*

— casualties

..... killed

..... injured

..... poisoned

— persons exposed to the major accident

.....

- material damage
- damage to the environment
- the danger is still present
- the danger no longer exists

7. Medium and long-term measures, particularly those aimed at preventing the recurrence of similar major accidents (to be submitted as the information becomes available).

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**ANNEX VII**

**STATEMENT RE ARTICLE 8**

*The Member States shall consult one another in the framework of their bilateral relations on the measures required to avert major accidents originating in a notified industrial activity within the meaning of Article 5 and to limit the consequences for man and the environment. In the case of new installations, this consultation shall take place within the time limits laid down in Article 5 (2).*

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**COUNCIL DIRECTIVE**  
of 19 March 1987  
**amending Directive 82/501/EEC on the major-accident hazards of certain industrial activities**

(87/216/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas Article 19 of Council Directive 82/501/EEC <sup>(4)</sup> requires the Council to review, on a proposal from the Commission, Annexes I, II and III thereof;

Whereas the protection of man and the environment and safety and health protection at work call for the provisions of Directive 82/501/EEC to be strengthened with regard to some industrial activities which involve, or may involve, particularly dangerous substances;

Whereas for some particularly toxic substances it is necessary to lower the threshold quantities set out in Annexes II and III in order that all industrial activities which involve, or may involve, these substances in quantities equal to or above the given threshold levels are covered by Article 5 of Directive 82/501/EEC, with a view to

reducing the hazards of major accidents and enabling the necessary steps to be taken to reduce their consequences;

Whereas it is necessary to cover the industrial activities which involve, or may involve, sulphur trioxide and liquid oxygen and the isolated storage of sulphur trioxide, as they may have serious consequences for man and the environment in the event of a major accident;

Whereas the industrial activities involving sulphur dioxide can pose a greater hazard than the isolated storage of sulphur dioxide;

Whereas it is necessary to define more closely some substances or groups of substances and to amend the corresponding threshold quantities in order to reflect the different range of hazards posed by the different forms and types of these substances or groups of substances;

Whereas it is appropriate that the industrial activities involving ammonium nitrate, sodium chlorate and liquid oxygen and the storage of these substances fall within the scope of Annexes II and III to Directive 82/501/EEC, whenever the respective threshold quantities set out in these Annexes are exceeded;

Whereas it is appropriate that certain amendments should be made to Annex I to Directive 82/501/EEC;

Whereas it is necessary to make it clear that the list of processes set out in Annex I (1) to Directive 82/501/EEC is not exhaustive, but merely gives examples of some important operations, and that all other operations which could be used for the production, processing or treatment of organic or inorganic chemicals are also covered by this Annex;

<sup>(1)</sup> OJ No C 305, 26. 11. 1985, p. 9.

<sup>(2)</sup> OJ No C 76, 23. 3. 1987.

<sup>(3)</sup> OJ No C 101, 28. 4. 1986, p. 10.

<sup>(4)</sup> OJ No L 230, 5. 8. 1982, p. 1.

Whereas the Advisory Committee on Safety, Hygiene and Health Protection at Work, set up by Council Decision 74/325/EEC<sup>(1)</sup>, has been consulted,

HAS ADOPTED THIS DIRECTIVE :

*Article 1*

Annexes I, II and III to Directive 82/501/EEC shall be amended in accordance with the Annex hereto.

*Article 2*

1. In the case of existing industrial activities which will be subject to the provisions of Directive 82/501/EEC for the first time following adoption of this amendment, the declaration provided for in Article 9 (3) of the said Directive shall be submitted to the competent authority within 24 months of notification of this Directive.

2. In these cases also, the supplementary declaration provided for in Article 9 (4) of Directive 82/501/EEC

shall be submitted to the competent authority within five years of notification of this Directive.

*Article 3*

1. Member States shall take the measures necessary to comply with this Directive not later than 18 months after notification of the Directive. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 19 March 1987.

*For the Council*

*The President*

M. SMET

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<sup>(1)</sup> OJ No L 185, 9. 7. 1974, p. 15.

**COUNCIL DIRECTIVE**  
**of 19 March 1987**  
**on the prevention and reduction of environmental pollution by asbestos**

(87/217/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas successive action programmes of the European Communities <sup>(4)</sup> on the environment emphasize the importance of preventing and reducing environmental pollution; whereas in this context asbestos has been listed among the first-category pollutants to be investigated on the grounds of their toxicity and of their potentially serious effects on human health and the environment;

Whereas Council Directive 83/478/EEC <sup>(5)</sup> inserted in Directive 76/769/EEC <sup>(6)</sup>, as last amended by Directive 85/467/EEC <sup>(7)</sup>, provisions restricting the marketing and use of crocidolite (blue asbestos) and products containing crocidolite fibres and special provisions concerning the labelling of products containing asbestos;

Whereas Council Directive 83/477/EEC <sup>(8)</sup> lays down provisions on the protection of workers from the risks related to exposure to asbestos at work;

Whereas Directive 84/360/EEC <sup>(9)</sup> lays down provisions on the combating of air pollution from industrial plants;

Whereas Member States should take the measures necessary to ensure that asbestos emissions into the air, asbestos discharges into the aquatic environment, and solid asbestos waste are, as far as possible, reduced at source or prevented;

Whereas it is appropriate to allow a sufficient period of time for the application of these measures to existing plants;

Whereas Member States should have the possibility, whilst respecting the provisions of the Treaty, to intro-

duce more stringent provisions in order to protect health and the environment;

Whereas disparities between the provisions in force or being amended in the Member States as regards the control of pollution from industrial plants can create unequal conditions of competition and thereby directly affect the functioning of the common market; whereas it is therefore necessary to approximate legislation in this field pursuant to Article 100 of the Treaty;

Whereas reducing pollution by asbestos serves to further one of the Community's objectives regarding the protection and improvement of the environment; whereas, however, specific powers for this purpose are not expressly provided for in the Treaty and Article 235 must therefore also be invoked,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. The objective of this Directive is to lay down measures and to supplement provisions already in force, with a view to preventing and reducing pollution by asbestos in the interests of the protection of human health and the environment.

2. This Directive shall be applied without prejudice to the provisions laid down by Directive 83/477/EEC.

*Article 2*

For the purpose of this Directive:

1. *Asbestos* means the following fibrous silicates:

- crocidolite (blue asbestos),
- actinolite,
- anthophyllite,
- chrysotile (white asbestos),
- amosite (brown asbestos),
- tremolite.

2. *Raw asbestos* means:

the product resulting from the primary crushing of asbestos ore.

3. *Use of asbestos* means:

activities which involve the handling of a quantity of more than 100 kilograms of raw asbestos per year and which concern:

<sup>(1)</sup> OJ No C 349, 31. 12. 1985, p. 27.

<sup>(2)</sup> Opinion delivered on 9 March 1987 (not yet published in the Official Journal)

<sup>(3)</sup> OJ No C 207, 18. 8. 1986, p. 21.

<sup>(4)</sup> OJ No C 112, 20. 12. 1973, p. 1, OJ No C 139, 13. 6. 1977, p. 1 and OJ No C 46, 17. 2. 1983, p. 1.

<sup>(5)</sup> OJ No L 263, 24. 9. 1983, p. 33.

<sup>(6)</sup> OJ No L 262, 27. 9. 1976, p. 201.

<sup>(7)</sup> OJ No L 269, 11. 10. 1985, p. 56.

<sup>(8)</sup> OJ No L 263, 24. 9. 1983, p. 25.

<sup>(9)</sup> OJ No L 188, 16. 7. 1984, p. 20.

- (a) the production of raw asbestos ore excluding any process directly associated with the mining of the ore, and/or
- (b) the manufacturing and industrial finishing of the following products using raw asbestos: asbestos cement or asbestos-cement products, asbestos friction products, asbestos filters, asbestos textiles, asbestos paper and card, asbestos jointing, packaging and reinforcement materials, asbestos floor coverings, asbestos fillers.

4. *Working of products containing asbestos* means:

activities other than the use of asbestos, which are liable to release asbestos into the environment.

5. *Waste* means:

any substance or object as defined in Article 1 of Directive 75/442/EEC<sup>(1)</sup>.

### Article 3

1. Member States shall take the measures necessary to ensure that asbestos emissions into the air, asbestos discharges into the aquatic environment, and solid asbestos waste are, as far as reasonably practicable, reduced at source and prevented. In the case of the use of asbestos, these measures should entail using the best available technology not entailing excessive cost, including where appropriate recycling or treatment.

2. In the case of existing plants, the requirement in paragraph 1 that best available technology not entailing excessive costs be used to reduce and eliminate emissions of asbestos into the air shall be applied taking into account the elements set out in Article 13 of Directive 84/360/EEC.

### Article 4

1. Without prejudice to Article 3, Member States shall take the measures necessary to ensure that the concentration of asbestos emitted through the discharge ducts into the air during use of asbestos does not exceed a limit value of 0,1 mg/m<sup>3</sup> (milligrams of asbestos per m<sup>3</sup> of air discharged).

2. Member States may exempt from the obligation referred to in paragraph 1 the plants emitting less than 5 000 m<sup>3</sup>/hour total gaseous discharges, where the discharge of asbestos into the air is not more than 0,5 grams per hour at any time under normal operating conditions.

When this exemption applies, the competent authorities of Member States shall take appropriate measures in order to ensure that the thresholds referred to in the first subparagraph are not exceeded.

### Article 5

Member States shall take the measures necessary to ensure that:

- (a) all aqueous effluent arising in the manufacture of asbestos cement is recycled. Where such recycling is

not economically feasible, Member States shall take the measures necessary to ensure that the disposal of liquid waste containing asbestos does not result in pollution of the aquatic environment and other sectors including the air.

To this end:

- the limit value of 30 grams of total suspended matter per m<sup>3</sup> of aqueous effluent discharged shall apply,
- the competent authorities of Member States shall, for each plant concerned, specify the volume of discharges into water of the total quantity of suspended matter discharged per tonne of product taking account of the specific situation of the plant.

These limits shall apply at the point where the waste waters leave the industrial plant.

- (b) All aqueous effluent arising in the manufacture of asbestos paper or board is recycled.

However, the discharge of aqueous effluent containing not more than 30 grams of suspended matter per m<sup>3</sup> of water may be authorized during routine cleaning or maintenance of the plant.

### Article 6

1. Member States shall take the measures necessary to ensure that measurements are taken at regular intervals of emissions into the air and of discharges of aqueous effluent from facilities to which the limit values provided for in Articles 4 and 5 apply.

2. For the purposes of checking compliance with the said limit values the sampling and analysis procedures and methods shall be in conformity with those described in the Annex or with any other procedure or method which gives equivalent results.

3. Member States shall notify to the Commission the procedures and methods they are using together with the information relevant to assess the pertinence of such procedures and methods. On the basis of this information, the Commission will keep under review the equivalence of the different procedures and methods and report to the Council five years after notification of the Directive.

### Article 7

Member States shall take the measures necessary to ensure that:

- activities involving the working of products containing asbestos do not cause significant environmental pollution by asbestos fibres or dust,
- the demolition of buildings, structures and installations containing asbestos and the removal therefrom of asbestos or materials containing asbestos involving the release of asbestos fibres or dust do not cause

<sup>(1)</sup> OJ No L 194, 25. 7. 1975, p. 47.



significant asbestos environmental pollution; to that end they shall satisfy themselves that the plan of work provided for in Article 12 of Directive 83/477/EEC prescribes the introduction of all the necessary preventive measures to this end.

#### Article 8

Without prejudice to Directive 78/319/EEC<sup>(1)</sup>, as last amended by the 1985 Act of Accession, Member States shall take the measures necessary to ensure that:

- in the course of the transport and deposition of waste containing asbestos fibres or dust, no such fibres or dust are released into the air and no liquids which may contain asbestos fibres are spilled,
- where waste containing asbestos fibres or dust is land-filled at sites licensed for the purpose, such waste is so treated, packaged or covered, with account being taken of local conditions, that the release of asbestos particles into the environment is prevented.

#### Article 9

A Member State may, in order to protect health and the environment, introduce provisions which are more stringent than those of this Directive, in compliance with the conditions laid down by the Treaty.

#### Article 10

The procedure provided for in Articles 11 and 12 is established for the adaptation of the Annex to technical progress and shall be followed for any modification of the methods of sampling and analysis mentioned in the Annex. This adaptation must not result in any direct or indirect modification of the limit values indicated in Articles 4 and 5.

#### Article 11

A Committee for the adaptation of this Directive to scientific and technical progress, hereinafter called 'the Committee', consisting of representatives of the Member States and chaired by a representative of the Commission, is hereby set up.

The Committee shall draw up its rules of procedure.

#### Article 12

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Committee, either on his own initiative or at the request of the representative of a Member State.
2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by a majority of 54 votes, the votes of the

Member States being weighted as provided for in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion.

(b) Where the intended measures are not in accordance with the opinion of the Committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

#### Article 13

1. The Commission shall periodically make a comparative assessment of the application of this Directive by Member States. Member States shall supply the Commission with all information relevant to this end. The confidential nature of any information supplied should be respected.

2. Where necessary, in the light of the evolution of knowledge in the medical field and that of technological progress, the Commission shall submit further proposals aimed at preventing and reducing pollution by asbestos in the interests of the protection of human health and the environment.

#### Article 14

1. Subject to paragraph 2, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1988. They shall forthwith inform the Commission thereof.

2. Member States shall adopt and publish the provisions necessary to comply with Articles 4 and 5 as soon as possible and in any case not later than 30 June 1991 for plants built or authorized before the date given in paragraph 1.

3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

#### Article 15

This Directive is addressed to the Member States.

Done at Brussels, 19 March 1987.

*For the Council*

*The President*

M. SMET

(1) OJ No L 84, 31. 3. 1978, p. 43.

## ANNEX

## METHODS OF SAMPLING AND ANALYSES

## A. DISCHARGE OF AQUEOUS EFFLUENT

The reference method of analysis to determine total suspended matter (filterable matter from the non precipitated sample) as expressed in mg/l shall be filtering through a 0,45 µm filter membrane, drying at 105 °C and weighing<sup>(1)</sup>.

Samples must be taken in such a way as to be representative of the discharge over a 24-hour period.

This determination must be conducted to a precision<sup>(2)</sup> of ± 5 % and an accuracy<sup>(2)</sup> of ± 10 %.

## B. SPECIFICATIONS TO BE MET WHEN SELECTING A METHOD FOR MEASURING EMISSIONS INTO THE AIR

## I. Gravimetric method

1. The method selected shall be a gravimetric method which is capable of measuring the total quantities of dust emitted through the discharge ducts.

Account shall be taken of the concentration of asbestos in dust. When concentration measurements are required, the concentration of asbestos in dust shall be measured or evaluated. The controlling authority shall decide on the periodicity of such measure, according to the characteristics of the plant and of its production, but this should be initially at least every six months. If a Member State has established that the concentration does not display any significant variation, the frequency of measurement may be reduced. Where periodical measures are not taken, the limit value specified in Article 4 of the Directive applies to the total dust emissions.

Sampling shall be conducted before any dilution of the flow to be measured.

2. The sampling must be conducted to a precision of ± 40 % and an accuracy of ± 20 % at the limit value. The limit of detection must be 20 %. At least two measurements under the same conditions shall be made in order to check the compliance with the limit value.

3. *Operation of the installation*

Measurements shall only be valid if sampling takes place while the installation is operating normally.

4. *Selecting the sampling point*

Sampling shall take place at a point where there is a laminar flow of air. As far as possible, care shall be taken to avoid turbulence, and obstacles which might disrupt the flow of air.

5. *Modifications required for sampling*

Suitable apertures shall be made in ducts where sampling is to take place and proper platforms shall be provided.

6. *Measurements to be taken before sampling*

Before sampling commences, it is first necessary to measure air temperature and pressure and the velocity of flow in the duct. Air temperature and pressure shall normally be measured along the sampling line at normal flow rates. Under exceptional conditions, it is also necessary to measure the water vapour concentration so that the results can be amended accordingly.

7. *General requirements of the sampling procedure*

The procedure requires a sample of air from a duct carrying the emissions of asbestos dust to be drawn through a filter, and the asbestos content of the dust retained in the filter to be measured.

- 7.1. The sampling line shall first be checked to ensure that it is airtight and that there are no leaks which might give rise to measurement errors. The sampler head shall be carefully sealed off and the sampler pump started up. The rate of leakage shall not exceed 1 % of the normal sampling flow.

<sup>(1)</sup> See Annex III to Directive 82/883/EEC (OJ No L 378, 31. 12. 1982, p. 1).

<sup>(2)</sup> These items are defined in Article 2 of Directive 79/869/EEC (OJ No L 271, 29. 10. 1979, p. 44) as amended by Directive 81/855/EEC (OJ No L 319, 7. 11. 1981, p. 16).

- 7.2. Normally sampling shall be conducted under isokinetic conditions.
- 7.3. Duration of sampling shall depend on the type of process being monitored and the sampling line used and the sampling period shall be sufficient to ensure that an adequate quantity of material is collected for weighing. It shall be representative of the full process being monitored.
- 7.4. When the sampler filter is not in the immediate proximity of the sampler head, it is essential to recover materials deposited in the sampling probe.
- 7.5. The sampler head and the number of points where samples must be taken shall be determined in accordance with the national standard adopted.

#### 8. *Nature of the sampler filter*

- 8.1. The filter appropriate to the technique of analysis used shall be chosen. For the gravimetric method, glassfibre filters are preferable.
- 8.2. A minimum filtration efficiency of 99 % is required, as defined with reference to the DOP test using an aerosol with particles of 0,3  $\mu\text{m}$  diameter.

#### 9. *Weighing*

- 9.1. An appropriate high precision balance shall be used.
- 9.2. In order to achieve the accuracy required for weighing it is essential to condition filters thoroughly before and after sampling.

#### 10. *Expression of results*

In addition to measurement data, results shall record temperature, pressure and flow data and shall include all relevant information, such as a simple diagram showing the location of sampling points, the dimensions of ducts, the volumes sampled and the method of calculation used to obtain the results. These results shall be expressed at normal temperature (273 K) and pressure (101,3 kPa).

## II. Countable fibres method

Where fibre counting procedures are used for the purpose of checking compliance with the limit value in Article 4 of the Directive, subject to the provisions of Article 6 (3) of the Directive, a conversion factor of two fibres/ml to 0,1  $\text{mg}/\text{m}^3$  of asbestos dust may be used.

For the purposes of the Directive a fibre is defined as any object of length greater than 5  $\mu\text{m}$ , breadth less than 3  $\mu\text{m}$ , and having a length/breadth ratio greater than 3/1, which is countable by phase contrast optical microscopy using the European reference method defined in Annex I of Directive 83/477/EEC.

A fibre counting method shall meet the following specifications :

1. The method shall be capable of measuring the concentration of countable fibres in the emitted gases.

The controlling authority shall decide on the periodicity of such measures, according to the characteristics of the plant and of its production, but this should be at least every six months. Where periodical measures are not taken, the limit value specified in Article 4 applies to the total dust emission.

Sampling shall be conducted before any dilution of the flow to be measured.

2. *Operation of the installation*

Measurement shall only be valid if sampling takes place while the installation is operating normally.

3. *Selecting the sampling point*

Sampling shall take place at a point where there is a laminar flow of air. As far as possible, care shall be taken to avoid turbulence and obstacles which might disrupt the flow of air.

4. *Modifications required for sampling*

Suitable apertures shall be made in ducts where sampling is to take place, and proper platforms shall be provided.

5. *Measurements to be taken before sampling*

Before sampling commences, it is first necessary to measure air temperature and pressure, and the velocity of flow in the duct. Air temperature and pressure shall normally be measured along the sampling line at normal flow rates. Under exceptional conditions, it is also necessary to measure the water vapour concentration so that the results can be amended accordingly.

6. *General requirements of the sampling procedure*

The procedure requires a sample of air from a duct carrying the emissions of asbestos dust to be drawn through a filter, and the countable asbestos fibres in the dust retained on the filter to be measured.

- 6.1. The sampling line shall first be checked to ensure that it is airtight, and that there are no leaks which might give rise to measurement errors. The sampling head shall be carefully sealed off and the sampling pump started up. The rate of leakage shall not exceed 1 % of the normal sampling flow.
- 6.2. Sampling of the emitted gases shall be conducted inside the emission duct under isokinetic conditions.
- 6.3. Duration of sampling shall depend on the type of process being monitored and the size of the sampling nozzle used. The sampling period shall be sufficient to ensure that the sample collection filter carries between 100-600 countable asbestos fibres/mm<sup>2</sup>. It shall be representative of the full process being monitored.
- 6.4. The sampling head and the number of points where samples must be taken shall be determined in accordance with the national standard adopted.

7. *Nature of the sampling collection filter*

- 7.1. The filter appropriate to the technique of measurement shall be chosen. For the countable fibre method, membrane filters (mixed esters of cellulose or cellulose nitrate) of nominal pore size 5 µm, with printed squares and a diameter of 25 mm shall be used.
- 7.2. The sample collection filter shall have a minimum filtration efficiency of 99 % with respect to countable asbestos fibres.

8. *Counting of fibres*

The fibre counting method shall conform to the European reference method, as set out in Annex I of Directive 83/477/EEC.

9. *Expression of results*

In addition to measurement data, results shall record temperature, pressure and flow data and shall include all relevant information, such as a simple diagram showing the location of sampling points, the dimensions of ducts, the volumes sampled and the method of calculation used to obtain the results. These results shall be expressed at normal temperature (273 K) and pressure (101,3 kPa).

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# Wastes

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**COUNCIL DIRECTIVE**

of 15 July 1975

on waste

(75/442/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament <sup>(1)</sup>;

Having regard to the Opinion of the Economic and Social Committee <sup>(2)</sup>;

Whereas any disparity between the provisions on waste disposal already applicable or in preparation in the various Member States may create unequal conditions of competition and thus directly affect the functioning of the common market; whereas it is therefore necessary to approximate laws in this field, as provided for in Article 100 of the Treaty;

Whereas it seems necessary for this approximation of laws to be accompanied by Community action so that one of the aims of the Community in the sphere of protection of the environment and improvement of the quality of life can be achieved by more extensive rules; whereas certain specific provisions to this effect should therefore be laid down; whereas Article 235 of the Treaty should be invoked as the powers required for this purpose have not been provided for by the Treaty;

Whereas the essential objective of all provisions relating to waste disposal must be the protection of human health and the environment against harmful effects caused by the collection, transport, treatment, storage and tipping of waste;

Whereas the recovery of waste and the use of recovered materials should be encouraged in order to conserve natural resources;

Whereas the programme of action of the European Communities on the environment <sup>(3)</sup>, stresses the need for Community action, including the harmonization of legislation;

Whereas effective and consistent regulations on waste disposal which neither obstruct intra-Community trade nor affect conditions of competition should be applied to movable property which the owner disposes of or is required to dispose of under the provisions of national law in force, with the exception of radioactive, mining and agricultural waste, animal carcasses, waste waters, gaseous effluents and waste covered by specific Community rules;

Whereas, in order to ensure the protection of the environment, provision should be made for a system of permits for undertakings which treat, store or tip waste on behalf of third parties, for a supervisory system for undertakings which dispose of their own waste and for those which collect the waste of others, and for a plan embracing the essential factors to be taken into consideration in respect of the various waste disposal operations;

Whereas that proportion of the costs not covered by the proceeds of treating the waste must be defrayed in accordance with the 'polluter pays' principle,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

For the purposes of this Directive:

- (a) 'waste' means any substance or object which the holder disposes of or is required to dispose of pursuant to the provisions of national law in force;

<sup>(1)</sup> OJ No C 32, 11. 2. 1975, p. 36.

<sup>(2)</sup> OJ No C 16, 23. 1. 1975, p. 12.

<sup>(3)</sup> OJ No C 112, 20. 12. 1973, p. 3.

(b) 'disposal' means:

- the collection, sorting, transport and treatment of waste as well as its storage and tipping above or under ground,
- the transformation operations necessary for its re-use, recovery or recycling.

#### Article 2

1. Without prejudice to this Directive, Member States may adopt specific rules for particular categories of waste.

2. The following shall be excluded from the scope of this Directive:

- (a) radioactive waste;
- (b) waste resulting from prospecting, extraction, treatment and storage of mineral resources and the working of quarries;
- (c) animal carcasses and the following agricultural waste: faecal matter and other substances used in farming;
- (d) waste waters, with the exception of waste in liquid form;
- (e) gaseous effluents emitted into the atmosphere;
- (f) waste covered by specific Community rules.

#### Article 3

1. Member States shall take appropriate steps to encourage the prevention, recycling and processing of waste, the extraction of raw materials and possibly of energy therefrom and any other process for the re-use of waste.

2. They shall inform the Commission in good time of any draft rules to such effect and, in particular, of any draft rule concerning:

- (a) the use of products which might be a source of technical difficulties as regards disposal or lead to excessive disposal costs;
- (b) the encouragement of:
  - the reduction in the quantities of certain waste,
  - the treatment of waste for its recycling and re-use,
  - the recovery of raw materials and/or the production of energy from certain waste;
- (c) the use of certain natural resources, including

energy resources, in applications where they may be replaced by recovered materials.

#### Article 4

Member States shall take the necessary measures to ensure that waste is disposed of without endangering human health and without harming the environment, and in particular:

- without risk to water, air, soil and plants and animals,
- without causing a nuisance through noise or odours,
- without adversely affecting the countryside or places of special interest.

#### Article 5

Member States shall establish or designate the competent authority or authorities to be responsible, in a given zone, for the planning, organization, authorization and supervision of waste disposal operations.

#### Article 6

The competent authority or authorities referred to in Article 5 shall be required to draw up as soon as possible one or several plans relating to, in particular:

- the type and quantity of waste to be disposed of,
- general technical requirements,
- suitable disposal sites,
- any special arrangements for particular wastes.

The plan or plans may, for example, cover:

- the natural or legal persons empowered to carry out the disposal of waste,
- the estimated costs of the disposal operations,
- appropriate measures to encourage rationalization, of the collection, sorting and treatment of waste.

#### Article 7

Member States shall take the necessary measures to ensure that any holder of waste:

- has it handled by a private or public waste collector or by a disposal undertaking,
- or disposes of it himself in accordance with the measures taken pursuant to Article 4.

*Article 8*

In order to comply with the measures taken pursuant to Article 4 any installation or undertaking treating, storing or tipping waste on behalf of third parties must obtain a permit from the competent authority referred to in Article 5, relating in particular to :

- the type and quantity of waste to be treated,
- general technical requirements,
- precautions to be taken,
- the information to be made available at the request of the competent authority concerning the origin, destination and treatment of waste and the type and quantity of such waste.

*Article 9*

The installations and undertakings referred to in Article 8 shall be periodically inspected by the competent authority referred to in Article 5 to ensure, in particular, that the conditions of the permit are being fulfilled.

*Article 10*

Undertakings transporting, collecting, storing, tipping or treating their own waste and those which collect or transport waste on behalf of third parties shall be subject to supervision by the competent authority referred to in Article 5.

*Article 11*

In accordance with the 'polluter pays' principle, the cost of disposing of waste, less any proceeds derived from treating the waste, shall be borne by:

- the holder who has waste handled by a waste collector or by an undertaking referred to in Article 8;
- and/or the previous holders or the producer of the product from which the waste came.

*Article 12*

Every three years, Member States shall draw up a situation report on waste disposal in their respective countries and shall forward it to the Commission. To this effect, the installations or undertakings referred to in Articles 8 and 10 must supply the competent authority referred to in Article 5 with the particulars on the disposal of waste. The Commission shall circulate this report to the other Member States.

The Commission shall report every three years to the Council and to the European Parliament on the application of this Directive.

*Article 13*

Member States shall bring into force the measures needed in order to comply with this Directive within 24 months of its notification and shall forthwith inform the Commission thereof.

*Article 14*

Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 15*

This Directive is addressed to the Member States.

Done at Brussels, 15 July 1975.

*For the Council*  
*The President*  
 M. RUMOR



**COUNCIL DIRECTIVE**  
**of 20 March 1978**  
**on toxic and dangerous waste**

(78/319/EEC)

as amended by the Act of Accession of Greece of 28 May 1979 (OJ L 291, 19.11.79, p. 17) and the Act of Accession of Spain and Portugal of 12 June 1985 (OJ L 302, 15.11.85, p. 9)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

for this purpose have not been provided for by the Treaty ;

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Whereas the 1973<sup>(1)</sup> and 1977<sup>(4)</sup> programmes of action of the European Communities on the environment stress the need for Community action in order to control the disposal of toxic and dangerous waste ;

Having regard to the proposal from the Commission,

Whereas the essential objective of all provisions relating to the disposal of toxic or dangerous waste must be the protection of human health and the safeguarding of the environment against harmful effects caused by the collection of toxic and dangerous waste as well as its carriage, treatment, storage and tipping ;

Having regard to the opinion of the European Parliament<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Whereas the prevention, recycling and recovery of toxic and dangerous waste and the use of recovered materials should be encouraged in order to conserve natural resources ;

Whereas any disparity between the provisions on disposal of toxic and dangerous waste already applicable or in preparation in the various Member States may create unequal conditions of competition and thus directly affect the functioning of the common market ; whereas it is therefore necessary to approximate laws in this field, as provided for in Article 100 of the Treaty ;

Whereas in order to ensure an effective protection of the environment, provision should be made for a uniform system of permits for undertakings which store, treat and/or tip toxic and dangerous waste ; whereas unauthorized holders of toxic and dangerous waste should have it stored and/or treated only by authorized undertakings ;

Whereas it seems necessary that this approximation of laws be accompanied by Community action so that one of the aims of the Community in the sphere of protection of the environment and improvement of the quality of life can be achieved by more extensive rules ; whereas certain specific provisions to this effect should therefore be laid down ; whereas Article 235 of the Treaty should be invoked as the powers required

Whereas that proportion of the cost of the disposal of toxic and dangerous waste not covered by the proceeds of treating the waste must be defrayed in accordance with the 'polluter pays' principle ;

<sup>(1)</sup> OJ No C 30, 17. 2. 1977, p. 27.

<sup>(2)</sup> OJ No C 77, 30. 3. 1977, p. 5.

<sup>(3)</sup> OJ No C 112, 20. 12. 1973, p. 3.

<sup>(4)</sup> OJ No C 139, 13. 6. 1977, p. 3.

Whereas provision should be made for a system of monitoring and supervision of all installations, establishments, or undertakings which produce, hold or dispose of toxic and dangerous waste, for the keeping of proper records regarding disposal, to ensure that any carriage of toxic and dangerous waste in the course of its disposal is accompanied by an identification form, and for the drawing up of programmes which take into account the various waste disposal operations;

Whereas, in order to coordinate action in this field, Member States should draw up a situation report on the disposal of toxic and dangerous waste;

Whereas technical progress necessitates rapid adaptation of the list of the toxic and dangerous waste to which this Directive applies; whereas, in order to facilitate the introduction of the measures required for this purpose, a procedure should be provided for whereby close cooperation would be established between the Member States and the Commission within a Committee on Adaptation to Technical Progress established under this Directive,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

For the purposes of this Directive:

- (a) 'waste' means any substance or object which the holder disposes of or is required to dispose of pursuant to the provisions of national law in force;
- (b) 'toxic and dangerous waste' means any waste containing or contaminated by the substances or materials listed in the Annex to this Directive of such a nature, in such quantities or in such concentrations as to constitute a risk to health or the environment;
- (c) 'disposal' means
  - the collection, sorting, carriage and treatment of toxic and dangerous waste, as well as its storage and tipping above or under ground;
  - the transformation operations necessary for its recovery, re-use or recycling.

#### *Article 2*

When Member States which are parties to one or more international conventions concerning the carriage of dangerous goods are applying those conventions, this shall be adequate for the purposes of this Directive so far as carriage is concerned, provided that the measures being applied in implementation of the

conventions are at least as stringent as those required for the implementation of the Directive.

#### *Article 3*

The following shall be excluded from the scope of this Directive:

- (a) radioactive waste;
- (b) animal carcasses and agricultural waste of faecal origin;
- (c) explosives;
- (d) hospital waste;
- (e) effluents discharged into sewers and water-courses;
- (f) emissions to the atmosphere;
- (g) household waste;
- (h) mining waste;
- (i) other toxic and dangerous waste covered by specific Community rules.

#### *Article 4*

Member States shall take appropriate steps to encourage, as a matter of priority, the prevention of toxic and dangerous waste, its processing and recycling, the extraction of raw materials and possibly of energy therefrom and any other process for the re-use of such waste.

#### *Article 5*

1. Member States shall take the necessary measures to ensure that toxic and dangerous waste is disposed of without endangering human health and without harming the environment, and in particular:
  - without risk to water, air, soil, plants or animals;
  - without causing a nuisance through noise or odours;
  - without adversely affecting the countryside or places of special interest.
2. Member States shall in particular take the necessary steps to prohibit the abandonment and uncontrolled discharge, tipping or carriage of toxic and dangerous waste, as well as its consignment to installations, establishments or undertakings other than those referred to in Article 9 (1).

#### *Article 6*

Member States shall designate or establish the competent authority or authorities to be responsible, in a given area, for the planning, organization, authorization and supervision of operations for the disposal of toxic and dangerous waste.

*Article 7*

Member States shall take the necessary steps to ensure that :

- toxic and dangerous waste is, where necessary, kept separate from other matter and residues when being collected, transported stored or deposited ;
- the packaging of toxic and dangerous waste is appropriately labelled, indicating in particular the nature, composition and quantity of the waste ;
- such toxic and dangerous waste is recorded and identified in respect of each site where it is or has been deposited.

*Article 8*

Member States may at any time take more stringent measures with regard to toxic and dangerous waste than those provided for in this Directive.

*Article 9*

1. Installations, establishments or undertakings which carry out the storage, treatment and/or deposit of toxic and dangerous waste must obtain a permit from the competent authorities. Such waste may be stored, treated, and/or deposited only by installations, establishments or undertakings holding such permits. Undertakings engaged in the carriage of toxic and dangerous waste shall be controlled by the competent authorities of the Member States.

2. The permit referred to in paragraph 1 shall cover in particular :

- the type and quantity of waste ;
- the technical requirements ;
- the precautions to be taken ;
- the disposal site(s) ;
- the methods of disposal.

This permit may also lay down the specific information to be made available at the request of the competent authorities.

3. Permits may include conditions and obligations. They may be granted for a specified period and may be renewed.

*Article 10*

Any person producing or holding toxic and dangerous waste without the permit referred to in Article 9 (1) shall as soon as possible have such waste stored, treated and/or deposited by an installation, establishment or undertaking authorized to do so under the said Article.

*Article 11*

1. In accordance with the 'polluter pays' principle, the cost of disposing of toxic and dangerous waste, less any proceeds from treating the waste, shall be borne by :

- the holder who has waste handled by a waste collector or by an installation, establishment or undertaking referred to in Article 9 (1) ;
- and/or
- the previous holders or the producer of the product from which the waste came.

2. If Member States charge levies on the monies used to cover the costs referred to in paragraph 1, the yield thereof may also be used for the following purposes :

- financing control measures relating to toxic and dangerous waste ;
- financing research pertaining to the elimination of toxic and dangerous waste.

*Article 12*

1. The competent authorities shall draw up and keep up to date plans for the disposal of toxic and dangerous waste. The plans shall cover in particular :

- the type and quantity of waste to be disposed of ;
- the methods of disposal ;
- specialized treatment centres where necessary ;
- suitable disposal sites.

The competent authorities of the Member States may include other specific aspects, in particular the estimated cost of the disposal operations.

2. The competent authorities shall make public the plans referred to in paragraph 1. The Member States shall forward these plans to the Commission.

3. The Commission, together with the Member States, shall arrange for regular comparisons of the plans in order to ensure that implementation of this Directive is sufficiently coordinated.

*Article 13*

In cases of emergency or grave danger, Member States shall take all necessary steps, including, where appropriate, temporary derogations from this Directive, to ensure that toxic and dangerous waste is so dealt with as not to constitute a threat to the population or the environment. The Member States shall inform the Commission of such derogations.

*Article 14*

1. Any installation, establishment, or undertaking which produces, holds and/or disposes of toxic and dangerous waste shall :

— keep a record of the quantity, nature, physical and chemical characteristics and origin of such waste, and of the methods and sites used for disposing of such waste, including the dates of receipt and disposal ;

and/or

— make this information available to the competent authorities on request.

2. When toxic and dangerous waste is transported in the course of disposal it shall be accompanied by an identification form containing at least the following details :

— nature ;

— composition ;

— volume or mass of the waste ;

— name and address of the producer or of the previous holder(s) ;

— name and address of the next holder or of the final disposer ;

— location of the site of final disposal where known.

3. Documentary evidence that the disposal operations have been carried out shall be kept for as long as the Member States deem necessary.

This evidence shall, where necessary, be addressed to the relevant authorities of the Member States concerned.

*Article 15*

1. Any installation, establishment or undertaking producing holding or disposing of toxic and dangerous waste shall be subject to inspection and supervision by the competent authorities to ensure that the provisions adopted in application of this Directive and the terms of any authorization are fulfilled.

2. To this end, Member States shall take the necessary measures to ensure that the installations, establishments or undertakings concerned afford the representatives of the competent authorities all necessary assistance to enable them to carry out any examinations, inspections or investigations concerning the waste, to take samples and to gather any information necessary for the fulfilment of their duties.

*Article 16*

1. Every three years, and for the first time three years following the notification of this Directive,

Member States shall draw up a situation report on the disposal of toxic and dangerous waste in their respective countries and shall forward it to the Commission. The Commission shall circulate this report to the other Member States.

2. The Commission shall report every three years to the Council and to the European Parliament on the application of this Directive.

*Article 17*

1. The amendments necessary for adapting this Directive to scientific and technical progress shall be :

— to state the name and composition of the toxic and dangerous substances and materials listed in the Annex ;

— to add to the Annex toxic and dangerous substances and materials unknown at the time of notification of this Directive.

They shall be adopted in accordance with the procedure referred to in Article 19.

2. In adapting the Annex to technical and scientific progress, account shall be taken of the immediate or long term hazard to man and the environment presented by waste by reason of its toxicity, persistence, bioaccumulative characteristics, physical and chemical structure and/or quantity.

*Article 18*

1. A Committee for adapting this Directive to technical progress (hereinafter called 'the Committee') is hereby set up. It shall consist of representatives of the Member States and be chaired by a representative of the Commission.

2. The Committee shall draw up its rules of procedure.

*Article 19*

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which may be determined by the chairman according to the urgency of the matter. It shall decide by a majority of 54 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where these are in accordance with the opinion of the Committee.
- (b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion has been given, the Commission shall forthwith propose to the Council the measures to be adopted. The Council shall act by a qualified majority.
- (c) If, within three months of the proposal being submitted to it, the Council has not acted, the measures proposed shall be adopted by the Commission.

*Article 20*

The Member States shall prohibit all acts which intentionally or unintentionally circumvent the provisions of this Directive.

*Article 21*

1. Member States shall bring into force the measures necessary to comply with this Directive

within 24 months of its notification. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 22*

This Directive is addressed to the Member States.

Done at Brussels, 20 March 1978.

*For the Council*

*The President*

K. HEINESEN

## ANNEX

## List of toxic or dangerous substances and materials

The following list consists of certain toxic or dangerous substances and materials selected as requiring priority consideration

1	Arsenic ; arsenic compounds
2	Mercury ; mercury compounds
3	Cadmium ; cadmium compounds
4	Thallium ; thallium compounds
5	Beryllium ; beryllium compounds
6	Chrome 6 compounds
7	Lead ; lead compounds
8	Antimony ; antimony compounds
9	Phenols ; phenol compounds
10	Cyanides, organic and inorganic
11	Isocyanates
12	Organic-halogen compounds, excluding inert polymeric materials and other substances referred to in this list or covered by other Directives concerning the disposal of toxic or dangerous waste
13	Chlorinated solvents
14	Organic solvents
15	Biocides and phyto-pharmaceutical substances
16	Tarry materials from refining and tar residues from distilling
17	Pharmaceutical compounds
18	Peroxides, chlorates, perchlorates and azides
19	Ethers
20	Chemical laboratory materials, not identifiable and/or new, whose effects on the environment are not known
21	Asbestos (dust and fibres)
22	Selenium ; selenium compounds
23	Tellurium ; tellurium compounds
24	Aromatic polycyclic compounds (with carcinogenic effects)
25	Metal carbonyls
26	Soluble copper compounds
27	Acids and/or basic substances used in the surface treatment and finishing of metals

## COUNCIL DIRECTIVE

of 6 December 1984

on the supervision and control within the European Community of the transfrontier shipment of hazardous waste

(84/631/EEC)

(as amended by Commission Directive 85/469/EEC of 22 July 1985 adapting to technical progress Council Directive 84/631/EEC (OJ L 272, 12.10.85, p. 1); Council Directive 86/121/EEC of 8 April 1986 (OJ L 100, 16.4.86, p. 20); Council Directive 86/279/EEC of 12 June 1986 (OJ L 181, 4.7.86, p. 13); and Council Directive 87/112/EEC of 23 December 1986 (OJ L 48, 17.2.87, p. 31))

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas the 1973 <sup>(4)</sup>, 1977 <sup>(5)</sup> and 1983 <sup>(6)</sup> programmes of action of the European Communities on the environment provide for Community action in order to control the disposal of hazardous waste;

Whereas, pursuant to Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste <sup>(7)</sup>, Member States are required to take the necessary measures to ensure that toxic and dangerous waste is disposed of without endangering human health and without harming the environment;

Whereas shipment of waste between Member States, or between Member States and other States, may be necessary in order to dispose of it under the best possible conditions;

Whereas any difference between the provisions on disposal of hazardous waste already applicable or in preparation in the various Member States may distort the conditions of competition and thus directly affect the functioning of the common market; whereas there are, in particular, differences between the procedures applying to the supervision and control of the transfrontier shipment of hazardous waste within the Community; whereas it is therefore necessary to approximate laws in this field, as provided for in Article 100 of the Treaty;

Whereas Council Directive 75/442/EEC of 15 July 1975 on waste <sup>(8)</sup>, Council Directive 76/403/EEC of 16 April 1976 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls <sup>(9)</sup> and Council Directive 78/319/EEC have already laid down certain provisions concerning the disposal of dangerous waste, but have not yet regulated the supervision and control of the transfrontier shipment of hazardous waste;

Whereas an efficient and coherent system of supervision and control of the transfrontier shipment of hazardous waste should neither create barriers to intra-Community trade nor affect competition;

<sup>(1)</sup> OJ No C 53, 25. 2. 1983, p. 3 and

OJ No C 186, 12. 7. 1983, p. 3.

<sup>(2)</sup> OJ No C 184, 11. 7. 1983, p. 50.

<sup>(3)</sup> OJ No C 176, 4. 7. 1983, p. 4.

<sup>(4)</sup> OJ No C 112, 20. 12. 1973, p. 3.

<sup>(5)</sup> OJ No C 139, 13. 6. 1977, p. 3.

<sup>(6)</sup> OJ No C 46, 17. 2. 1983, p. 1.

<sup>(7)</sup> OJ No L 84, 31. 3. 1978, p. 43.

<sup>(8)</sup> OJ No L 194, 25. 7. 1975, p. 39.

<sup>(9)</sup> OJ No L 108, 26. 4. 1976, p. 41.

Whereas the growing volume of long-distance trans-frontier shipments of hazardous waste in the Community results in increased risk necessitating supervision and control of hazardous waste from the moment of its formation until its treatment or ultimate safe disposal ;

Whereas this requires compulsory notification of transfrontier shipments of hazardous waste and a uniform consignment note ;

Whereas the competent authorities of the Member States of destination of waste should be able to raise objections to shipments of waste ; whereas any objection should fulfil certain criteria and be duly substantiated ;

Whereas it is also desirable for the Member State of dispatch and the Member State of transit to be able, subject to certain criteria, to lay down conditions in respect of the shipment of waste on their territory ;

Whereas, moreover, in certain situations and subject to certain conditions, the Member State of dispatch should be able to object to a shipment ;

Whereas in the case of waste shipped outside the Community, the third State of destination and, where appropriate, the third State of transit should also be notified ;

Whereas in this case, in order effectively to control transfrontier shipments of hazardous waste, the customs authorities of the last Member State through which the shipment is due to pass should send a copy of the consignment note to the competent authority of that Member State ; whereas the holder should certify to the competent authorities of the Member State of dispatch that the waste has left the Community ;

Whereas in certain circumstances a general notification procedure may be used ;

Whereas information relating to the waste concerned, the producers, the existence of a contractual agreement with the consignee, the provisions made for routes and insurance and the conditions for the exercise of the transport operations should be sent to the competent authorities of the Member States concerned as part of the notification procedure ;

Whereas in order to ensure that hazardous waste does not constitute an unnecessary risk it should be properly packaged and labelled ; whereas the instructions to be followed in the event of danger or accident should accompany the waste in order to protect man and the environment from any danger that might arise during the operation ;

Whereas the Member States may fix border crossing-points after consulting the Commission ;

Whereas in accordance with the 'polluter pays' principle, the costs of implementing the notification procedure, including the costs of control and analysis, should be borne by the holder and/or the producer of the waste ;

Whereas it is important that the liability of the producer and that of any other person who may be accountable for damage should be defined and the conditions of application determined in order to guarantee effective and fair compensation for damage which may be caused during the shipment of dangerous waste ; whereas the Council should act at the latest within three years of the application of this Directive ; whereas the Council should also take a decision within the same time limit on a system of insurance ;

Whereas, subject to certain conditions, non-ferrous metal waste intended for re-use, regeneration or recycling should be exempted from the provisions of this Directive ;

Whereas Member States should communicate to the Commission any information relevant to the implementation of this Directive and must in particular prepare reports every two years on the basis of which the Commission will draw up a summary report ;

Whereas the Technical Committee set up under Directive 78/319/EEC should also be empowered to draw up and adapt as necessary the uniform consignment note on the uniform declaration provided for in this Directive and also to adapt the list of Conventions annexed to this Directive,

HAS ADOPTED THIS DIRECTIVE :

#### *Article 1*

Member States shall, in accordance with the provisions of this Directive, take the necessary measures for the supervision and control, with a view to the protection of human health and the environment, of the trans-frontier shipment of hazardous waste both within the Community and on its entering and/or leaving the Community.

#### *Article 2*

1. For the purposes of this Directive :

(a) 'hazardous waste', hereinafter referred to as 'waste', means :



- toxic and dangerous waste as defined in Article 1 (b) of Directive 78/319/EEC, except for the chlorinated and organic solvents referred to in points 13 and 14 of the Annex to that Directive,
  - PCB as defined in Article 1 (a) of Directive 76/403/EEC;
- (b) 'competent authorities' of the Member States concerned means the competent authority or authorities, designated in accordance with Article 16, of the Member State of destination of the waste, of the Member State of dispatch of the waste and, where applicable, of the Member State or States of transit of the waste;
- (c) 'the producer of the waste' means anyone whose activities produce waste ('original producer') and/or anyone who carries out pre-processing, mixing or other operations resulting in a change in the nature or composition of this waste;
- (d) 'the holder of the waste' means the producer of the waste or any other person or undertaking who or which proposes to carry out or to have carried out a transfrontier shipment of waste;
- (e) 'the consignee of the waste' means the person or undertaking to whom or to which the waste is shipped for disposal;
- (f) 'disposal' means disposal within the meaning of Article 1 (c) of Directive 78/319/EEC.
2. The off-loading to shore of waste produced by the normal operation of ships, including waste water and residues, shall not be considered a transfrontier shipment of waste within the meaning of this Directive.

### Article 3

1. Where the holder of the waste intends to ship it or to have it shipped from one Member State to another, to have it routed through one or more Member States, or to ship it to a Member State from a third State or from a Member State to a third State, he shall notify the competent authority of the Member State responsible for issuing the acknowledgement of receipt, with a copy to the competent authorities of the other Member States concerned and, where applicable, to the third State of destination and/or the third State(s) of transit.
2. Notification shall be effected by means of a uniform consignment note, hereinafter referred to as the 'consignment note', to be drawn up in accordance with Article 15 and the contents of which are set out in Annex I.
3. When so notifying the competent authority of the Member State responsible for issuing the acknowledgement of receipt, the holder of the waste shall provide it with satisfactory information on the following in particular:

- the source and composition of the waste, including the producer's identity, and in the case of waste from various sources, a detailed inventory of the waste and, where such information exists, the identity of the original producers,
- the provision made for routes and insurance against damage to third parties,
- the measures to be taken to ensure safe transport and, in particular, compliance by the carrier with the conditions laid down by the Member States concerned for the exercise of such transport operations,
- the existence of a contractual agreement with the consignee of the waste, who should possess adequate technical capacity for the disposal of the waste in question under conditions presenting no danger to human health or the environment. Where the waste is stored, treated or dumped in a Member State, the consignee must also possess a permit in accordance with Article 9 of Directive 78/319/EEC or Article 6 of Directive 76/403/EEC.

4. In the case of a shipment from a Member State to a third State, the holder of the waste shall obtain the agreement of the third State of destination before embarking upon the notification procedure provided for in paragraph 3. The notification must include satisfactory information on such agreement.

### Article 4

1. Transfrontier shipment may not be effected before the competent authorities of the Member States referred to in paragraph 2 (a), (b) or (c) have acknowledged receipt of the notification. The acknowledgement shall be entered on the consignment note.
2. Not later than one month after receipt of the notification, the acknowledgement of receipt or any objection raised in accordance with paragraph 3 shall be forwarded to the holder of the waste:
  - (a) either by the competent authorities of the Member State of destination; or
  - (b) in the case of shipments of waste from a third State in transit through the Community for disposal outside the Community, by the competent authorities of the last Member State through which the shipment is due to pass; or
  - (c) in the case of shipments of waste from a Member State for disposal outside the Community in a third

State, by the competent authorities of the Member State of dispatch, except in the case provided for in the last subparagraph of this paragraph

with a copy to the consignee of the waste and to the competent authorities of the other Member States concerned, and where applicable, to the third State of destination and the third State(s) of transit.

Where the waste is disposed of in a third State bordering on the last Member State of transit, the latter shall be entitled to issue the acknowledgement of receipt or to raise any objection in place of the Member State referred to in (c). A Member State of transit intending to exercise the right conferred upon it in this subparagraph shall communicate it to the Commission and other Member States. It may not exercise this right earlier than three months following such communication.

3. Objections must be substantiated on the basis of laws and regulations relating to environmental protection, public policy and public security or health protection which are in conformity with this Directive, with other Community instruments or with international conventions on this subject concluded by the Member State concerned prior to notification of this Directive.

4. Once the competent authorities of the Member State referred to in paragraph 2 are satisfied that the problems giving rise to their objections have been resolved, they shall immediately send an acknowledgement to the holder of the waste with a copy to the consignee of the waste and to the competent authorities of the other Member States concerned, and, where applicable, to the third State of destination and the third State(s) of transit.

5. The acknowledgement forwarded by the competent authorities of the Member State referred to in paragraph 2 to the holder of the waste pursuant to this Article shall not release the producer of such waste or any other person from his obligations under existing national and Community provisions.

6. Without prejudice to paragraphs 1 and 2, the competent authorities of the Member State of dispatch, and those of the Member State or States of transit, if any, shall have 15 days following the notification in which to lay down, if appropriate, conditions in respect of the shipment of waste in their national territory. These conditions, which shall be forwarded to the holder of the waste, with a copy to the competent authorities of the Member States concerned, may not be more stringent than those laid down in respect of similar shipments effected wholly within the Member

State in question and shall take due account of existing agreements. The holder of the waste must comply with these conditions to be able to carry out shipment.

Not later than 20 days after receipt of the notification, the competent authorities of the Member State of dispatch may raise objections on the grounds that the shipment of waste adversely affects the implementation of plans drawn up pursuant to Article 12 of Directive 78/319/EEC or Article 6 of Directive 76/403/EEC or that it conflicts with obligations resulting from international agreements on this subject concluded by it prior to notification of this Directive. Such objections shall be forwarded to the holder of the waste with a copy to the competent authorities of the Member States concerned.

#### *Article 5*

1. The holder of the waste may use a general notification procedure where waste having the same physical and chemical characteristics is shipped regularly to the same consignee via the same customs office of exit of the Member State of dispatch, via the same customs office of entry of the Member State of destination and, in the case of transit, via the same customs offices of entry and exit of the Member State or States of transit.

2. The competent authorities of the Member State referred to in Article 4 (2) and, where applicable, those of the Member State or States of transit, may make their agreement to the use of this general notification procedure subject to the supply of certain information, such as the exact quantities or periodical lists of waste to be shipped.

3. Under a general notification procedure, a single acknowledgement within the meaning of Article 4 (1) may cover several shipments of waste during a maximum period of one year.

4. General notification shall be by means of the consignment note.

#### *Article 6*

1. Upon receipt of the acknowledgement referred to in Articles 4 and 5, the holder of the waste shall complete the consignment note and send copies to the competent authorities of the Member States concerned and to the third States concerned before shipment is carried out.

2. A copy of the consignment note, including the acknowledgement, shall accompany each shipment.

3. All undertakings subsequently involved in the operation shall complete the consignment note where indicated, sign it and retain a copy of it.

4. Within 15 days following receipt of the waste, the consignee of the waste shall forward to the holder of the waste, to the competent authorities of the Member States concerned and to the third States concerned copies of the duly completed consignment note. These copies shall be kept for at least two years.

#### Article 7

1. By way of derogation from Article 6 (4), when waste leaves the Community for disposal outside the Community, the customs service in the last Member State through which the shipment passes shall forward a copy of the consignment note to the competent authorities in that Member State, which, in the case referred to in Article 4 (2) (c), shall also forward a copy to the competent authorities in the Member State of dispatch. These copies shall be kept for at least two years.

2. The holder of the waste shall also declare or certify to the competent authorities of the Member State referred to in Article 4 (2) (b) or (c), not later than six weeks after the waste has left the Community, that the waste has reached its proper destination and shall indicate the last customs post in the Community through which the shipment passed.

#### Article 8

1. Transfrontier shipments must comply with the following conditions:

- (a) The waste must be properly packed.
- (b) The containers must have appropriate labels indicating, in addition to the nature, composition and quantity of the waste, the telephone number(s) of the person(s) from whom instructions or advice may be obtained at all times during shipment.
- (c) The instructions to be followed in the event of danger or accident must accompany the waste.
- (d) The labels and instructions referred to in (b) and (c) must be in the languages of the Member States concerned.

2. The conditions referred to in paragraph 1 shall be deemed to be met where a Member State applies the provisions applicable in the matter under the international transport conventions listed in Annex II to which it is a party in so far as those conventions cover the waste to which this Directive refers.

#### Article 9

Member States may designate border crossing-points for the shipment of waste where necessary and after consulting the Commission.

#### Article 10

In accordance with the 'polluter pays' principle, the cost of implementing the notification and supervision procedure, including the necessary analyses and controls, shall be chargeable to the holder and/or the producer of the waste by the Member State concerned, provided that this cost is comparable to that entailed by the same operations concerning the same types of waste and relating to shipments taking place entirely within that Member State.

#### Article 11

1. Without prejudice to national provisions concerning civil liability, irrespective of the place in which the waste is disposed of, the producer of the waste shall take all necessary steps to dispose of or arrange for the disposal of the waste so as to protect the quality of the environment in accordance with Directives 75/442/EEC and 78/319/EEC and with this Directive.

2. Member States shall take all necessary steps to ensure that the obligations laid down in paragraph 1 are carried out.

3. The Council shall, acting in accordance with the procedure referred to in Article 100 of the Treaty, determine not later than 30 September 1988 the conditions for implementing the civil liability of the producer in the case of damage or that of any other person who may be accountable for the said damage and shall also determine a system of insurance.

#### Article 12

1. Member States shall forward to the Commission not later than 31 December 1985 the name(s), address(es) and telephone and telex numbers of the competent authorities and of the installations, establishments or undertakings with a permit within the meaning of the last indent of Article 3 (3) to dispose of waste.

Member States shall forward regularly to the Commission any modifications to the data.

2. The Commission shall forward information referred to under paragraph 1 without delay to the other Member States.

#### Article 13

1. Every two years, and for the first time on 1 October 1987, Member States shall forward to the Commission reports on the implementation of this Directive and on the situation with regard to transfrontier shipments concerning their respective territories.

2. These reports shall in particular comprise the following information:

- transfrontier shipments of waste arising from major accidents, in particular within the meaning of Article 1 of Council Directive 82/501/EEC of 24 June 1982 on the major-accident hazards of certain industrial activities<sup>(1)</sup>,
- any significant irregularities in transfrontier shipment of waste covered by this Directive which has involved or may yet involve serious hazards for man or the environment,
- the quantity and type of waste which has entered their territory for disposal and the quality and type of waste produced in their territory and subsequently definitively exported.

<sup>(1)</sup> OJ No L 230, 5. 8. 1982, p. 1.

*Article 14*

On the basis of the reports referred to in Article 13, the Commission shall prepare a summary report every two years, which it shall submit to the European Parliament, the Council and the Economic and Social Committee.

*Article 15*

The Technical Committee set up under Article 18 of Directive 78/319/EEC, and acting under the procedure laid down in Article 19 of that Directive, shall be empowered to draw up, in accordance with the information given in Annexes I and III respectively, the consignment note including the general instructions and the uniform declaration document referred to in Article 17. The Committee shall also be empowered, under the same procedure, to adapt to technical progress the consignment note, the declaration document and the list of international transport conventions contained in Annex II.

*Article 16*

Member States shall designate the competent authorities for the purpose of Article 4.

*Article 17*

Waste (including in particular waste, scrap, sludge, ash and dust) from non-ferrous metals which is intended for re-use, regeneration, or recycling on the basis of a contractual agreement regarding such operations shall be exempt from the provisions of this Directive provided that the following conditions are fulfilled:

- (a) the holder must make a declaration on a uniform document, the contents of which is set out in Annex III, and which must accompany the shipment, to the effect that these materials are

intended for the operations in question, and must forward a copy of this document to the competent authorities of the Member State referred to in Article 4 (2) (a) or (b);

- (b) the consignee must declare in the same document, which he shall forward to the competent authorities of the Member State referred to in (a) not later than 15 days from receipt of the materials that these operations will actually be carried out.

*Article 18*

1. Member States shall take the measures necessary to comply with this Directive as from 1 October 1985. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive. The Commission shall inform the other Member States thereof.

*Article 19*

This Directive is addressed to the Member States.


Done at Brussels, 6 December 1984.

*For the Council*

*The President*

L. KAVANAGH

EUROPEAN COMMUNITY ANNEX I TRANSFRONTIER SHIPMENT OF HAZARDOUS WASTE

COPY FOR THE AUTHORITY ISSUING THE ACKNOWLEDGEMENT	1 Holder of the waste <input type="checkbox"/>			2 ACCOMPANYING DOCUMENT No UN / 0 0 0 0 0 in the context of a (*) <input type="checkbox"/> NOTIFICATION FOR A SINGLE SHIPMENT <input type="checkbox"/> GENERAL NOTIFICATION		
	4 Consignee of the waste  Licence details Tel: _____ Telex: _____			5 Producer of the waste  Person to be contacted Tel: _____ Telex: _____		
	6 Carrier of the waste  Licence No (where applicable): Tel: _____ Telex: _____			7 Contractual agreement between holder and consignee dated _____		8 Number of annexes attached _____
	13 Mode of transport _____			14 First shipment on _____	15 Last shipment on _____	
	16 Total number of shipments intended _____			11 Provisions made for insurance against damage to third parties (*) <input type="checkbox"/> YES <input type="checkbox"/> NO Insurer (if required): _____		
	18 Intended packaging _____			19 Dispatch code _____	20 Destination code _____	21 Intended quantity (kg) _____
	22 Name, physical characteristics and chemical composition of the waste _____					24 UN Classification _____
	23 Process by which the waste was generated _____			25 Nature of the risks (*) 		
	27 Outward appearance of the waste at _____ °C (*) <input type="checkbox"/> powdery/powder <input type="checkbox"/> solid <input type="checkbox"/> viscous/paste <input type="checkbox"/> sludgy <input type="checkbox"/> liquid <input type="checkbox"/> gaseous <input type="checkbox"/> other _____ Colour _____					
	28 Code numbers of competent authorities of the Member States concerned _____				29 Method of disposal of the waste _____	
30 Customs offices of entry in the Member States of transit and in the Member State of destination _____						
TO BE COMPLETED BY THE COMPETENT AUTHORITY						
ACKNOWLEDGEMENT No _____ valid for (*) <input type="checkbox"/> A SINGLE SHIPMENT <input type="checkbox"/> SEVERAL SHIPMENTS  to be carried out not later than on _____						
Special transport conditions (*) Notification received on _____ Signature _____			<input type="checkbox"/> YES <input type="checkbox"/> NO Acknowledgement sent on _____ Stamp _____			
Name and full address of competent authority _____			33 Place _____  Date _____ Signature of holder _____			

(\*) Enter X in the appropriate box



EUROPEAN COMMUNITY TRANSFRONTIER SHIPMENT OF HAZARDOUS WASTE

COPY FOR THE HOLDER OF THE WASTE	<b>2</b> 1 Holder of the waste <input type="checkbox"/>		<b>2 ACCOMPANYING DOCUMENT</b> No UK / 00000 in the context of a (*) <input type="checkbox"/> NOTIFICATION FOR A SINGLE SHIPMENT <input type="checkbox"/> GENERAL NOTIFICATION		
	Registration No Tel: _____ Telex: _____		<b>4 Consignee of the waste</b>  Licence details Tel: _____ Telex: _____		
	<b>4</b> Consignee of the waste  Licence details Tel: _____ Telex: _____		<b>5 Producer of the waste</b>  Person to be contacted Tel: _____ Telex: _____		
	<b>6</b> Carrier of the waste  Licence No (where applicable) Tel: _____ Telex: _____		<b>7 Contractual agreement between holder and consignee dated</b>	<b>8 Number of annexes attached</b>	
	<b>13 Mode of transport</b>	<b>14 First shipment on</b>	<b>15 Last shipment on</b>	<b>9 Place of generator</b>	
	<b>16 Total number of shipments intended</b>	<b>11 Provisions made for insurance against damage to third parties (*)</b> <input type="checkbox"/> YES <input type="checkbox"/> NO Insurer (if required): _____			
	<b>18 Intended packaging</b>	<b>19 Dispatch code</b>	<b>20 Destination code</b>	<b>21 Intended quantity (kg)</b>	
	<b>22 Name, physical characteristics and chemical composition of the waste</b>				<b>24 UN Classification</b>
	<b>25 Process by which the waste was generated</b>		<b>26 Nature of the risks (*)</b> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> </div>		
	<b>27 Outward appearance of the waste at °C (*)</b> <input type="checkbox"/> powdery powder <input type="checkbox"/> solid <input type="checkbox"/> viscous/paste <input type="checkbox"/> sludgy <input type="checkbox"/> liquid <input type="checkbox"/> gaseous <input type="checkbox"/> other _____ Colour _____				
<b>28 Code numbers of competent authorities of the Member States concerned</b>			<b>29 Method of disposal of the waste</b>		
<b>30 Customs offices of entry in the Member States of transit and in the Member State of destination</b>					
TO BE COMPLETED BY THE COMPETENT AUTHORITY <b>ACKNOWLEDGEMENT No</b> valid for (*) <input type="checkbox"/> A SINGLE SHIPMENT <input type="checkbox"/> SEVERAL SHIPMENTS  to be carried out not later than on _____  Special transport conditions (*) <input type="checkbox"/> YES <input type="checkbox"/> NO Notification received on _____ Acknowledgement sent on _____ Signature _____ Stamp _____			<b>33 Place</b>  Date _____ Signature of holder _____		
Name and full address of competent authority			Date _____ Signature of holder _____		

(\*) Enter X in the appropriate box





EUROPEAN COMMUNITY TRANSFRONTIER SHIPMENT OF HAZARDOUS WASTE

COPY ACCOMPANYING THE WASTE	<b>3</b> 1 Holder of the waste <input type="checkbox"/>		<b>2 ACCOMPANYING DOCUMENT</b> No UK / 00000 in the context of a (*) <input type="checkbox"/> NOTIFICATION FOR A SINGLE SHIPMENT <input type="checkbox"/> GENERAL NOTIFICATION		3 Serial No of shipment
	Registration No Tel: _____ Telex: _____		<b>5</b> Producer of the waste  Person to be contacted Tel: _____ Telex: _____		
	<b>4</b> Consignee of the waste  Licence details Tel: _____ Telex: _____		<b>7</b> Contractual agreement between holder and consignee dated _____		<b>8</b> Number of annexes attached
	<b>6</b> Carrier of the waste  Licence No (where applicable): Tel: _____ Telex: _____		<b>9</b> Place of generation		<b>10</b> Place of disposal
	<b>12</b> Identity of means of transport		<b>11</b> Provisions made for insurance against damage to third parties (*) <input type="checkbox"/> YES <input type="checkbox"/> NO Insurer (if required)		
	<b>13</b> Mode of transport		<b>14</b> First shipment on	<b>15</b> Last shipment on	
	<b>16</b> Total number of shipments intended		<b>17</b> Actual date of shipment		
	<b>18</b> Number and kind of packages		<b>19</b> Dispatch code	<b>20</b> Destination code	<b>21</b> Intended quantity (kg)
	<b>22</b> Name, physical characteristics and chemical composition of the waste		<b>23</b> Actual quantity (kg)		<b>24</b> UN Classification
	<b>25</b> Process by which the waste was generated		<b>26</b> Nature of the risks (*) <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> <div style="text-align: center;"> <input type="checkbox"/></div> </div>		
<b>27</b> Outward appearance of the waste at _____ °C (*) <input type="checkbox"/> powdery/powder <input type="checkbox"/> solid <input type="checkbox"/> viscous/paste <input type="checkbox"/> sludgy <input type="checkbox"/> liquid <input type="checkbox"/> gaseous <input type="checkbox"/> other _____ Colour					
<b>28</b> Code numbers of competent authorities of the Member States concerned		<b>29</b> Method of disposal of the waste			
<b>30</b> Customs offices of entry in the Member States of transit and in the Member State of destination					
<b>TO BE COMPLETED BY THE COMPETENT AUTHORITY</b> <b>ACKNOWLEDGEMENT</b> No valid for (*) <input type="checkbox"/> A SINGLE SHIPMENT <input type="checkbox"/> SEVERAL SHIPMENTS  to be carried out not later than on _____  Special transport conditions (*) <input type="checkbox"/> YES <input type="checkbox"/> NO Notification received on _____ Acknowledgement sent on _____ Signature _____ Stamp _____  Name and full address of competent authority			<b>31 TO BE COMPLETED BY THE CARRIER</b> Date _____ Signature _____  Person to be contacted _____ Tel: _____ Telex: _____		
			<b>32 TO BE COMPLETED BY THE CONSIGNEE</b> Net quantity received (kg) _____ Date _____ Signature _____  Person to be contacted _____ Tel: _____ Telex: _____		
			<b>33</b> Place _____  Date _____ Signature of holder: _____  Person to be contacted _____ Tel: _____ Telex: _____		

(\*) Enter X in the appropriate box

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**IMPORTANT NOTES**

The boxes underneath must contain:

- the name and christian name or the company name and the full address of the carrier;
- the nature and the registration number of the means of transport;
- the date at which the waste was collected for carriage;
- the signature of the carrier or his representative, the name and christian name of the person to be contacted and his telephone and telex number.

BY SIGNING THIS FORM THE CARRIER OR HIS REPRESENTATIVE CERTIFIES THAT THE INFORMATION HE HAS PROVIDED IS COMPLETE

34 SUCCESSIVE INTENDED CARRIERS OR NEW CARRIER IN THE CASE OF FORCE MAJEURE	
Name and full address	Date Signature of carrier or his representative
Identity of means of transport	Person to be contacted  Tel: _____ Telex: _____
Name and full address	Date Signature of carrier or his representative
Identity of means of transport	Person to be contacted  Tel: _____ Telex: _____
Name and full address	Date Signature of carrier or his representative
Identity of means of transport	Person to be contacted  Tel: _____ Telex: _____

35 ENDORSEMENT BY THE CUSTOMS OFFICE OF EXIT FROM THE COMMUNITY	
The waste described overleaf has left the Community on	
Signature	Stamp
NOTE: The customs office concerned must send this copy to the competent authority of the Member State to which the office belongs.	

36 TRANSLATION OF PARTICULARS SHOWN IN BOX 27 OVERLEAF								
ESPAÑOL	polvo	pulverulento	sólido	pastoso	viscoso	fangoso	líquido	gaseoso
DANSK	pulveragtig	støvetagtig	fast	pastagtig	tykflydende	slæmagtig	flydende	luftformig
DEUTSCH	pulverförmig	staubförmig	fest	pastös	breiig	schlammig	flüssig	gasförmig
ΕΛΛΗΝΙΚΑ	αυχίνη	αυχινώδες	στερεό	μαζώδες/πυκνό	εμπυκνωμένο	λεπτοκόκκο	υγρό	αέριο
ENGLISH	powder	powdery	solid	paste	viscous	sludge	liquid	gaseous
FRANÇAIS	poudreux	pulvérulent	solide	pâteux	sirupeux	boueux	liquide	gazeux
ITALIANO	polvere	pulverulento	solido	vischioso	sciropposo	fangoso	liquido	gaseoso
NEDERLANDS	poeder	poederachtig	vast	vettauis	stroperig	slibachtig	vloeibaar	gasvormig
PORTUGUÊS	em pó	pulverulento	sólido	pastoso	viscoso	lamacento	líq. do	gasoso

## ANNEX II

LIST OF INTERNATIONAL TRANSPORT CONVENTIONS REFERRED TO IN  
ARTICLE 8 (2)<sup>(1)</sup>

1. **ADR :**  
European Agreement concerning the International Carriage of Dangerous Goods by Road (1957);
2. **CIM :**  
International Convention concerning the Carriage of Goods by Rail (1924)<sup>(2)</sup>,  
including in Annex I:  
**RID :**  
International Regulations concerning the Carriage of Dangerous Goods by Rail (1924);
3. **SOLAS Convention :**  
International Convention for the Safety of Life at Sea (1974);
4. **IMDG Code<sup>(3)</sup> :**  
International Maritime Dangerous Goods Code;
5. **Chicago Convention :**  
Convention on International Civil Aviation (1944) *Annex 18* to which deals with the carriage of dangerous goods by air (T.I. : Technical Instructions for the Safe Transport of Dangerous Goods by Air);
6. **MARPOL Convention :**  
International Convention for the Prevention of Pollution from Ships (1973/1978);
7. **ADNR :**  
Regulation of the Carriage of Dangerous Substances on the Rhine (1970).

<sup>(1)</sup> This list contains those Conventions in force at the time of adoption of this Directive and may be adapted by the Technical Committee referred to in Article 15.

<sup>(2)</sup> From 1 May 1985 this Convention will be called :  
COTIF : Convention concerning International Carriage by Rail.

The RID will become an Annex to the COTIF called :  
'Regulations concerning the international carriage of dangerous goods by rail'.

<sup>(3)</sup> From 1 January 1985, the IMDG code will be incorporated in the SOLAS Convention.



EUROPEAN COMMUNITY

ANNEX III

<p>1 Holder of the waste (name and full address)</p> <p><input type="checkbox"/></p>	<p><b>DECLARATIONS CONCERNING WASTE FROM NON-FERROUS METALS FOR RE-USE, REGENERATION OR RECYCLING</b></p> <p>No UK / 0 0 0 0 0</p> <p><b>1 COPY FOR THE CONSIGNEE OF THE WASTE</b></p>
<p>2 Consignee of the waste (name and full address)</p>	<p><b>INSTRUCTIONS</b></p> <p>1 Boxes 1 to 5 and box 7 on the four copies of this form must be completed by the holder of the waste. The form must be completed in typescript or in manuscript in the latter case it must be completed in ink and in printed capitals. There may be no erasures or superimposed corrections. Amendments must be made by striking through the incorrect particulars and where appropriate adding those required. Any such amendments must be initialed by the person making them.</p>

- 2 Copies 1 and 2 of the form must accompany the waste and be handed to the consignee
- 3 The holder of the waste must keep copy 3 of the form and, before the shipment is carried out, send copy 4 to the competent authority of the Member State of destination or, in case of waste exported from the Community, to the competent authority of the Member State of dispatch and the Member State where the waste will leave the Community (photocopy).
- 4 The consignee of the waste must complete box 6 on copies 1 and 2, keep copy 1 and send copy 2 to the competent authority of the Member State referred to under 3 above not later than 15 days after receipt of the waste.

THIS FORM MAY BE USED ONLY FOR WASTE COVERED BY ARTICLE 17 OF DIRECTIVE 84 / 631 / EEC		
3 Item No	4 Usual commercial description of the waste	5 Net quantity (kg)
<p><b>6 CONSIGNEE'S DECLARATION</b></p> <p>It is hereby certified that the waste described above will actually be RE-USED, REGENERATED OR RECYCLED</p> <p>Date _____</p> <p>Signature _____</p>	<p><b>7 HOLDER'S DECLARATION</b></p> <p>The waste described above is intended for RE-USE, REGENERATION OR RECYCLING on the basis of a contractual agreement with the consignee shown in box 2</p> <p>Date _____</p> <p>Signature _____</p>	

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**EUROPEAN COMMUNITY**

<b>1</b> Holder of the waste (name and full address): <input type="checkbox"/>	<b>DECLARATIONS CONCERNING WASTE FROM NON-FERROUS METALS FOR RE-USE, REGENERATION OR RECYCLING</b> No UK / 0 0 0 0 0
<b>2</b> Consignee of the waste (name and full address):	<b>2</b> <b>COPY FOR THE COMPETENT AUTHORITY</b>  INSTRUCTIONS 1 Boxes 1 to 5 and box 7 on the four copies of this form must be completed by the holder of the waste. The form must be completed in typescript or in manuscript in the latter case it must be completed in ink and in printed capitals. There may be no erasures or superimposed corrections. Amendments must be made by striking through the incorrect particulars and, where appropriate adding those required. Any such amendments must be initialed by the person making them.

- 2 Copies 1 and 2 of the form must accompany the waste and be handed to the consignee
- 3 The holder of the waste must keep copy 3 of the form and, before the shipment is carried out, send copy 4 to the competent authority of the Member State of destination or in case of waste exported from the Community to the competent authority of the Member State of dispatch and the Member State where the waste will leave the Community (photocopy)
- 4 The consignee of the waste must complete box 6 on copies 1 and 2, keep copy 1 and send copy 2 to the competent authority of the Member State referred to under 3 above not later than 15 days after receipt of the waste.

THIS FORM MAY BE USED ONLY FOR WASTE COVERED BY ARTICLE 17 OF DIRECTIVE 84/631/EEC		
3 Item No	4 Usual commercial description of the waste	5 Net quantity (kg)
<b>6 CONSIGNEE'S DECLARATION</b> It is hereby certified that the waste described above will actually be RE-USED, REGENERATED OR RECYCLED Date Signature	<b>7 HOLDER'S DECLARATION</b> The waste described above is intended for RE-USE, REGENERATION OR RECYCLING on the basis of a contractual agreement with the consignee shown in box 2 Date Signature	

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**EUROPEAN COMMUNITY**

<p>1 Holder of the waste (name and full address)</p> <p><input type="checkbox"/></p>	<p><b>DECLARATIONS CONCERNING WASTE FROM NON-FERROUS METALS FOR RE-USE, REGENERATION OR RECYCLING</b></p> <p>No UK / 0 0 0 0 0</p>
<p>2 Consignee of the waste (name and full address)</p>	<p><b>3 COPY FOR THE HOLDER OF THE WASTE</b></p> <p><b>INSTRUCTIONS</b></p> <p>1 Boxes 1 to 5 and box 7 on the four copies of this form must be completed by the holder of the waste. The form must be completed in typescript or in manuscript in the latter case it must be completed in ink and in printed capitals. There may be no erasures or superimposed corrections. Amendments must be made by striking through the incorrect particulars and where appropriate adding those required. Any such amendments must be initialled by the person making them.</p> <p>2 Copies 1 and 2 of the form must accompany the waste and be handed to the consignee.</p> <p>3 The holder of the waste must keep copy 3 of the form and, before the shipment is carried out, send copy 4 to the competent authority of the Member State of destination or in case of waste exported from the Community, to the competent authority of the Member State of dispatch and the Member State where the waste will leave the Community (photocopy).</p> <p>4 The consignee of the waste must complete box 6 on copies 1 and 2, keep copy 1 and send copy 2 to the competent authority of the Member State referred to under 3 above not later than 15 days after receipt of the waste.</p>

- through the incorrect particulars and where appropriate adding those required. Any such amendments must be initialled by the person making them.
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- 3 The holder of the waste must keep copy 3 of the form and, before the shipment is carried out, send copy 4 to the competent authority of the Member State of destination or in case of waste exported from the Community, to the competent authority of the Member State of dispatch and the Member State where the waste will leave the Community (photocopy).
- 4 The consignee of the waste must complete box 6 on copies 1 and 2, keep copy 1 and send copy 2 to the competent authority of the Member State referred to under 3 above not later than 15 days after receipt of the waste.

THIS FORM MAY BE USED ONLY FOR WASTE COVERED BY ARTICLE 17 OF DIRECTIVE 64 / 631 / EEC		
3 Item No	4 Usual commercial description of the waste	5 Net quantity (kg)
		<p><b>7 HOLDER'S DECLARATION</b></p> <p>The waste described above is intended for  <b>RE-USE, REGENERATION OR RECYCLING</b>  on the basis of a contractual agreement with the consignee shown in box 2</p> <p>Date _____</p> <p>Signature _____</p>

Printed by



**EUROPEAN COMMUNITY**

<b>1</b> Holder of the waste (name and full address) <input type="checkbox"/>	<b>DECLARATIONS CONCERNING WASTE FROM NON-FERROUS METALS FOR RE-USE, REGENERATION OR RECYCLING</b> No UK / 0 0 0 0
<b>2</b> Consignee of the waste (name and full address)	<b>4</b> <b>COPY FOR THE COMPETENT AUTHORITY</b>

**INSTRUCTIONS**

1 Boxes 1 to 5 and box 7 on the four copies of this form must be completed by the holder of the waste. The form must be completed in typescript or in manuscript in the latter case it must be completed in ink and in printed capitals. There may be no erasures or superimposed corrections. Amendments must be made by striking

through the incorrect particulars and, where appropriate, adding those required. Any such amendments must be initialed by the person making them.

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3 The holder of the waste must keep copy 3 of the form and, before the shipment is carried out, send copy 4 to the competent authority of the Member State of destination or, in case of waste exported from the Community, to the competent authority of the Member State of dispatch and the Member State where the waste will leave the Community (photocopy).

4 The consignee of the waste must complete box 6 on copies 1 and 2, keep copy 1 and send copy 2 to the competent authority of the Member State referred to under 3 above not later than 15 days after receipt of the waste.

THIS FORM MAY BE USED ONLY FOR WASTE COVERED BY ARTICLE 17 OF DIRECTIVE 84 / 631 / EEC		
3 Item No	4 Usual commercial description of the waste	5 Net quantity (kg)
		<b>7 HOLDER'S DECLARATION</b> The waste described above is intended for <b>RE-USE, REGENERATION OR RECYCLING</b> on the basis of a contractual agreement with the consignee shown in box 2 Date _____ Signature _____

Printed by



COMMISSION DIRECTIVE  
of 22 July 1985

adapting to technical progress Council Directive 84/631/EEC on the supervision and control within the European Community of the transfrontier shipment of hazardous waste

(85/469/EEC)

(as amended by Council Directive 87/112/EEC of 23 December 1986 (OJ L 48, 17.2.87, p. 31))

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste <sup>(1)</sup>, and in particular Article 18 thereof,

Having regard to Council Directive 84/631/EEC of 6 December 1984 on the supervision and control within the European Community of the transfrontier shipment of hazardous waste <sup>(2)</sup>, and in particular Article 15 thereof,

Whereas it is necessary to finalize Annexes I and III to Directive 84/631/EEC;

Whereas, in order to ensure effective supervision and control, it is necessary that the holder of waste intending to ship it or to have it shipped from one Member State to another or through one or more Member States or to ship it to a Member State from a third State should notify the competent authorities of the Member States concerned;

Whereas such notification must be made by means of a uniform consignment note, the contents of which are set out in Annex I to Directive 84/631/EEC;

Whereas, in the case of non-ferrous metal waste intended for re-use, regeneration or recycling on the basis of a contractual agreement regarding such operations, only declarations on a

uniform document are required, the content of which is given in Annex III to Directive 84/631/EEC;

Whereas this uniform document should conform with the layout-key drawn up under the auspices of the United Nations Economic Commission for Europe;

Whereas the measures provided for in this Directive are in conformity with the opinion of the Committee for adaptation to technical progress of Directive 78/319/EEC,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Annex I to Directive 84/631/EEC is hereby replaced by Annex I to this Directive.

*Article 2*

Annex III to Directive 84/631/EEC is hereby replaced by Annex II to this Directive.

*Article 3*

The forms set out in Annexes I and II must conform to the technical conditions set out in Annex III and must be completed in accordance with the instructions given in Annex IV.

<sup>(1)</sup> OJ No L 84, 31. 3. 1978, p. 43.

<sup>(2)</sup> OJ No L 326, 13. 12. 1984, p. 31.

*Article 4*

Member States shall take the measures necessary to ensure that Annex IV is brought to the attention of all parties required to complete the form contained in Annex I.

*Article 5*

Member States shall take the measures necessary to comply with this Directive as from 1 October 1985. They shall forthwith inform the Commission thereof.

*Article 6*

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1985.

*For the Commission*  
Stanley CLINTON DAVIS  
*Member of the Commission*

## ANNEX III

## PROVISIONS CONCERNING THE FORMS

1. The form for the uniform consignment note shall comprise:
  - the copy for the authority issuing the acknowledgement,
  - the copy for the holder of the wastes,
  - the accompanying copy,  
in that order.
2. The form for the declarations concerning non-ferrous metal wastes intended for re-use, regeneration or recycling shall comprise:
  - the copy for the consignee,
  - the copy for the competent authority, to be sent by the consignee,
  - the copy for the holder of the wastes,
  - the copy for the competent authority, to be sent by the holder in that order.
3. White paper, dressed for writing purposes and weighing at least 40 g/m<sup>2</sup>, shall be used.
4. The dimensions of the forms shall be 210 × 297 mm.
5. The Member States shall be responsible for printing the forms. They may also be printed by printing houses approved by a Member State, in which case the authorization in question shall be marked on each form. Each form shall bear the name and address or sign of the printer.
6. Copies 1 and 2 of the form referred to in paragraph 1 and copies 1, 2, 3 and 4 of the form referred to in paragraph 2 shall bear a form serial number. This number shall be preceded by the following letters according to the Member State from which the waste is shipped: BE for Belgium, DK for Denmark, DE for the Federal Republic of Germany, FR for France, GR for Greece, IE for Ireland, IT for Italy, LU for Luxembourg, NL for Netherlands and UK for United Kingdom.
7. The forms shall be printed in black print in one of the official languages of the Community to be specified by the competent authorities of the Member State from which the waste is shipped.
8. The form referred to in paragraph 1 shall be such that the information contained in boxes 6, 8, 18 and 33 of copies 1 and 2 is not repeated in the equivalent boxes of copy 3.

## ANNEX IV

## GENERAL INSTRUCTIONS CONCERNING THE UNIFORM CONSIGNMENT NOTE

**NB:** Any competent authority may require further information or documentation to supplement the information provided on the consignment note.

The uniform consignment note contains provisions for:

1. Notification of a shipment to the competent authority.
2. Acknowledgement by the competent authority of destination.
3. Mention of the arrangements concerning the transport, the wastes and other transport matters.
4. Receipt by the consignee (copy 3).
5. Custom endorsement, when the waste leaves the Community for final disposal (back of copy 3).

**Procedure****A. The holder of the waste sends**

1. In the case of a single shipment of waste the disposal of which will take place inside the Community, the three copies of the form to the competent authority of the Member State of destination.
2. in the case of a single shipment of waste, the disposal of which will take place outside the Community, the three copies of the form to the competent authority of the Member State of dispatch, or to the competent authority of the Member State of exit from the Community where disposal of the waste takes place in a third State bordering on the latter and that Member State exercises its right to issue the acknowledgement of receipt in accordance with the last subparagraph of Article 4 (2) of Directive 84/631/EEC as amended by Directive 86/279/EEC;
3. in the case of a single shipment of waste from a third State routed through the Community for disposal outside the Community, the three copies of the form to the competent authority of the Member State of exit from the Community;
4. in the case of several shipments (general notification), copies 1 and 2 of the form and a number of copies 3 corresponding to the number of shipments to be carried out, to the competent authorities referred to under A.1, A.2 or A.3;
5. in all the cases referred to under 1 to 4, a photocopy of copy 1 of the form to the competent authorities of all the other States concerned: Member States of dispatch and transit, third State(s) of transit and destination.



- B. The competent authority of the Member State making the acknowledgment keeps copy 1 of the form and returns copy 2 and all the copies 3 received to the holder of the waste not later than the day on which it is sure that no objection has been raised and any additional conditions have been notified to the holder. The holder must keep copy 2.

The competent authority of the Member State making the acknowledgment sends a photocopy of copy 2 to the competent authorities of the other Member States concerned and, where appropriate, to the third State of destination and to the third State or States of transit and to the consignee.

- C. Upon receipt of the copies referred to under B, the holder of the waste completes a copy 3 for each consignment to be carried out and sends a photocopy of that copy 3 to the competent authorities referred to under A.1 and A.4, before the transport.
- D. The actual shipment of the waste takes place under cover of a copy 3. That copy must be signed in box 31 by the first carrier, in box 34 by subsequent carriers and in box 33 by the holder.
- E. The carrier must keep a photocopy of each copy 3 and surrender copy 3 to the consignee of the waste where the consignee is situated in a Member State.

In the case of a shipment of waste the disposal of which will take place outside the Community, copy 3 must be lodged with the customs office through which the waste finally leaves the Community.

- F. A consignee located in a Member State must complete box 32 of copy 3, and within 15 days following the receipt of the waste forward photocopies of the completed form to the holder, to the competent authorities of the Member States concerned and to the third States concerned.
- G. In the case of export of waste from the Community for disposal outside the Community the holder of the waste must certify to the competent authority of the Member State which issued the acknowledgement of the notification of shipment, not later than six weeks after the waste has left the Community, that the waste has reached its destination and shall indicate the last customs office through which the waste finally left the Community.

- H. All the documents (copies and photocopies) shall be kept for at least two years.

#### INSTRUCTIONS FOR FILLING IN THE FORM

##### A. General remarks

1. The form must be filled in:
  - in the case of wastes being dispatched from a Member State, in one of the official languages of the Community to be designated by the competent authorities of the Member State of dispatch,
  - in the case of wastes dispatched from a third State, in English or French.
2. The form must be filled in in typescript or in manuscript; in the latter case it must be completed in ink and in printed characters. There may be no erasures or superimposed corrections or any other amendments.
3. The dates are indicated by a six digit number, the two first of which show the year, the following two the month, and the last two the day. For example: 31 July 1985 will read: 85 07 31.
4. The signatures must all be original and not be reproduced in any way.

**B. Instructions for filling in copies 1, 2 and 3 of the form:**

- Box 1** — Full name or company's name and address, telephone and telex number,  
— Where applicable, enter the registration No.
- Box 4** — Full name or company's name and address, telephone and telex number,  
— Enter the permit No, granted from the competent authority or the reference to this permit. This is the permit referred to in Article 9 of Directive 78/319/EEC or in Article 6 of Directive 76/403/EEC.
- Box 5** Full name or company's name and address, telephone and telex number of the plant or the establishment where the wastes were produced, and the name of the person to be contacted.  
When the wastes were produced by more than one producer, enter the words 'SEE ATTACHED LIST', and attach a list indicating the information required for each producer.  
(If the producer and the holder are one and the same person or company enter the words 'SEE BOX 1' in box 5.)
- Box 6** — Full name or company's name and address, telephone and telex number of the first carrier.  
— Where applicable, the licence No.  
*Note:* A carrier who is not required to hold a licence should be able to demonstrate that he complies with the rules of the Member States concerned in respect of transport of the wastes designated in the form.  
If more than one carrier is involved, enter the words 'SEE ATTACHED LIST' and attach a list indicating the information required for each carrier.
- Box 8** Attach the information, signed by the consignee, relating to the contractual agreement between the holder and the consignee concerning the waste referred to in the notification in question. If applicable, attach :  
— lists of producers/carriers (boxes 5 and 6),  
— details concerning the waste (box 22),  
— proof of the agreement to the shipment of the third State of destination, in the case of shipment of waste from a Member State for disposal in the third State.
- Box 9** If the wastes were generated by more than one producer, enter 'several'.
- Box 11** Enter 'X' in the appropriate box. If 'YES' state the name and full address of the insurer, number of policy and the last day of validity of the policy.
- Box 13** Enter the following code number:  
1: Sea, 2: Rail, 3: Road, 4: Air, 8: Inland waterway.
- Box 14/15** — In the case of a notification for a single shipment, state the intended date of the shipment.  
— In the case of a general notification, state the expected date of the first shipment, and state in box 15 the expected date of the last shipment.

- Box 16 Enter, in the case of a general notification, the total number (digits) of the planned transfers.  
*This box is not filled in in the case of a notification for a single shipment.*
- Box 18 Indicate the type of packaging proposed: drums, etc.
- Box 19/20 The code number of the waste in the country of destination and the country of origin will be entered when such a code is used in the country of destination (box 20) and in the country of origin (box 19).
- Box 21 Enter the intended quantity of the total amount of waste to be shipped.
- Box 22 The nature and the concentration of the most characteristic or significant components, in terms of the toxicity and other dangers presented by the waste will be required together with, if possible, an analysis referring to the method of disposal envisaged, particularly in the case of an initial shipment.
- Box 24 United Nations classification number.
- Box 27 Enter 'X' in the appropriate box.  
Enter the temperature of the waste during the transportation in degrees Celsius. The translation of all terms in box 27 is printed at the back of the third copy. When the outward appearance of the waste shows several forms, enter 'X' in the appropriate boxes.
- Box 28 Enter the code number of the competent authority of each Member State on whose territory the shipment will take place. These code numbers will be entered after they are published in the *Official Journal of the European Communities*.
- Box 33 The full name and status of the signatory must be indicated clearly. In signing the form the holder certifies that the information that he has provided is correct. The signatures must be original on copies 1 and 2.

**C. Instructions for filling in copy 3**

Boxes 3, 6, 8, 12, 17, 18, 23, 31 and 33 (and when necessary 34) are to be filled in by the holder with the carrier's agreement after receipt of the acknowledgement by the competent authority.

- Box 3 Indicate the serial number assigned to each shipment (starting with 1).  
Not to be filled in if the notification relates to a single consignment.
- Box 8 Where appropriate, attach any special conditions made by the competent authority of the Member States of dispatch and of transit in respect to the shipment of the waste on their territory and instructions to be followed in the event of danger or an accident.
- Box 12 Indicate the type and registration number or name of the means of transport (lorry, wagon, ship, aeroplane) on to which the waste is loaded.
- Box 17 Give the date on which the shipment commences.
- Box 18 Give the number (digits) and type of the packages containing the waste.
- Box 23 Give the actual net quantity of waste transported.
- Box 31/34 Give the date, and the full name and telephone and telex numbers of the person to be contacted. The signature must be that of the carrier or his authorized representative. In signing the form the carrier certifies that the information he has provided is correct.
- Box 32 Give the net quantity received, the date and the full name and telephone and telex numbers of the person to be contacted. The signature must be that of the consignee or his authorized representative. In signing the form the consignee certifies that the information he has provided is correct.
- Box 33 Give the date and the full name and telephone and telex numbers of the person to be contacted. The signature must be that of the holder or his authorized representative. In signing the form the holder certifies that the information he has provided is correct.

**COUNCIL DIRECTIVE**  
**of 16 June 1975**  
**on the disposal of waste oils**  
**(75/439/EEC)**

(as amended by the Act of Accession of Spain and Portugal of 12 June 1985 (OJ L 302, 15.11.85, p. 9) and Council Directive 87/101/EEC of 22 December 1986 (OJ L 42, 12.2.87, p. 43))

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament <sup>(1)</sup>;

Having regard to the Opinion of the Economic and Social Committee <sup>(2)</sup>;

Whereas any disparity between the provisions on the disposal of waste oils already applicable or in preparation in the various Member States may create unequal conditions of competition and thus directly affect the functioning of the common market; whereas it is therefore necessary to approximate laws in this field as provided for in Article 100 of the Treaty;

Whereas it seems necessary for this approximation of laws to be accompanied by Community action so that one of the aims of the Community in the sphere of protection of the environment can be achieved by wider regulations; whereas certain specific provisions to this effect should therefore be laid down; whereas Article 235 of the Treaty should be invoked as the powers required for this purpose have not been provided by the Treaty;

Whereas all provisions relating to the disposal of waste oils should have as one of their essential objectives the protection of the environment against the harmful effects caused by the discharge, deposit or treatment of these oils;

Whereas the recycling of waste oils may be conducive to a fuel supply policy;

Whereas the programme of action of the European Communities on the environment <sup>(3)</sup> underlines the importance of the problem of the disposal of waste oils without harmful effects upon the environment;

Whereas the quantities of waste oils and in particular of emulsions have increased in the Community;

Whereas an efficient and coherent system of treatment for waste oils, which will neither create barriers to intra-Community trade nor affect competition, should apply to all such products, even those which are composed only in part of oil, and should provide for their safe treatment under economically satisfactory conditions;

Whereas such a system should regulate the treatment, discharge, deposit and collection of waste oils and provide for a system of permits for undertakings which dispose of such oils, for compulsory collection and/or disposal of such oils in certain cases and for suitable inspection procedures;

Whereas in cases where certain undertakings are required to collect and/or dispose of waste oils, compensation by indemnities of that part of their costs relating thereto and not covered by their earnings should be possible and whereas these indemnities may be financed, among other methods, by a charge on new or regenerated oils,

HAS ADOPTED THIS DIRECTIVE:

**ARTICLE 1**

For the purposes of this Directive:

— "waste oils" means:

any mineral-based lubrication or industrial oils which have become unfit for the use for which they were originally intended, and in particular

<sup>(1)</sup> OJ No C 85, 18. 7. 1974, p. 6.

<sup>(2)</sup> OJ No C 125, 16. 10. 1974, p. 33.

<sup>(3)</sup> OJ No C 112, 20. 12. 1973, p. 3.

used combustion engine oils and gearbox oils, and also mineral lubricating oils, oils for turbines and hydraulic oils ;

— *"disposal"* means :

the processing or destruction of waste oils as well as their storage and tipping above or under ground ;

— *"processing"* means :

operations designed to permit the re-use of waste oils, that is to say, regeneration and combustion ;

— *"regeneration"* means :

any process whereby base oils can be produced by refining waste oils, in particular by removing the contaminants, oxidation products and additives contained in such oils ;

— *"combustion"* means :

the use of waste oils as fuel with the heat produced being adequately recovered ;

— *"collection"* means :

all operations whereby waste oils can be transferred from the holders to undertakings which dispose of such oils.

#### Article 2

Without prejudice to the provisions of Directive 78/319/EEC<sup>(1)</sup>, Member States shall take the necessary measures to ensure that waste oils are collected and disposed of without causing any avoidable damage to man and the environment.

#### Article 3

1. Where technical, economic and organizational constraints so allow, Member States shall take the measures necessary to give priority to the processing of waste oils by regeneration.

2. Where waste oils are not regenerated, on account of the constraints mentioned in paragraph 1 above, Member States shall take the measures necessary to ensure that any combustion of waste oils is carried out under environmentally acceptable conditions, in accordance with the provisions of this Directive, provided that such combustion is technically, economically and organizationally feasible.

3. Where waste oils are neither regenerated nor burned, on account of the constraints mentioned in paragraphs 1 and 2, Member States shall take the measures necessary to ensure their safe destruction or their controlled storage or tipping.

#### Article 4

Member States shall take the necessary measures to ensure the prohibition of :

(a) any discharge of waste oils into inland surface water, ground water, territorial sea water and drainage systems ;

(b) any deposit and/or discharge of waste oils harmful to the soil and any uncontrolled discharge of residues resulting from the processing of waste oils ;

(c) any processing of waste oils causing air pollution which exceeds the level prescribed by existing provisions.

#### Article 5

1. Where necessary in order to achieve the objectives of this Directive and without prejudice to the provisions of Article 2, Member States shall carry out public information and promotional campaigns to ensure that waste oils are stored appropriately and collected as far as possible.

2. Where the objectives defined in Articles 2, 3 and 4 cannot otherwise be achieved, Member States shall take the necessary measures to ensure that one or more undertakings carry out the collection and/or disposal of waste oils offered to them by holders, where appropriate in the area assigned to them by the competent authorities.

3. To achieve the objectives defined in Articles 2 and 4, Member States may decide to allocate the waste oils to any of the types of processing set out in Article 3. To this end, they may institute appropriate checks.

4. To ensure compliance with the measures taken pursuant to Article 4, any undertaking which collects waste oils must be subject to registration and adequate supervision by the competent national authorities, possibly including a system of permits.

#### Article 6

1. In order to comply with the measures taken pursuant to Article 4, any undertaking which disposes of waste oils must obtain a permit. Where necessary, this permit shall be granted after examination of the installations.

2. Without prejudice to the requirements laid down by national and Community provisions with a purpose other than that of this Directive, a permit may be granted to undertakings which regenerate waste oils or use waste oils as fuel only where the competent authority has satisfied itself that all appropriate environmental and health protection measures have been taken, including use of the best technology available, where the cost is not excessive.

<sup>(1)</sup> OJ No L 84, 31. 3. 1973, p. 43.

*Article 7*

Where waste oils are regenerated, Member States shall take the measures necessary to ensure that :

- (a) the operation of the regeneration plant will not cause avoidable damage to the environment.

To this end, the Member States shall ensure that the risks associated with the quantity of residues of regeneration and with the toxic and dangerous character of such residues are reduced to a minimum and that the residues are disposed of in accordance with Article 9 of Directive 78/319/EEC ;

- (b) the base oils derived from regeneration do not constitute a toxic and dangerous waste as defined in Article 1 (b) of Directive 78/319/EEC and do not contain polychlorinated biphenyls and polychlorinated tophenyls (PCB/PCT) in concentrations beyond the limits laid down in Article 10.

Member States shall inform the Commission of these measures. On the basis of this information, the Commission shall, within five years of the date of notification of this Directive, submit a report to the Council, accompanied if necessary by appropriate proposals.

*Article 8*

1. Without prejudice to the provisions of Directive 84/360/EEC<sup>(1)</sup> and Article 3 (1) of this Directive, where waste oils are used as fuel, Member States shall take the measures necessary to ensure that operation of the plant will not cause any significant level of air pollution, in particular by the emission of substances listed in the Annex. To this end :

- (a) Member States shall satisfy themselves that in the case of the combustion of oils in plants with a thermal input of 3 MW or more based on the lower heating value (LHV), the emission limit values set in that Annex are being observed.

Member States may at any time set limit values more stringent than those given in the Annex. They may also set limit values for substances and parameters other than those listed in the Annex ;

- (b) Member States shall take such measures as they consider necessary to ensure that combustion of waste oils in plants with a thermal input of less than 3 MW based on the lower heating value (LHV) is subject to adequate control.

They shall inform the Commission of these measures. On the basis of this information the Commission shall, within five years of the date of notification of this Directive, submit a report to the Council, accompanied if necessary by appropriate proposals.

2. The Member States shall further ensure that :

- (a) the residues from the combustion of waste oils are disposed of in accordance with Article 9 of Directive 78/319/EEC ;
- (b) the waste oils used as fuel do not constitute a toxic and dangerous waste as defined in Article 1 (b) of Directive 78/319/EEC and do not contain PCB/PCT in concentrations beyond 50 ppm ;

3. Observance of the limit values set out in the Annex may alternatively be ensured by means of an appropriate system of control of concentrations of pollutants in waste oils, or mixtures of waste oils and other fuels, intended for combustion taking account of the technical characteristics of the plant.

In the case of plants where emissions of substances listed in the Annex may arise additionally from heating products, Member States shall ensure, through an established control system, that the proportion of these substances arising from the combustion of waste oils does not exceed the limit values fixed in the Annex.

*Article 9*

A person holding waste oils must, if he is unable to comply with the measures taken pursuant to Article 4, place them at the disposal of the undertaking or undertakings referred to in Article 5.

*Article 10*

1. During storage and collection, holders and collectors must not mix waste oils with PCBs and PCTs within the meaning of Directive 76/403/EEC<sup>(1)</sup> nor with toxic and dangerous waste within the meaning of Directive 78/319/EEC.

2. Except as provided for in paragraph 3, the provisions of Directive 76/403/EEC shall apply to waste oils containing more than 50 ppm of PCB/PCT.

Member States shall further take such special technical measures as are necessary to ensure that any waste oils containing PCB/PCTs are disposed of without any avoidable damage to man and the environment.

3. The regeneration of waste oils containing PCBs or PCTs may be permitted if the regeneration processes make it possible either to destroy the PCBs and PCTs or to reduce them so that the regenerated oils do not contain PCB/PCT beyond a maximum limit which in no case may exceed 50 ppm.

<sup>(1)</sup> OJ No L 188, 16. 7. 1984, p. 10

4. The reference method of measurement to determine the PCB/PCT content of waste oils shall be fixed by the Commission after consultation of the Committee for adaptation to technical progress established under Article 18 of Directive 78/319/EEC.

5. Waste oils contaminated by substances which fall within the definition of toxic and dangerous waste as laid down in Article 1 (b) of Directive 78/319/EEC shall be disposed of in accordance with the provisions of that Directive.

#### Article 11

Any establishment producing, collecting and/or disposing of more than a given quantity of waste oils per year, to be specified by each Member State but not higher than 500 litres, must:

- keep a record of the quantity, quality, origin and location of such oils and of their despatch and receipt, including the dates of the latter and/or
- convey such information to the competent authorities on request.

Member States are authorized to fix the quantity of waste oils in accordance with the first subparagraph in terms of an equivalent quantity of new oil calculated according to a reasonable conversion factor.

#### Article 12

Any undertaking which collects, holds and/or disposes of waste oils must convey to the competent authorities, at their request, any information concerning the collection and/or disposal of waste oils or their residues.

#### Article 13

1. The undertakings referred to in Article 6 shall be inspected periodically by the Member States, particularly as regards their compliance with the conditions of their permits.

2. The competent authorities shall examine trends in the state of technical development and/or of the environment with a view to revising, where necessary, permits granted to undertakings in accordance with this Directive.

#### Article 14

As a reciprocal concession for the obligations imposed on them by the Member States pursuant to Article 5, indemnities may be granted to collection and/or disposal undertakings for the service rendered. Such indemnities must not exceed annual uncovered costs actually recorded by the undertaking taking into account a reasonable profit.

The amount of these indemnities must be such as not to cause any significant distortion of competition or to give rise to artificial patterns of trade in the products.

#### Article 15

The indemnities may be financed, among other methods, by a charge imposed on products which after use are transformed into waste oils, or on waste oils.

The financing of indemnities must be in accordance with the 'polluter pays' principle.

#### Article 16

Member States may, whilst respecting the provisions of the Treaty, take measures for the purpose of environmental protection which are more stringent than those provided for in this Directive.

#### Article 17

Each Member State shall periodically convey to the Commission information concerning its technical expertise and the experience gained and results obtained through the application of measures taken pursuant to this Directive.

The Commission shall send an overall summary of such information to the Member States.

#### Article 18

Every three years, Member States shall draw up a situation report on the disposal of waste oils in their respective countries and shall send it to the Commission.

(<sup>1</sup>) OJ No L 108, 26. 4. 1976, p. 41.

## Article 19

Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

## Article 20

This Directive is addressed to the Member States.

Done at Luxembourg, 16 June 1975.

For the Council  
The President  
R. RYAN

## ANNEX

Emission limit values <sup>(1)</sup> for certain substances emitted as a result of the combustion of waste oils in plants with a thermal input of 3 MW (LHV) or more

Pollutant	Limit value mg/Nm <sup>3</sup>																				
Cd	0,5																				
Ni	1																				
Cr	<table style="border: none; margin-left: 20px;"> <tr> <td style="border: none;">}</td> <td style="border: none;">either <sup>(2)</sup></td> <td style="border: none;">or <sup>(2)</sup></td> <td style="border: none;">}</td> <td style="border: none;">5</td> </tr> <tr> <td style="border: none;">1,5</td> <td style="border: none;">Cr</td> <td style="border: none;">Cr</td> <td style="border: none;">}</td> <td style="border: none;"></td> </tr> <tr> <td style="border: none;">5</td> <td style="border: none;">Cu</td> <td style="border: none;">Cu</td> <td style="border: none;">}</td> <td style="border: none;"></td> </tr> <tr> <td style="border: none;"></td> <td style="border: none;">V</td> <td style="border: none;">V</td> <td style="border: none;">}</td> <td style="border: none;"></td> </tr> </table>	}	either <sup>(2)</sup>	or <sup>(2)</sup>	}	5	1,5	Cr	Cr	}		5	Cu	Cu	}			V	V	}	
}		either <sup>(2)</sup>	or <sup>(2)</sup>	}	5																
1,5		Cr	Cr	}																	
5		Cu	Cu	}																	
	V	V	}																		
Cu																					
V																					
Pb																					
Cl <sup>(3)</sup>	100																				
F <sup>(4)</sup>	5																				
SO <sub>2</sub> <sup>(5)</sup>	—																				
Dust (total) <sup>(5)</sup>	—																				

<sup>(1)</sup> These limit values, which may not be exceeded when waste oils are burned, indicate the mass concentration of emissions of the aforementioned substances in waste gas, in terms of the volume of waste gas in the standard state (273 K ; 1 013 hPa), after deduction of the water vapour moisture content, and of a 3 % oxygen content by volume in waste gas.

In the case of the second subparagraph of Article 8 (3), the oxygen content will be that which corresponds to normal operating conditions in the particular process concerned.

<sup>(2)</sup> It shall be for the Member States to lay down which of these options shall apply in their country.

<sup>(3)</sup> Inorganic gaseous compounds of chlorine expressed as hydrogen chloride.

<sup>(4)</sup> Inorganic gaseous compounds of fluorine expressed as hydrogen fluoride.

<sup>(5)</sup> It is not possible to determine limit values for these substances at this stage. The Member States will independently set emission standards for discharges of these substances taking into account the requirements of Directive 80/779/EEC (OJ No L 229, 30. 8. 1980, p. 30).

## STATEMENT

## The Article 10 (3) of Directive 75/439/EEC

The Council considers that the limit given in Article 10 (3) is in fact a maximum limit for the output of the regeneration process. Bearing in mind the desirability of eliminating PCB/PCT wherever possible from the environment, it invites Member States to make every effort to stay well below this limit. It further invites the Commission to review this limit and to come forward with appropriate proposals for a new limit within five years of the notification of this Directive.



## COUNCIL DIRECTIVE

of 12 June 1986

on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture

(86/278/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas the aim of this Directive is to regulate the use of sewage sludge in agriculture in such a way as to prevent harmful effects on soil, vegetation, animals and man, while encouraging its correct use;

Whereas the disparity between the Member States' provisions on the agricultural applications of sewage sludge might affect the functioning of the common market; whereas in this field the approximation of laws provided for under Article 100 of the Treaty should therefore be instigated;

Whereas sewage sludge used in agriculture is not covered by Council Directive 75/442/EEC of 15 July 1975 on waste <sup>(4)</sup>;

Whereas the measures for which provision is made in Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste <sup>(5)</sup> also apply to sewage sludge containing or contaminated by substances or materials listed in the Annex to that Directive which are of such a nature or are present in such quantities or concentrations that they represent a hazard to human health or to the environment;

Whereas special arrangements should be made to ensure that man, animals, plants and the environment are fully safeguarded against the harmful effects arising from the uncontrolled use of sludge;

Whereas this Directive also aims at establishing certain initial Community measures in connection with soil protection;

Whereas sludge can have valuable agronomic properties and it is therefore justified to encourage its application in agriculture provided it is used correctly; whereas the use of sewage sludge must not impair the quality of the soil and of agricultural products;

Whereas some heavy metals may be toxic to plants and also to man through their presence in crops and whereas it is necessary to lay down mandatory limit values for these elements in the soil;

Whereas the use of sludge should be prohibited when the concentration of these metals in the soil exceeds these limit values;

Whereas, moreover, it is necessary to prevent these limit values from being exceeded as a result of the use of sludge; whereas, to this end, it is necessary to limit the amount of heavy metals added to cultivated soil either by setting maximum quantities for the amounts of sludge used per annum and ensuring that the limit values for the concentration of heavy metals in the sludge used are not exceeded or by seeking to ensure that limit values for the quantities of heavy metals that can be added to the soil on the basis of a 10-year average are not exceeded;

Whereas sludge must be treated before being used in agriculture; whereas Member States may nevertheless authorize, on certain conditions, the use of untreated sludge, without risk to human or animal health, if it is injected or worked into the soil;

Whereas a certain period must elapse between using the sludge and putting stock out to pasture or harvesting fodder crops or certain crops which are normally in direct contact with the soil and normally consumed raw; whereas the use of sludge on fruit and vegetable crops during the

<sup>(1)</sup> OJ No C 264, 8.10.1982, p. 3 and OJ No C 154, 14.6.1984, p. 6.

<sup>(2)</sup> OJ No C 77, 19.3.1984, p. 136.

<sup>(3)</sup> OJ No C 90, 5.4.1983, p. 27.

<sup>(4)</sup> OJ No L 194, 25.7.1975, p. 39.

<sup>(5)</sup> OJ No L 84, 31.3.1978, p. 43.

growing season, except for fruit-tree crops, must be prohibited;

Whereas sludge should be used under conditions which ensure that the soil and the surface and ground water are protected, in accordance with Directives 75/440/EEC <sup>(1)</sup> and 80/68/EEC <sup>(2)</sup>;

Whereas to this end it is necessary to monitor the quality of sludges and of the soils on which they are used and hence to make analyses and to communicate certain results to the users;

Whereas a certain amount of essential information should be kept to ensure better awareness of the use of sludge in agriculture and whereas such information should be forwarded in the form of periodic reports to the Commission; whereas, in the light of these reports, the Commission will if necessary draw up proposals to ensure greater protection for the soil and the environment;

Whereas sludge from small sewage-treatment plants which treat primarily domestic waste water represents little danger to human, animal and plant health and to the environment and should therefore be exempt from some of the obligations laid down relating to information and analysis;

Whereas Member States should be able to draw up more stringent provisions than those laid down in this Directive; whereas such provisions should be communicated to the Commission;

Whereas technical and scientific progress may make necessary the rapid adaptation of certain of the requirements laid down in this Directive; whereas, in order to facilitate the introduction of the measures required for this purpose, a procedure should be laid down whereby close cooperation could be established between the Member States and the Commission; whereas such cooperation should take place within a Committee on Adaptation to Technical and Scientific Progress;

Whereas the Treaty has not provided the necessary powers, other than those of Article 235,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

The purpose of this Directive is to regulate the use of sewage sludge in agriculture in such a way as to prevent harmful effects on soil, vegetation, animals and man,

thereby encouraging the correct use of such sewage sludge.

#### Article 2

For the purposes of this Directive:

(a) 'sludge' means:

- (i) residual sludge from sewage plants treating domestic or urban waste waters and from other sewage plants treating waste waters of a composition similar to domestic and urban waste waters;
- (ii) residual sludge from septic tanks and other similar installations for the treatment of sewage;
- (iii) residual sludge from sewage plants other than those referred to in (i) and (ii);

(b) 'treated sludge' means:

sludge which has undergone biological, chemical or heat treatment, long-term storage or any other appropriate process so as significantly to reduce its fermentability and the health hazards resulting from its use;

(c) 'agriculture' means:

the growing of all types of commercial food crops, including for stock-rearing purposes;

(d) 'use' means:

the spreading of sludge on the soil or any other application of sludge on and in the soil.

#### Article 3

1. The sludge referred to in Article 2 (a) (i) may only be used in agriculture in accordance with this Directive.

2. Without prejudice to Directives 75/442/EEC and 78/319/EEC:

- the sludge referred to in Article 2 (a) (ii) may be used in agriculture subject to any conditions that the Member State concerned may deem necessary for the protection of human health and the environment,
- the sludge referred to in Article 2 (a) (iii) may be used in agriculture only if its use is regulated by the Member State concerned.

#### Article 4

Values for concentrations of heavy metals in soil to which sludge is applied, concentrations of heavy metals in sludge

<sup>(1)</sup> OJ No L 194, 25. 7. 1975, p. 26.

<sup>(2)</sup> OJ No L 20, 26. 1. 1980, p. 43.

and the maximum annual quantities of such heavy metals which may be introduced into soil intended for agriculture are given in Annexes I A, I B and I C.

#### Article 5

Without prejudice to Article 12:

1. Member States shall prohibit the use of sludge where the concentration of one or more heavy metals in the soil exceeds the limit values which they lay down in accordance with Annex I A and shall take the necessary steps to ensure that those limit values are not exceeded as a result of the use of sludge.
2. Member States shall regulate the use of sludge in such a way that the accumulation of heavy metals in the soil does not lead to the limit values referred to in paragraph 1 being exceeded. To achieve this, they shall apply one or other of the procedures provided for in (a) and (b) below:
  - (a) Member States shall lay down the maximum quantities of sludge expressed in tonnes of dry matter which may be applied to the soil per unit of area per year while observing the limit values for heavy metal concentration in sludge which they lay down in accordance with Annex I B; or
  - (b) Member States shall ensure observance of the limit values for the quantities of metals introduced into the soil per unit of area and unit of time as set out in Annex I C.

#### Article 6

Without prejudice to Article 7:

- (a) sludge shall be treated before being used in agriculture. Member States may nevertheless authorize, under conditions to be laid down by them, the use of untreated sludge if it is injected or worked into the soil;
- (b) sewage-sludge producers shall regularly provide users with all the information referred to in Annex II A.

#### Article 7

Member States shall prohibit the use of sludge or the supply of sludge for use on:

- (a) grassland or forage crops if the grassland is to be grazed or the forage crops to be harvested before a certain period has elapsed. This period, which shall be set by the Member States taking particular account of their

geographical and climatic situation, shall under no circumstances be less than three weeks;

- (b) soil in which fruit and vegetable crops are growing, with the exception of fruit trees;
- (c) ground intended for the cultivation of fruit and vegetable crops which are normally in direct contact with the soil and normally eaten raw, for a period of 10 months preceding the harvest of the crops and during the harvest itself.

#### Article 8

The following rules shall be observed when using sludge:

- the sludge shall be used in such a way that account is taken of the nutrient needs of the plants and that the quality of the soil and of the surface and ground water is not impaired,
- where sludge is used on soils of which the pH is below 6, Member States shall take into account the increased mobility and availability to the crop of heavy metals and shall, if necessary, reduce the limit values they have laid down in accordance with Annex I A.

#### Article 9

Sludge and soil on which it is used shall be analyzed as outlined in Annexes II A and II B.

The reference methods for sampling and analysis are indicated in Annex II C.

#### Article 10

1. Member States shall ensure that up-to-date records are kept, which register:

- (a) the quantities of sludge produced and the quantities supplied for use in agriculture;
- (b) the composition and properties of the sludge in relation to the parameters referred to in Annex II A;
- (c) the type of treatment carried out, as defined in Article 2 (b);
- (d) the names and addresses of the recipients of the sludge and the place where the sludge is to be used.

2. The records shall be available to the competent authorities and shall provide a basis for the consolidated report referred to in Article 17.

3. Information on the methods of treatment and the results of the analyses shall be released upon request to the competent authorities.

*Article 11*

Member States may exempt from Article 6 (b) and Article 10 (1) (b), (c) and (d) and paragraph 2, sludge from sewage treatment plants with a treatment capacity below 300 kg BOD<sub>5</sub> per day, corresponding to 5 000 person equivalents, which are designed primarily for the treatment of domestic waste water.

*Article 12*

Where conditions so demand, Member States may take more stringent measures than those provided for in this Directive.

Any decision of this nature shall be communicated to the Commission in accordance with existing agreements.

*Article 13*

Adaptation to technical and scientific progress, in accordance with the procedure referred to in Article 15, shall cover the provisions of the Annexes to the Directive, except for the parameters and values listed in Annexes I A, I B and I C, any factors likely to affect the evaluation of the values, and the parameters for analysis referred to in Annexes II A and II B.

*Article 14*

1. A committee for adapting this Directive to technical and scientific progress (hereinafter called 'the Committee') is hereby set up. It shall consist of representatives of the Member States with a representative of the Commission as chairman.

2. The Committee shall draw up its own rules of procedure.

*Article 15*

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a period to be determined by the chairman according to the urgency of the matter. It shall decide by a majority of 54 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where these are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee or if no opinion has been given, the Commission shall forthwith propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the measures proposed shall be adopted by the Commission.

*Article 16*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within three years of its notification.

They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

*Article 17*

Five years after notification of this Directive, and every four years thereafter, Member States shall prepare a consolidated report on the use of sludge in agriculture setting out the quantities used, the criteria followed and any difficulties encountered; they shall forward this report to the Commission, which shall publish the information contained therein. In the light of that report, the Commission shall if necessary submit appropriate proposals for increased protection of the soil and the environment.

*Article 18*

This Directive is addressed to the Member States.

Done at Luxembourg, 12 June 1986.

*For the Council*

*The President*

P. WINSEMIUS

## ANNEX I A

## LIMIT VALUES FOR CONCENTRATIONS OF HEAVY METALS IN SOIL

(mg/kg of dry matter in a representative sample, as defined in Annex II C, of soil with a pH of 6 to 7)

Parameters	Limit values <sup>(1)</sup>
Cadmium	1 to 3
Copper <sup>(2)</sup>	50 to 140
Nickel <sup>(2)</sup>	30 to 75
Lead	50 to 300
Zinc <sup>(2)</sup>	150 to 300
Mercury	1 to 1,5
Chromium <sup>(3)</sup>	—

<sup>(1)</sup> Member States may permit the limit values they fix to be exceeded in the case of the use of sludge on land which at the time of notification of this Directive is dedicated to the disposal of sludge but on which commercial food crops are being grown exclusively for animal consumption. Member States must inform the Commission of the number and type of sites concerned. They must also seek to ensure that there is no resulting hazard to human health or the environment.

<sup>(2)</sup> Member States may permit the limit values they fix to be exceeded in respect of these parameters on soil with a pH consistently higher than 7. The maximum authorized concentrations of these heavy metals must in no case exceed those values by more than 50 %. Member States must also seek to ensure that there is no resulting hazard to human health or the environment and in particular to ground water.

<sup>(3)</sup> It is not possible at this stage to fix limit values for chromium. The Council will fix these limit values later on the basis of proposals to be submitted by the Commission, within one year following notification of this Directive.

## ANNEX I B

## LIMIT VALUES FOR HEAVY-METAL CONCENTRATIONS IN SLUDGE FOR USE IN AGRICULTURE

(mg/kg of dry matter)

Parameters	Limit values
Cadmium	20 to 40
Copper	1 000 to 1 750
Nickel	300 to 400
Lead	750 to 1 200
Zinc	2 500 to 4 000
Mercury	16 to 25
Chromium <sup>(1)</sup>	—

<sup>(1)</sup> It is not possible at this stage to fix limit values for chromium. The Council will fix these limit values later on the basis of proposals to be submitted by the Commission within one year following notification of this Directive.

## ANNEX I C

## LIMIT VALUES FOR AMOUNTS OF HEAVY METALS WHICH MAY BE ADDED ANNUALLY TO AGRICULTURAL LAND, BASED ON A 10-YEAR AVERAGE

(kg/ha/yr)

Parameters	Limit values <sup>(1)</sup>
Cadmium	0,15
Copper	12
Nickel	3
Lead	15
Zinc	30
Mercury	0,1
Chromium <sup>(2)</sup>	—

<sup>(1)</sup> Member States may permit these limit values to be exceeded in the case of the use of sludge on land which at the time of notification of this Directive is dedicated to the disposal of sludge but on which commercial food crops are being grown exclusively for animal consumption. Member States must inform the Commission of the number and type of sites concerned. They must also ensure that there is no resulting hazard to human health or the environment.

<sup>(2)</sup> It is not possible at this stage to fix limit values for chromium. The Council will fix these limit values later on the basis of proposals to be submitted by the Commission within one year following notification of this Directive.

## ANNEX II A

## SLUDGE ANALYSIS

- As a rule, sludge must be analyzed at least every six months. Where changes occur in the characteristics of the waste water being treated, the frequency of the analyses must be increased. If the results of the analyses do not vary significantly over a full year, the sludge must be analyzed at least every 12 months.
- In the case of sludge from the treatment plants referred to in Article 11, if a sludge analysis has not been carried out in the 12 months preceding the implementation, in each Member State, of this Directive, an analysis must be carried out within 12 months of such implementation, or, where appropriate, within six months of the decision authorizing the use in agriculture of sludge from such a plant. Member States shall decide on the frequency of further analyses on the basis of the results of the initial analysis, any changes in the nature of treated waste water and any other relevant factors.
- Subject to the provisions of paragraph 4, analysis should cover the following parameters:
  - dry matter, organic matter,
  - pH,
  - nitrogen and phosphorus,
  - cadmium, copper, nickel, lead, zinc, mercury, chromium.
- In the case of copper, zinc and chromium, where it has been shown, to the satisfaction of the competent authority of the Member State concerned that they are either not present at all or present only in negligible quantities in the waste water treated by the sewage plant, Member States shall decide on the frequency of the analyses to be carried out.

**ANNEX II B****SOIL ANALYSIS**

1. Whenever sludge other than sludge from the treatment plants referred to in Article 11 is used, Member States must first ensure that the heavy metal content of the soil does not exceed the limit values laid down in accordance with Annex IA. For this purpose, Member States shall decide what analyses to carry out, taking account of available scientific data on soil characteristics and homogeneity.
2. Member States shall decide on the frequency of further analyses, taking account of the metal content of the soil prior to the use of sludge, the quantity and composition of the sludge used and any other relevant factors.
3. Analysis should cover the following parameters:
  - pH,
  - cadmium, copper, nickel, lead, zinc, mercury and chromium.

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**ANNEX II C****SAMPLING AND ANALYSIS METHODS****1. Soil sampling**

The representative soil samples for analysis should normally be made up by mixing together 25 core samples taken over an area not exceeding 5 hectares which is farmed for the same purpose.

The samples must be taken to a depth of 25 cm unless the depth of the surface soil is less than that value; however, the sampling depth in the latter case must not be less than 10 cm.

**2. Sludge sampling**

Sludge must be sampled after processing, but before delivery to the user, and should be representative of the sludge production.

**3. Methods of analysis**

Analysis for heavy metals must be carried out following strong acid digestion. The reference method of analysis must be that of atomic absorption spectrometry and the limit of detection for each metal should be no greater than 10 % of the appropriate limit value.

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