

Overview of some important directives relating to community level risk reduction of chemicals

Foreword

Background

Council Regulation (EEC 793/93) on the evaluation and control of the risks of existing substances aims at the protection of man from exposure to dangerous substances via all possible routes as well as of all compartments of the environment. The Commission and the Member States draw up lists of priority substances that will undergo the risk assessment. The Member State rapporteur, acting on behalf of the Community, performs the evaluation of the risks. If the conclusion of the assessment is that there is a risk to human health and the environment, and that the risk is not adequately managed, the rapporteur is required to propose a strategy to reduce the risks.

Member States rapporteurs have at present (December 2001) completed the first draft Risk Assessment Reports on 88 out of a total 141 priority substances listed on the four first priority lists. Conclusions have been agreed for 56 of the 88 substances, resulting in a need for risk reduction measures for 45 substances.

Member State rapporteurs have developed proposals for risk reduction strategies for 24 of those 45 substances. 9 strategies have resulted in Commission recommendations on measures. The number of risk reduction strategies finalised within the Existing Substances Programme, and the number of rapporteur countries producing such strategies, is increasing.

On the basis of the risk evaluation and the recommended risk reduction strategy the Commission shall decide to propose Community measures. The strategy might involve restrictions on marketing and use of dangerous substances and preparations or other relevant existing Community instruments. Also other tools for risk reduction may be used, such as voluntary agreements or economic instruments.

With regard to regulatory control through other relevant existing Community instruments, a large number of directives is available as tools for the reduction of risks posed by chemicals. Consequently, there is a need for a basic understanding of the options available. Such an understanding will provide the foundation for discussions in national consultations.

Some of these directives are listed and briefly described in Annex B of the Technical Guidance Document (TGD) on Development of Risk Reduction Strategies. The directives are divided into six groups in the annex:

- A. General measures
- B. Protection of workers
- C. Protection of consumers
- D. Emissions to water
- E. Emissions to air
- F. Waste management

Nordic co-operation in preparing for the work as rapporteur

The Nordic countries have a long tradition of co-operation. Under the Nordic Council of Ministers and, more specifically, its Nordic Chemicals Group, a project on risk reduction within the Existing Substances Programme was established in 1999. The purpose of the project has primarily been to enhance the methodology of the rapporteur work in individual Nordic countries.

This report from the Nordic project consists of an overview of forty directives with some relating to risk reduction of chemicals at Community level. The overview is focused on how the directives may be used to help fulfil risk reduction objectives.

The selection of directives is based on Annex B of the Technical Guidance Document on Development of Risk Reduction Strategies. The list has been updated and complemented according to the group members' expertise. It should, however, be noted that other complementary directives may be relevant as well.

The descriptions contain the following headlines

- Legal basis in the treaties
- Scope and structure of the directive
- Measures, procedures and time frame for applying the tool to additional substances
- Evaluation of applicability of the tool in reducing the risks from chemicals, e.g. situations when it can be used.

Descriptions have been drafted and discussed in the Nordic project group. In general, the texts have been circulated also to other relevant Nordic experts for comments. Members of the project group are:

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As indicated above, the aim of the compilation has primarily been to facilitate the rapporteur work in Nordic countries. Furthermore, the compilation is not exhaustive and should rather be seen as a state-of -the-art document that needs to be revised and complemented regularly. For instance, recently launched or coming directives are difficult to evaluate, since their applicability can be understood only preliminarily. Interest for the work has however been expressed by other rapporteurs to the EU programme for Existing Substances. It is therefore our hope that this report can contribute to the work carried out in other countries.

[2001-12-21]

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A. Dangerous substances in general

Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to *restrictions on the marketing and use of certain dangerous substances and preparations*

Legal basis in the treaties

The original legal basis for the directive was article 100 (later 100.a) of the Treaty of Rome, which corresponds to article 95 of the present treaty.

Scope and structure of the directive

The directive was introduced in 1976 to deal with situations where classification and labelling of chemicals were not sufficient to protect health and the environment and Member States were introducing national restrictions of the marketing and use of chemicals thus creating barriers to trade. The directive sets out detailed rules for restrictions on marketing and use, harmonising the legislation throughout the Community and at the same time providing for a high level of protection of man and the environment.

The directive creates a framework for bans or restrictions by means of an Annex, where the controlled substances and/or products are listed. These can only be placed on the market subject to the conditions specified. The provisions of the directive are not applicable to transport of dangerous substances or preparations, to transport in transit regime, nor to marketing and use for research and development or analysis purposes. Up to now (February 2000), the directive has been amended 17 times and 40 classes of substances or preparations have been listed in the Annex.

Two different general concepts of restrictions on marketing and use exist, which can be designated as “ban with exemptions” and “controlled use”. A ban with exemptions means that marketing and use of the substances are prohibited except for applications that are explicitly allowed. Controlled use means that marketing and use of a substance and the preparations and products containing it are allowed except those which are specifically forbidden.

In practice, the concept of "controlled use" is predominant. The only existing total ban is the one for PCB and some substitutes to PCB. The restriction for pentachlorophenol may be seen as an example of a ban with exemptions. The absolute majority of the restrictions are designed as controlled use, i.e. a ban limited to e.g. the general public (e.g. benzidine, chlorinated hydrocarbons) and/or certain applications e.g. cadmium.

The provisions may be related to concentration limits for the substance in a preparation or a product (e.g. emission limit for nickel in jewellery). There are also requirements for specific labelling and other safety measures (e.g. asbestos).

A special mechanism for risk reduction in the Directive, provided by the 14th amendment in 1994, is that substances classified as carcinogenic, mutagenic or toxic to reproduction (category 1 and 2) may be banned for consumer use. Thus, this directive is linked to Council

Directive 67/548/EEC. This mechanism is, however, not automatic and each new substance has to be included in an amendment of the directive, adopted by the Council and the Parliament in the co-decision procedure. More than 850 such CMR substances are currently restricted in this way (among these are several hundred complex substances derived from coal and oil).

Another example of systematic use restriction through this directive is that “ornamental lamps and ashtrays, tricks, jokes, games for one or more participants” may not contain substances or preparations that are dangerous to health.

The provisions in Directive 76/769/EEC do not cover areas where harmonised legislation already exists, e.g. risks to human health from cosmetics and medicinal products.

Measures and procedures

Proposals for most of the amendments of Directive 76/769 have originated in notifications from the Member States under Directive 83/189, i.e. of the intention to unilaterally introduce limitations at a national level. Council resolutions have been the major driving force for the restrictions of CMR-substances and cadmium. Work of OSPARCOM has also been the reason for the proposition and adoption of two amendments. New substances notification under 67/548 has led to the restriction of a family of PCB-substitutes. Also, a safeguard clause in the Aerosols directive has been the origin for one amendment. Short chain chlorinated paraffins (SCCP) will be the first example of an amendment initiated by a risk assessment from the Existing Substances Regulation.

Before an issue is put on the agenda, a report on advantages and drawbacks is carried out by independent consultants. The work should be done in a transparent way and include all stakeholders. Guidance on the methodology is given in the DG III Working Paper on Risk Management in the framework of Council Directive 76/769/EEC (Doc.98/RiMa03).

Proposals for amending the Directive are adopted according to the co-decision procedure between the European Parliament and Council.

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

Applicability in reducing the risks from chemicals

The Directive may be used as an effective and flexible instrument for risk reduction measures. Measures can be aimed at the marketing and use of chemicals and may thereby effect the direct exposure of consumers as well as workers. Moreover, the measures may effect point sources of emissions as well as diffuse sources, and that includes all sorts of manufactured articles, i.e. not only chemical substances and preparations.

In a comparison between the two concepts for restrictions identified above, a "ban with exemptions" may theoretically be preferable to "controlled use" in situations where both risks and uses are widespread. This is because the ban effectively reduces all risks (also those arising from applications that may not have been identified) and at the same time is resource saving for the authority, as no excessive investigation in details is needed. Monitoring measures should also be less costly for the authorities, as the monitoring efforts to a great extent may be focused on a limited number of suppliers and to a lesser extent on the numerous users.

Another advantage of "ban with exemptions" concerns the transparency to users and the public. The restrictions for the marketing and use of cadmium (for plating and in polymers as pigment and stabiliser) is an example of poor transparency resulting from the "controlled use" approach. In this case the list of exemptions consists of some 40 application areas.

For industry, the "ban with exemptions" approach may result in larger differences in risk reduction costs between the different application areas, and larger overall costs, than what would have been the result with the "controlled use" approach. Such drawbacks are always weighed against the advantages for society of a "ban with exemptions", i.e. a more effective risk reduction and lower administrative costs

In situations where the risk appears to be limited to certain applications and/or users, "controlled use" is a more natural choice.

[2001-02-18]

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*

and

Council Directive 88/379 of 7 June 1988 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of *dangerous preparations*

and

Commission Directive 93/112/EC of 10 December 1993 amending Commission Directive 91/155/EEC defining and laying down detailed arrangements for the system of *specific information relating to dangerous preparations* in implementation of Article 10 of Council Directive 88/379/EEC

Legal basis in the treaties

The original legal basis was article 100 of the Treaty of Rome, which now corresponds to article 95 of the Treaty.

Scope and structure

The first community legislation with regards to chemicals control was Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ("the Substances Directive"). The aim of the directive is to achieve a high level of protection of human health and the environment from the hazards that dangerous chemicals may cause when placed on the market and used as well as to ensure the elimination of technical barriers to trade.

The original directive has been amended eight times until now and the annexes have been modified 27 times. The structure of the directive has become very complex and many provisions of the directive are dispersed among different pieces of legislation.

New and existing substances

Until the sixth amendment, the directive covered only classification and labelling of dangerous substances. It was through the sixth amendment of the Substances Directive that a distinction was introduced between "existing chemicals", i.e. chemicals on the market at a specific point in time (1981), and "new chemicals", planned to be put on the market after that time. Furthermore, an inventory of existing chemicals was established.

The seventh amendment of the directive modified some of the obligations for the placing of new chemicals on the market and introduced the requirement for a formal risk assessment of new substances. Principles for this assessment were laid down in Commission Directive 93/67/EEC. These principles were subsequently used as the basis for risk assessment of existing substances.

Classification and labelling of substances and preparations

Information on the hazard of a chemical substance form an important basis for risk reduction measures. The objective is to inform by adequate labelling all persons that could possibly come into contact with the chemical during manufacturing, storage, handling, application and use, as well as during disposal, thus allowing for a minimisation of exposure.

Classification of dangerous substances into one of the currently fifteen classes of danger is performed according to principles laid down in Annex VI of the Substances Directive and taking into account the results of testing of intrinsic properties detailed in Annex V. Such a classification of a substance requires appropriate labelling on the package. The information is made available by danger symbols and risk phrases, each of which expresses possible hazards as described in Annex II and III. Standardised safety phrases describing the necessary precautions are given in Annex IV. The classification and labelling of nearly 5.000 dangerous substances are listed in Annex I of the directive. Existing substances that are dangerous but not listed in Annex I have to be classified and provisionally labelled by the manufacturer, distributor or importer.

The corresponding provisions for mixtures of substances (preparations) have been laid down in Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations ("the Preparations Directive"). The sheer number of preparations makes classification on the basis of laboratory tests problematic, as the resulting number of test animals needed would make such a procedure impractical and not compatible with animal welfare. Therefore, calculation methods have been developed, where the classification of a preparation can be calculated from knowledge of the classification of the component substances and their concentrations in the preparation.

Clearly there is a close link between these two directives. Not only does the Preparations Directive use the substance classifications of the Substance Directive, it also uses the same classes of danger, the same criteria for labelling, the same labelling scheme, the same test methods (where needed) and the same packaging rules. The Preparations Directive has been continuously developed over the past ten years. A new legal instrument has been developed as replacement: **Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations**. This new directive is to be implemented into national law by Member States before 30 July 2002 (the measures for pesticides and biocides will apply as from 30 July 2004). Through this directive dangers to the environment will be included in the system for classification and labelling of dangerous preparations. Furthermore, information on risks will be improved for already sensitised persons since the new directive will introduce rules for the labelling of preparations that contain substances classified as sensitisers without being classified as dangerous preparations.

System for specific information (safety data sheets) for dangerous preparations

The information provided by the labelling of dangerous substances and preparations may indicate potential dangers to the users. For industrial users, however, this basic information needs to be supplemented, especially regarding handling, use, transport and disposal. More specific information, for example first measures in case of fire or accident, will enable the

user to take measures that are necessary to ensure the protection of health and safety at the workplace.

The Preparations Directive therefore requires specific information for industrial users in the form of safety data sheets. The details are set up in a separate implementing directive, the Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC. These provisions were extended to dangerous substances through Commission Directive 93/112/EEC, where information relevant for the environment was also included. The provisions are included in, and will in fact be improved by, the new Preparations Directive as safety data sheets will be required also for preparations that not are classified as dangerous but may nevertheless pose dangers to health or to the environment through their content of more than 1% of a dangerous substance.

Procedure and time frame for additional substances and measures

The commission regularly convenes a number of working groups (e.g. for human health, particularly CMR; specialised experts; environment; competent authorities) for co-operation with the Member States in relation to the Substances Directive. Proposals for modifications (“Adaptations to Technical Progress, ATP”) are developed and agreed in a working group before the decision on a formal Commission proposal is taken by votes in the regulatory committee (“Technical Progress Committee, TPC”). This decision procedure is described in article 29 in the Substances Directive. In practice, the time between the first discussions on additional classifications and the adoption of the ATP may be one to two years.

The commission working groups also take part in drafting proposals for amendments of the original directive. In such cases, the actual decisions are taken in a co-decision procedure between the European Parliament and Council. Such a decision may under normal circumstances take at least two additional years.

Links to risk reduction measures in down stream legislation

The Substances Directive provides a significant platform for a range of down stream legislation. Its classification criteria and approach to hazard identification impacts upon the operation of many other pieces of community legislation. Some more or less automatic connections are outlined in the following. Mostly they concern human health, due to the much later inclusion of dangers to the environment into the Substances Directive.

Classification of dangerous substances and preparations may have repercussions on the marketing and use of a chemical. This is regulated through the Restrictions Directive. In a systematic way, the marketing to the general public may be prohibited for substances and preparations classified as category 1 or 2 of the danger classes carcinogenic, mutagenic or toxic to reproduction. It should be noted, however, that restrictions do not follow automatically upon the classification of a substance.

The directives concerning biocidal and plant protection products provide similar restrictions on the marketing and use of substances which meet the criteria for classification as category 1 or 2 carcinogenic, mutagenic or toxic to reproduction.

Also, Directive (1999/13/EC) on the limitation of emissions of volatile organic compounds (“VOCs”) due to the use of organic solvents in certain activities and installations contains specific provisions for carcinogens.

Directive (89/391/EEC) on the introduction of measures to encourage improvements in the safety and health of workers at work is a framework directive that sets out general rules for worker protection. A number of more specific directives have been adopted with reference to this directive. Workplace controls are imposed on the use of substances or preparations which meet the criteria for classification as a carcinogen of category 1 or 2 according to the Substances or the Preparations Directives. This definition not only covers substances which are intentionally placed on the market, but also substance which may incidentally appear at the workplace, for instance during a production process.

In addition, some other community legislation regulates the use of dangerous substances and preparations.

For instance, Directive (88/378/EEC) on the approximation of the laws of the Member States concerning the safety of toys requires that toys must not contain dangerous substances or preparations within the meaning of the Substances and the Preparations Directives in amounts which may harm the health of children using them.

The directive (91/689) on hazardous waste and its list of hazardous waste largely uses the criteria of the Substances Directive to define hazards.

In the regulation (EEC 880/92) on a community Eco-label award scheme it is stipulated that the eco-label shall in no case be awarded to products which are substances or preparations classified as dangerous in accordance with the Substances or the Preparations Directive. The label may however be awarded to products containing a substance or preparation classified as dangerous in accordance with these directives in so far as the product fulfils the general criteria for the directive. These provisions are intended to ensure that whilst no dangerous chemicals as such can be awarded an eco-label, products which contain dangerous chemicals can however receive the award.

The concerns addressed in the directive (96/82/EC) on the control of major-accident hazards involving dangerous substances relate mainly to acute effects from chemicals. Therefore, only relevant categories of danger defined in the Substances Directive are used in this piece of legislation.

Applicability in reducing the risks from chemicals

Efficiency depends on compliance and enforcement

The Substances and the Preparations Directives are central and well known tools for risk reduction, impacting upon a range of community legislation on the supply and use of chemicals substances. It has been found, however, that the provisions on classification and labelling are not sufficiently applied and enforced in all Member States. Some substances and preparations on the market are not classified at all by the manufacturer/importer, even if it can be reasonably expected that they are potentially dangerous; some are classified differently by different manufacturers/importers.

During an inspection of 100 companies manufacturing “new” dangerous substances in the field of photochemicals, paints, intermediates, dyestuffs and paper industry chemicals, classification of over 500 substances was examined. All substances were registered in Annex I of the Substances Directive and selecting the appropriate classification and labelling should therefore have been an easy task. However, the classification was not correct for 25% of the examined substances and over 40% were not correctly labelled.

The degree of compliance regarding provisions in the Substance Directive will furthermore influence the risk reducing efficiency of connecting legislation down-stream. It should be pointed out that the links to down stream legislation mostly concern risks to human health, due to the later inclusion of dangers to the environment into the Substances Directive.

[2001-02-18]

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of *plant protection products* on the market

Legal basis in the treaties

The legal basis for this directive is article 100a of the Treaty of Rome, presently article 95 of the Treaty.

Scope and structure of the directive

The aim of the directive is primarily to assure the free movement on the market for plant protection products. It is also stated that the directive should assure a high level of protection for human health, ground water and the environment. The directive lays down the criteria and procedures for the evaluation of active substances and for plant products. All active substances that existed on the market 15 July 1993 shall be evaluated according to a review programme. Additives/other chemical ingredients are not regulated in the directive.

Measures and procedures

The approval of an active substance is done at the Community level. If a substance is found to be acceptable and consequently approved, it will be included on the list for permitted substances (Annex I). At present (November 2000), there are eight substances listed in Annex I. Approvals may be associated with certain conditions for the use.

After the inclusion in Annex I, an application for approval of a plant protection product containing the active substance may take place. Also before the inclusion in Annex 1 Member States may grant provisional approval for a product containing a new active substance if the requirements for approval are met (Art 15). The company applies for approval in any of the Member States. According to the principle of mutual approval laid down in the directive, a plant product that has been approved in one Member State should in principle also be approved in the other states. The directive opens for refusal of approval due to specific differences in agricultural and environmental (including climate) conditions.

Applicability in reducing the risks from chemicals

As additives are not part of the directive, it is at present up to every Member State to decide on risk reduction measures aimed at such substances. For example, in some Nordic countries authorities have used a combination of voluntary agreements and stricter approval/re-licensing criteria since 1996 to achieve a phase-out of nonylphenoethoxylates by the year 2000 or within the registration period. A total phase-out is expected within a few years time.

An extension of the directive to also comprise additives has been discussed, up to now without result. The directive is therefore at present not useful for risk reduction in the context of the Existing Substances Regulation.

[2001-02-18]

Directive (98/8/EC) of the European Parliament and of the Council of 16 February 1998 concerning the placing of *biocidal products* on the market

Legal basis in the treaties

The legal basis for this directive is article 100a of the Treaty of Rome, presently article 95 of the Treaty.

Scope and structure of the directive

The objective of this directive is to achieve a high level of protection, especially in relation to the environment, health and a sustainable development, and to minimise barriers to trade in biocidal products and in products treated with them.

The directive provides a framework of rules concerning

- the authorisation and the placing on the market for use of biocidal products within Member States
- the mutual recognition of authorisations within the Community
- the establishment at Community level of positive lists of active substances which may be used in biocidal products

It applies to biocidal products, defined as:

active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any harmful organism by chemical or biological means. Annex V of the directive contains an exhaustive list of 23 product types in the four main product groups, which are disinfectants (e.g. drinking water disinfectants), preservatives (e.g. wood preservatives), pest controls (e.g. rodenticides) and other biocidal products (e.g. anti-fouling).

Biocidal products should not be placed on the market unless they have complied with the relevant procedures. Harmonised community provisions for evaluation and rules for inclusion on a positive list of biologically active substances and authorisation of biocidal products will provide the control of risks posed by biocidal products. These provisions are close to the system for agricultural pesticides 91/414 placing of plant protection products on the market. Classification and labelling of authorised biocidal products will, however, be performed according to the new Preparations Directive.

Measures, procedures and time frame for applying the tool to additional substances

Three community lists of active substances will be produced, which permit the inclusion of active substances in biocidal products. In addition to the list of active substances (Annex I) there will be a list of low-risk products (I A) and basic substances (I B). The substances will be included in the lists after the evaluation procedure. An active substance cannot be included in annex IA if it is classified according to Directive 67/548/EEC as:

- carcinogenic,
- mutagenic,

- toxic for reproduction,
- sensitising, or
- is bioaccumulative and does not readily degrade.

The marketing and use of biocidal products containing substances which meet the criteria for classification as category 1 or 2 carcinogens, mutagens or toxic to reproduction shall normally not be authorised for marketing to, or use by, the general public.

Furthermore, the inclusion of an active substance to the lists may be refused or removed

- if an evaluation shows that, under normal conditions under which it may be used in authorised biocidal products, risks to health or the environment still give rise to concern.

When an active substance is evaluated it is necessary to cover the same aspects as in risk assessments made for new and existing substances under 92/32/EEC or 793/93.

- if there is another active substance permitted for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment. When such a refusal or removal is considered, an assessment of an alternative active substance shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment (comparative assessment).

Applicability in reducing the risks from chemicals

The full implementation will not be achieved for several years. Meanwhile, 76/769 provides a framework to complement the development of the positive list by limitations of the marketing and use of certain active substances and products or groups thereof

[2001-02-18]

B. Protection of workers (occupational safety and health)

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage *improvements in the safety and health of workers at work*

Legal basis in the treaties

The original legal basis was Article 118a in the Treaty of Rome, presently Article 138 of the Treaty. The directive shall lay down minimum requirements for encouraging improvements in the working environment to guarantee a better level of protection of the safety and health of workers.

Scope and structure

The directive is a framework directive and sets out the principles for legislation on workers' safety and health. In the Annex some of the areas which need special regulation are listed. The need for protection of vulnerable groups is described. A number of more specific directives have been adopted with reference to this directive.

Thus, there are no specific rules regarding chemical agents in this directive. Article 6 lists the general principles of prevention:
 avoiding risks; evaluating the risks which cannot be avoided; combating the risks at source; adapting the work to the individual, especially as regards the design of work places, the choice of work equipment and the choice of working and production methods, with a view, in particular, to alleviating monotonous work and work at a predetermined work-rate and to reducing their effect on health; adapting to technical progress; replacing the dangerous by the non-dangerous or the less dangerous; developing a coherent overall prevention policy which covers technology, organization of work, working conditions, social relationships and the influence of factors related to the working environment; giving collective protective measures priority over individual protective measures; giving appropriate instructions to the workers.

Measures, procedures and time frame for applying the tool to additional substances

Article 17 describes the Committee procedure:

For purely technical adjustments to the individual directives provided for in Article 16 (1) to take account of:

- the adoption of directives in the field of technical harmonisation and standardisation,
 - technical progress, changes in international regulations or specifications, and new findings,
- the Commission shall be assisted by a committee composed of representatives of the Member States and chaired by a representative of the Commission.

Applicability in reducing the risks from chemicals

[2001-12-21]

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to *chemical agents* at work

Legal basis in the treaties

This directive is the fourteenth individual directive within the meaning of Article 16(1) of the framework directive 89/391/EEC. The original legal basis was Article 118a in the Treaty of Rome, presently Article 138 of the Treaty.

Scope and structure

This directive concerns work with chemical agents and lays down minimum requirements for work with hazardous chemical agents. It replaces and revises a number of existing directives covering exposure to chemical, physical and biological agents at work (80/1107/EEC) and metallic lead and ionic compounds (82/605/EEC). It also replaces Directive 88/364/EEC on banning certain specific agents and/or work activities. Its provisions apply without prejudice to the more stringent and/or specific requirements of the Carcinogens Directive.

Hazardous chemical agents include any chemical substance and preparation which meets the criteria in Directive 67/548/EEC and 88/379/EEC, whether or not a harmonised classification and labelling has been decided. This directive also covers any chemical substance which, although they do not meet these criteria, may present a risk to safety and health of workers due to their physicochemical, chemical or toxicological properties. However, substances and preparations that only are “dangerous for the environment” are not covered.

The Directive (Article 3) provides a framework for setting occupational exposure limit values (OELVs; time-weighted average air concentrations of a chemical agent) and biological limit values (concentration in the appropriate biological medium of the chemical agent, its metabolite, or an indicator of its effect).

The Directive requires that risks arising from chemical agents are identified by employers through risk assessment (Article 4) and reduced by application of a set of general principles (Articles 5 and 6). These principles in general follow the requirements of the Carcinogens Directive and as such include substitution, prevention, protection and control. In those instances where a national OELV is exceeded, the employer is to remedy the situation through preventative and protective measures.

The Directive also makes provision for the Commission to draw up practical guidelines to assist in the implementation of the Directive (Article 12). These are to be of a non-binding nature and will relate to:

- * the development of standardised methods for the measurement and evaluation of workplace air concentrations in relation to OELVs;
- * methodologies for the determination and assessment of risk and for the review and adjustment of such methodologies; and
- * preventative and protective measures to control risk.

Member States are to implement the Chemical Agents Directive not later than 5th May 2001 and report to the Commission every five years on its practical implementation.

Measures, procedures and time frame for applying the tool to additional substances

The procedure for setting occupational exposure limit values begins with an evaluation of the relationship between the health effects of a hazardous chemical agent and the level of exposure. The evaluation is made by the Commission's Scientific Committee on Occupational Exposure Limit Values (SCOEL) and reported in a summary document. The Commission proposes a limit value after having consulted the tripartite Advisory Committee on Safety, Hygiene and Health protection at Work. The indicative limit value shall then be established in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC. A first list of indicative occupational exposure limit values was established in Commission Directive 2000/39/EC of 8 June 2000. Member states shall set national limit values taking account of the European indicative limit values.

As an alternative a binding limit value may be established by a decision of the Council and the Parliament. In addition to the factors considered when establishing indicative limit values, feasibility factors (technical and economical) shall be reflected in a binding limit value. Member States are required to set a corresponding national binding limit value, based on but not exceeding the European binding limit value.

Binding occupational exposure limit values are laid down in **Annex I** while binding biological limit values are laid down in **Annex II** to the Directive. Up to this day the only substance with a binding limit values in Annex I and II is Lead (Pb).

To prevent the exposure of workers to health risks from certain chemical agents and/or certain activities involving chemical agents, the production, manufacture or use at work of the chemical agents and activities set out in **Annex III** shall be prohibited to the extent specified therein. Up to this day there is prohibition on the use of some benzidine compounds and other aromatic amino compounds.

Applicability in reducing the risks from chemicals

The provisions for risk assessment may be difficult to implement at small and medium-sized enterprises. Occupational exposure limit values are important risk reduction tools in specific work scenarios. Resources for control are required. Furthermore, the provisions are not applicable to chemicals posing risks to the environment.

Prohibitions specified in Annex III may be used instead of restrictions on marketing and use through directive 76/769 when the prohibition has no impact on the inner market. Such prohibitions may be difficult to implement and control at small and medium-sized enterprises. In the case that enforcement tools are utilised, prohibitions on production, manufacture or use at work would be useful for risk management.

[2001-12-21]

Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to *carcinogens* at work

Legal basis in the treaties

This is the sixth individual Directive within the meaning of Article 16(1) of the framework directive 89/391/EEC. The original legal basis was Article 118a in the Treaty of Rome, presently Article 138 of the Treaty.

Scope and structure

This directive provides a step-by-step approach for controlling the risks associated with workplace substances and preparations which meet the criteria for carcinogens and mutagens (category 1 and 2) in Directive 67/548/EEC and 88/379/EEC. The definition not only covers substances and preparations which are intentionally placed on the market, but any substance which may incidentally appear at the workplace, for instance during a production process.

The directive places a number of requirements on employers aimed at preventing and reducing exposure (Article 5). These include undertaking an assessment of risk, replacing carcinogens and mutagens with less hazardous products (where possible) and the use of closed systems for manufacture and use. Where a closed system is not technically possible, the level of exposure is to be reduced to as low a level as possible. In addition, employers are to design processes and engineering control measures so as to avoid or minimise releases the workplace.

Employers are further required to use appropriate measuring procedures, to use suitable working procedures and methods and to use collective or (where exposure cannot be avoided by other means) individual protective measures. The directive recognises that for some activities, such as maintenance, there is the potential for a significant increase in worker exposure (Article 8) and specifically requires the use of protective clothing and individual respiratory protective equipment in such circumstances. These measures are further backed up by a requirement for worker training on, for example, precautions to be taken to prevent exposure and the wearing and use of protective equipment and clothing (Article 11).

Where risk assessments reveal a risk to health or safety, employers are required to keep an up-to-date list of the workers engaged in these activities and associated exposures if available (Article 12). Provision is also made for the Member States to establish arrangements for carrying out health surveillance of workers (Article 14). Such information is to be kept for at least 40 years (Article 15).

Finally, binding limit values can be set for carcinogens (Article 16). Binding limit values have been established for benzene, vinyl chloride monomer and hard wood dust through amending directives 97/42/EC and 1999/38/EC.

Annex I

List of carcinogenic processes.

Annex II

Guidelines for 'Health surveillance'

Annex III

Limit values

Measures, procedures and time frame for applying the tool to additional substances

Annexes I and III may be amended only in accordance with the procedure laid down in Article 118a/138 of the Treaty, while the recommendations under Annex II can be changed in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

Applicability in reducing the risks from chemicals

The provisions are important risk reduction tools in specific work scenarios but may be difficult to implement at small and medium-sized enterprises. Resources for control are required.

[2001-12-21]

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of *pregnant workers and workers who have recently given birth or are breastfeeding*

Legal basis in the treaties

This is the tenth individual directive within the meaning of Article 16 (1) of directive 89/391/EEC. The original legal basis was Article 118a in the Treaty of Rome, presently Article 138 of the Treaty.

Scope and structure of the directive

This directive covers work of pregnant workers and workers who have recently given birth or are breastfeeding. The employer is required to assess the exposure to certain chemical agents. This includes *carcinogenic* substances (all categories) as well as *mutagenic* substances. Furthermore, the employer is prohibited to employ young people for work involving exposure to harmful agents, including carcinogenic substances and preparations.

For all activities liable to involve a specific risk of exposure to agents, processes or working conditions of which a non-exhaustive list is given in Annex I, the employer shall assess the nature, degree and duration of exposure, in the undertaking and/or establishment concerned, either directly or by way of the protective and preventive services referred to in Article 7 of Directive 89/391/EEC. This shall be done in order to:

- assess any risks to the safety or health and any possible effect on the pregnancy or breastfeeding
- decide what measures should be taken.

Substances on Annex I:

- (a) substances labelled R 40, R 45, R 46, and R 47 under Directive 67/548/EEC in so far as they do not yet appear in Annex II;
- (b) chemical agents in Annex I to Directive 90/394/EEC;
- (c) mercury and mercury derivatives;
- (d) antimetabolic drugs;
- (e) carbon monoxide;
- (f) chemical agents of known and dangerous percutaneous absorption.

In addition to the general provisions concerning the protection of workers, in particular those relating to the limit values for occupational exposure, cases in which exposure is prohibited are listed in Annex II:

- Pregnant workers may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure, which would jeopardise safety or health, to the agents and working conditions listed in Annex II, Section A;
- Workers who are breastfeeding, may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure, which would jeopardise safety or health, to the agents and working conditions listed in Annex II, Section B.

Chemical agents in Annex II:

Lead and lead derivatives in so far as these agents are capable of being absorbed by the human organism.

Measures, procedures and time frame for applying the tool to additional substances

New substances can be added to Annex I of this Directive. This shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC. Annex II may be amended only in accordance with the procedure laid down in Article 118a of the Treaty.

Applicability in reducing the risks from chemicals

The provisions are important risk reduction tools in specific work scenarios but may be difficult to implement at small and medium-sized enterprises. Resources for control are required.

[2001-12-21]

Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of *personal protective equipment* at the workplace

Legal basis in the treaties

The directive is the third individual directive within the meaning of art. 16 (1) of directive 89/391/EEC. The original legal basis was Article 118a of the Treaty of Rome, presently Article 138 of the Treaty.

Scope and structure of the directive

The directive gives minimum requirements for personal protective equipment (PPE) used by workers at work. Personal protective equipment is defined to include all equipment designed to be worn or held by the worker to protect him against one or more hazards likely to endanger his safety and health at work, and any addition or accessory designed to meet this objective.

Primarily risks should be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organisation. When this cannot be done, personal protective equipment shall be used. Personal protective equipment could be seen as last option to protect workers.

The directive gives the obligation to the employer to provide personal protective equipment free of charge and to give information to the workers of the risks against which the wearing of the PPE protects him. It is the employer's obligation also to ensure that the PPE is appropriate for the risks involved without itself leaving to any increased risk.

Measures and procedures

The employer is required, before choosing PPE, to make an analysis and assessment of risks which cannot be avoided by other means. An analysis shall involve the definition of the characteristics which PPE must have in order to be effective against the risk. Also comparison of the characteristics of the PPE must be included.

Member States are obliged to establish general rules for the use of PPE which cover cases and situations where the employer is obliged to provide the PPE. The directive refers to employers' and workers' organisations that Member States must consult before establishing the rules.

Applicability in reducing the risks from chemicals

In the risk assessment process within the EU (Regulation 793/93), risks following the proper use and functioning of PPE are to be considered in combination with probabilities of non-usage of PPE. If there is a likelihood that PPE is not used and if the risk is not acceptable on comparing the use and non-use of PPE, further risk reduction measures are normally recommended.

The directive doesn't give detailed information to the employer how to select a proper PPE. However personal protective equipment must comply with the relevant Community provisions

on design and manufacture with respect to safety and health. Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment gives the basic requirements which PPE must satisfy. The basic requirements are considered to be fulfilled, if the PPE bears the EC mark and is thus specified and tested in accordance with the harmonised standards. Depending of the properties of the substance, the period for which the PPE is worn, the frequency of exposure, the materials used for e.g. gloves which provide protection from the substance are essential to know. Permeability of different materials of the gloves may vary a lot. Also, the choice of respiratory protective device depends on the properties of the substance and the duration and the frequency of the exposure.

However, according to the directive 67/548/EEC, manufacturer, importer or distributor of a substance must provide a safety data sheet to the professional users when delivering the dangerous substance for the first time. According to the directive 91/155/EEC concerning the safety data sheets, it is stated that in the safety data sheets of the substance or preparation, the information of exposure control and personal protection must be given. Concerning PPE, the type and quality of equipment related to respiratory, hand, eye and skin protection must be defined. When recommending a special PPE, CEN-standards ought to be referred.

[2001-02-21]

C. Protection of consumers

Council Directive 98/83/EC of 3 November 1998 on the quality of *water intended for human consumption*

Legal basis in the treaties

The directive was adopted under Article 130s of the Treaty of Rome, which is now Article 175 of the Treaty.

Scope and structure of the directive

The directive was given in 1998 and Member States shall bring it into force within two years of its entry into force (23.11.2000). The directive 80/778/EEC is thus repealed with this directive within certain time period.

The directive concerns the quality of water intended for human consumption, which means all water either in its original state or after treatment as well as water used in food industry. The purpose of the directive is to protect human health from the adverse effects of any contaminant of water by ensuring that it is wholesome and clean. If contaminated water causes a potential danger to human health, the supply of such water should be prohibited or its use restricted.

The directive gives individual parametric values for several substances, based on public health considerations and risk assessments (Annex I: Parameters and parametric values; Part A; Microbiological parameters, Part B; Chemical parameters). Among the chemical parameters there are substances like acrylamide, benzene, fluoride and nitrate. Member States have possibility to set additional parameters or more stringent values if necessary, but they must notify the Commission of those measures. The principles and rules of the Treaty must however be respected.

The directive gives also parameters that have an indicator function for monitoring purposes (Annex I: Part C; Indicator parameters). Among them are parameters like aluminium, chloride, conductivity, odour and taste. Member States shall consider whether the non-compliance of these parameters poses any risk to human health and if necessary take remedial actions to restore the quality of the water.

Individual parameters and parameters which have an indicator function concern all water intended for human consumption such as private wells.

General obligation of Member States is to ensure, that measures hindering any deterioration of the present quality of water which poses a risk for human health or any increase in the pollution of waters used for the production of drinking water are sufficient.

Member States shall establish monitoring programmes to check that water intended for human consumption meets the requirements of the directive. Annex II of the directive gives parameters which must be monitored, but Member States can add other parameters to this list if they deem it appropriate. Local needs can be taken into account and therefore the minimum monitoring requirements are given in this directive. Member States may exempt from the provisions water from an individual supply providing less than 10 m³ a day as an average or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity. This exemption concerns mainly monitoring programme. Annex III of the directive comprises specifications for the analysis of parameters.

Measures, procedures and time frames for applying the tool to additional substances

At least every five years, the Commission shall review Annex I in the light of and adapt Annexes II and III to scientific and technical progress and make proposals for amendments. By way of notification (directive 98/34/EC) national amendments to these Annexes can be done.

Applicability in reducing the risks from chemicals

If a risk assessment of the Existing Substances Programme concludes that measures are needed to limit the risks posed by a substance via drinking water, it is possible to propose changes in a individual parametric values set in the annex I or to propose adding a substance to the list.

If drinking water quality is seen as a risk, it is possible to refer to the directive and remedial measures should be taken. This would, however, be the latest possible action. In many cases the remedial actions are taken under other legislation. For example if the source for drinking water (e.g. ground water) is contaminated, actions are taken based on environmental legislation like ground water directive.

[2001-02-21]

Council Directive 89/107/EEC of 21 December 1989 concerning *food additives* authorized for use in foodstuffs intended for human consumption*Legal basis in the treaties*

The legal basis for this directive is article 100a of the Treaty of Rome, presently article 95 of the Treaty.

Scope and structure of the directive

This directive applies to additives for use in foodstuffs. It is set as a framework directive in that area, on which other directives regarding additives will be based. The purpose of the directive is to protect the health of consumers and to guarantee a free movement of foodstuffs on the internal market.

The directive contains a positive list of additives, i.e. only those food additives included in the list may be used in the manufacture or preparation of foodstuffs and only under the conditions of use specified therein.

The Directive applies to food additives which are used or intended to be used as ingredients during the manufacture or preparation of a foodstuff either for a technological purpose, processing, preparation, treatment, packaging, transport or storage of foods. It does not apply to: processing aids as defined in the directive, pesticides, flavouring or substances added for their nutritional function.

The use of food additives belonging to specific categories should be authorized only on the basis of agreed scientific and technological criteria laid down by the Council.

The Scientific Committee for Food should be consulted when drawing up lists of additives and the conditions for their use, before the adoption of provisions likely to affect public health.

[2000-06-15]

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for *contaminants in food*.

Legal basis in the treaties

The legal basis for this directive is article 100a of the Treaty of Rome, presently article 95 of the Treaty.

Scope and structure of the directive

The Regulation concerns contaminants contained in food. It is set forward as a frame regulation in that area, on which other regulations regarding contaminants in food will be based. The main purpose of the regulation is to protect the health of consumers and to guarantee a free flow of foodstuffs in the Community (the internal market).

The regulation sets forth a definition of a contaminant and should provide for a list of contaminants to which the regulation does not apply. Many provisions in this regulation are directed at the Commission and not at the Member States directly. For instance, further provisions regarding contaminants and the setting of maximum tolerances for specific contaminants will be established by a Committee procedure, as determined by the regulation. Through Commission Regulation 194/97 maximum levels have been set for certain contaminants in foodstuffs. Any provision which may have an effect upon public health shall be adopted after consultation of the Scientific Committee for Food.

In the absence of Community legislation, Member States may apply national provisions regarding contaminants in foodstuffs.

Applicability in reducing the risks from chemicals

The Regulation might be used in cases where indirect exposure has been identified as a concern, and where the foodstuffs (plant, animal, fish, etc.) which are the main sources of the contamination have been identified.

[2000-06-15]

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to *cosmetic products*

Legal basis in the treaties

The initial directive was adopted under article 100 of the Treaty of Rome, but subsequent amendments have been adopted under article 100a, which corresponds to article 95 of the present treaty.

Scope and structure of the directive, including links to other directives

The directive was adopted in 1976 and the scope of the directive is to secure human health and to harmonise the European regulation of cosmetic products. The directive regulates the marketing of cosmetic products, including requirements concerning labelling and instructions for use. The directive is not applicable to pharmaceuticals, medical devices or food products. The way a product is claimed and marketed decides under which regulatory framework it falls. Examples of cosmetic products are shampoos, lipsticks and hair dyes.

The main rule of the directive is that cosmetic products may not be hazardous to health under normal and foreseeable use, and that it is the responsibility of the industry to secure this. The directive consists of an initial regulatory part which establishes general requirement concerning safety, labelling and information duties. This part is succeeded by 7 annexes listing substances, which are either banned or restricted or positive lists of substances which may be used as colouring agents, preservatives or UV-filters.

The original directive has been amended 6 times and the annexes have been adapted 25 times by Commission directives.

Measures, procedures and time frame for applying the tool to additional substances

Proposals for new substances to be introduced in one of the annexes are raised by the cosmetic industry (mainly substances to be included in the positive lists) or by Member States (mainly substances to be banned or restricted). The proposed substances will be reviewed by the SCCNFP (Scientific Comity on Cosmetics and Non Food Products) and based on the scientific opinion the Commission (DG Enterprise) will draft a new adaptation, which shall be adopted by the Member States by a qualified majority.

Applicability in reducing the risks from chemicals

The directive only regulates on health and safety. In general the regulation of cosmetic products is regarded as successful.

Amendments and adaptations to technical progress of this directive with relevant product categories and concentration limits will reduce exposure and risks for consumers.

[2000-06-15]

Council Directive 91/442/EEC on dangerous preparations the packaging of which must be fitted with *child-resistant fastenings*

Scope and structure of the directive

According to the Preparations Directive (88/379/EEC), all preparations labelled with the category of danger Very toxic, Toxic or Corrosive and offered or sold to the general public are to be fitted with child-resistant fastenings. This somewhat complicated wording has been changed in Annex IV of the new Preparations Directive 1999/45/EC and there is no longer any specific reference to "categories of danger".

Directive 91/442 gives a possibility to require child-resistant fastenings also for preparations that do not fall into the categories mentioned but nevertheless may present a danger to children. Such preparations may belong to other categories of danger (presently: R65 Harmful - may cause lung damage if swallowed) or contain certain substances in considerable amounts. Up to now, only two substances have been added to the annex of the directive: methanol (>3%) and dichloromethane (>1%). In the case of methanol this concentration is the same as the specific concentration limit in Annex I to the Substances Directive 67/548/EEC, for dichloromethane it is the general concentration limit for category 3 carcinogens.

Applicability in reducing the risks from chemicals

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[2000-06-15]

Council Directive 92/59/EEC of 11 August 1992 on general *product safety*

Legal basis in the treaties

The original legal basis for the directive was article 100, but subsequent amendments have been adopted under article 100a of the Treaty of Rome, presently article 95 of the Treaty.

Scope and structure

The Directive has two complimentary objectives: ensuring a high and consistent level of protection for consumer health and safety throughout Europe *and* the proper functioning of the Internal Market. The directive has recently been revised (2001/95/EC) in order to improve its effectiveness to ensure that only safe products are put on the market.

The directive places a general obligation on the importers and manufacturers of products intended for consumer use to ensure that their products do not present unacceptable risks to human health or property under normal and reasonably foreseeable conditions of use. The manufacturer shall provide consumers with the relevant information to enable them to assess the risk inherent in a product throughout the normal or reasonably foreseeable period of its use, and to take precautions against those risks.

The directive covers products which are not subject to sectorial legislation and also those that are subject to sectorial legislation which does not address risk and safety aspects.

Measures and procedures

Member States shall nominate authorities to monitor the compliance with the obligation to place only safe products on the market and to arrange for such authorities to have the necessary powers to take appropriate measure incumbent upon them under this directive.

Member States shall organize appropriate checks on the safety of products, requiring all necessary information from the parties concerned, taking samples of a product or product line and subjecting them to safety checks, subjecting product marketing to prior conditions designed to ensure product safety and requiring suitable warnings to be affixed regarding the risks which the product may present. The Member States shall also arrange prohibiting when necessary and organise effective and immediate withdrawal of dangerous products and product batches already on the market, and if necessary their destruction. To this end a system for rapid exchange of information has been established (Rapex).

The Commission shall be assisted by a Committee on Product Safety Emergencies. Every two years the Commission shall submit a report on the implementation of this Directive to the European Parliament and the Council.

Applicability in reducing the risks from chemicals

The allocation of responsibilities has not led to a satisfactory evaluation of the safety of chemical. It is expected that the revision of the directive will improve this.

[2001-12-10]

Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the *safety of toys*

Legal basis in the treaties

The legal basis for this directive is article 100a of the Treaty of Rome, which corresponds to article 95 of the present treaty. The directive is harmonising the laws and regulations relating to the safety of toys.

Scope and structure of the directive

It is stated that toys placed on the market should not jeopardise the safety and/or health of users or of third parties. Toys are defined as any product or material designed or clearly intended for use in play by children of less than 14 years of age.

The standard of safety of toys should be determined in relation to the criterion of the use of the product as intended. But allowance should also be made for any foreseeable use, bearing in mind the normal behaviour of children who do not generally show the same degree of care as the average adult user.

Measures, procedures and time frame for applying the tool to additional substances

The directive requires that toys must not contain dangerous substances or preparations within the meaning of the Substances and the Preparations Directives in amounts which may harm the health of children using them. However, when a limited number of substances or preparations are essential for the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardisation (CEN).

In annex 1 products not covered by the directive are listed, e.g. Christmas decorations, sport equipment etc.

In annex 2 essential safety requirements for toys are given. The chemical properties are described in part II, article 3:

1. Toys may not present health hazards or risks of physical injury by ingestion, inhalation or contact with skin, mucous tissues or eyes.
2. For certain metals the bioavailability from the use of toys may not exceed some exact levels per day, other values for these or other substances may be laid down in other Community legislation based on scientific evidence.
3. Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC in amounts which may harm the health of children using them

The requirement of the directive shall be fulfilled with harmonised standards on the essential safety requirement in annex 2. At this time, the only standard dealing with chemicals is EN71.

Annex 3 deals with conditions to approved bodies.

Annex 4 deals with warning and indications of precaution. In article 4 on toys containing inherently dangerous substances or preparations (chemical toys) is stated that the instruction for use shall bear a warning of the dangerous nature of these substances or preparations and an indication of the precaution to be taken.

There is no restriction on use of specified substances, the use is dependent on the actual risk.

Applicability in reducing the risks from chemicals

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[2000-06-15]

Council Directive 93/42/EEC on *Medical Devices*
and
Council Directive 98/79/EEC on medical devices to in vitro-diagnostic

Legal basis in the treaties

The legal basis for these directives is article 100a of the Treaty of Rome, which corresponds to article 95 of the present treaty.

Scope and structure of the directive

The directives are harmonising the laws and regulations relating to medical devices, with the objective to remove barriers to trade and to ensure security of medical devices.

According to principles set out in 1985 in connection with the new approach to technical harmonization and standardisation, rules regarding design and manufacture of medical devices must be confined to the provisions required to meet essential requirements. These requirements are described in general terms, among them are considerations on risk and benefits, safety of material and biocompatibility. In order to demonstrate and verify conformity with the essential requirements, harmonized European standards may be used. The standards are recommendations and will not be binding on manufacturers. Compliance with the requirements can also be verified in other ways. Any product monographs in the European Pharmacopoeia will remain in force.

Medical devices should as a general rule, be labelled with the CE mark to indicate their conformity with the provisions of this directive and to enable them to move freely within the community. The manufacturer is responsible for labelling the product with the CE mark.

Medical devices are classified in four product classes based on the vulnerability of the human body and taking into account the potential risks associated with the technical design and manufacture of the device. The classes are denoted I (low risk) IIa, IIb and III (high risk).

The manufacturer is thus responsible for classifying medical devices and for verifying their compliance with the directive. In case of products in risk class IIa, or higher, a notified body however must certify the compliance with the requirements.

The Member States shall notify the Commission of the bodies that they have designated. The Commission shall compile and publish a list of the notified bodies. A notified body assures the compliance with the Directive by regular inspections of facilities and documentation. Up to date there are approximately 65 notified bodies within the Community, where almost 50 % of them are situated in Germany. Only the actual notified body and the manufacturer of the medical device have the knowledge of the content of chemical substances and the outcome of the risk-benefit analyses.

According to a safeguard clause in the directive, Member States shall take interim measures to withdraw devices, which may compromise the health or safety, from the market or prohibit or restrict them from being placed on the market or put into force. The Member State shall

immediately inform the Commission of any such measures and the reason for taken the measures. The Commission shall ensure that the Member States are kept informed about the progress and the outcome of the procedure.

The Committee on Medical devices is set up by Article 6 of the Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices. This committee supervises issues regarding the legislation on medical devices and delivers its opinion on proposed amendments to the legislation. The Commission may also seek the assistance of a Scientific Committee on Medical devices. The representatives in this committee are scientists in different fields related to medical devices.

Furthermore, Commission may be assisted in the elaboration and evaluation of technical standards by a Committee on Standards and Technical Regulations, set up according to Article 5 of Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations.

Measures, procedures and time frame for applying the tool to additional substances

Annex I to the directive contains the essential requirements. The risk associated with a medical device must be acceptable when weighted against the benefits to the patients and that the device must be compatible with a high level of protection of health and safety. The devices must be designed and manufactured to minimize the risks posed by substances leaking out from the device. Furthermore, the Annex contains requirements on the information supplied by the manufacturer.

Applicability in reducing the risks from chemicals

The directive may be useful for risk reduction on substances when medical devices are handled in special ways; e.g. when certain sterilisation methods are used.

The fact that content of chemical substances, risk assessment behind the classification and the risk-benefit analysis of a medical device is restricted knowledge makes it difficult to survey the different medical devices and to take action on Community level against certain chemical substances.

[2001-12-21]

Council Directive 89/106/EEC on *Building Materials*

Legal basis in the treaties

The legal basis for this directive is article 100a of the Treaty of Rome, which corresponds to article 95 of the present treaty. The directive is harmonising the laws and regulations relating to building materials.

Scope and structure of the directive

The directive is a framework directive. It has been changed by directive 93/68/EEC. The requirement in relation to hygiene, health and the environment is that buildings must be constructed and erected in a manner, which entails no risk in terms of hygiene or health to residents or neighbours.

The Commission shall in relation to attest of a building material choose between to procedures in article 13, 3 and in all cases choose the most economic procedure fulfilling the safety requirements. One possibility is to choose a product control system on the producers responsibility another possibility is to involve an authorized certifying institution.

The directive is to be supplemented by CEN standards, and a list of national regulation on dangerous substances is included in an annex. The mandates to standardisation are under continuous development.

Applicability in reducing the risks from chemicals

Standards may be developed where demands on technical performance are in conflict with the need to reduce risks relating to harmful substances.

The directive may not be directly useful for risk reduction on a specific chemical. However, the standardisation requirements in relation to hygiene, health and the environment may in a longer perspective influence the environmental performance of building materials.

[2000-06-15]

D. Emissions to water

Council Directive 96/61/EC of 24 September 1996 concerning *integrated pollution prevention and control (IPPC)*

Legal basis in the treaties

The directive is based on article 130 s of the Treaty of Rome, presently article 175 of the Treaties.

Scope and structure of the directive

The aim of the directive is to lay down measures designed to prevent or control emissions in order to achieve a high level of protection of the environment as a whole. It integrates provisions and measures dealing with emissions to air, water and land, including measures concerning wastes.

The directive covers medium-sized and large industrial installations, waste management installations and installations for the intensive rearing of poultry and pigs (Annex I). For some of the industrial branches installations with low production capacity are left out of the scope of the directive (e.g., iron and steel mills with capacity less than 2.5 tonnes per day or paper and board mills with capacity less than 20 tonnes per day)

Council Directive 84/360/EEC setting up scheme for authorising new industrial plants and alterations to existing plants in order to limit emissions will after 11 years transition time be replaced by the IPPC directive.

Articles related to reduction of risks caused by chemicals

A) Permits

Installations listed in Annex I have to have a permit. New installations have to have a permit in accordance with the IPPC directive before they are put into operation. Existing installations (in operation before October 2000) have to have a permit in accordance with this directive at the latest 2007. (Art. 4 and 5)

An application for a permit has to include inter alia descriptions of raw and auxiliary materials, nature and quantities of foreseeable emissions, proposed technology or other techniques for preventing or reducing emissions, and measures planned to monitor emissions. (Art. 6)

The permit shall include emission limit values for pollutants likely to be emitted from the installations in significant quantities. Annex III includes an indicative list of main polluting substances to be taken into account when considering emission limits. The list includes some

specific substances, such as dioxins, but also large groups of substances, such as "persistent and bioaccumulative organic toxic substances". (Art 9.3)

Emission limit values shall be based on best available techniques. (Art 9.4) Annex IV includes issues to be taken into account when determining best available techniques. For instance the use of less hazardous substances (point 2), the nature, effects and volume of the emissions concerned (point 6), and the consumption and nature of raw materials (point 9) have to be considered.

The Commission shall organise an exchange of information between Member States and the industries on best available techniques. (Art. 16) The results of this information exchange are published as IPPC BAT Reference Documents (BREFs). The BREFs aim at providing reference information for the permitting authority to be taken into account when determining emission limit values.

The permit shall contain suitable release monitoring requirements. (Art 9.5)

Permit conditions have to be reconsidered and updated periodically. (Art 13)

B) Community emission limit values

The Council can set common emission limit values for the categories of installations listed in Annex I and for the substances referred to in Annex III. (Art 18)

Applicability in reducing the risks from chemicals

A) BREF documents

BREFs should cover at least the most important emission which have to be taken into account in the permitting process. Also the means to reduce emissions as well as achievable emission limit values have to be described in BREFs. Producing this information may require a considerable amount of work. It is important to bear in mind that BREFs are not prescriptive and they do not propose emission limit values but contain information facilitating the permitting procedure of industrial installations. It should also be noted that so far BREFs have not included much information on chemicals but focussed on "traditional" emission parameters (e.g., BOD, SO₂, etc.).

BREFs are an important source of information on the need and possibilities to reduce risks of a certain industry branch. Such risk reduction possibilities include both substitution of the chemical in question and process internal and external measures preventing or reducing the emissions to non harmful levels. This risk reduction measure is suitable for substances for which there are sufficiently effective process internal or external measures for risk reduction. If the substitution is in practice the only effective measure, it is more advisable to use marketing and use restrictions.

The measure suits industrial branches listed in Annex I. It has to be considered case by case whether production capacity limits set in Annex I will hinder the use of this tool and how to overcome any difficulties.

The BREFs will be reviewed and updated as appropriate. In practise, however, it may take time before a BREF is updated with regard to a certain chemical especially if the BREF in question is new or newly revised. If there are several industrial branches for which the selected risk reduction measure would be information through BREFs, the total amount of work and time required before all BREFs include sufficient information may be considerable.

The BREFs are used by national authorities when granting a permit. Permits are granted plant by plant. These permits are reviewed periodically but in practise it will take several years before the emission limit values for the chemical are in place for all relevant industrial installations throughout the EU.

Compliance with the emission limit values have to be monitored. Depending on the substance and industry branch this may be costly.

B) Adding the chemical into Annex III

If the chemical is listed in Annex III, national authorities have to include emission limit values for that chemical in the permits. If no need to reduce emissions of the chemical is mentioned in the relevant BREFs, expert knowledge is needed on where the chemical is likely to be emitted in significant quantities. In other words, the risk reduction need has to be communicated to national authorities by other means. In addition to that, authorities have to find the knowledge on emission reduction possibilities, which may require a lot of work.

Again, it may take fairly long before all relevant industrial installations have a limit value in force.

C) Community emission limit values

Community emission limit values could be given to the relevant industrial branches if they are mentioned in Annex I. Also, the production capacity limits would apply to such general limit values. Setting such standards would require knowledge on emission levels achievable by the best available techniques and predicted non-effect concentrations from risk assessment reports.

Community emission limit values require monitoring and supervising as do the plant-by-plant emission limits. Monitoring requirements for industrial branches could be set in plant-by-plant permits or as general requirements according to national legislation. Depending on the substance and industrial branch, this may be costly.

[2000-06-15]

Council Directive 76/464/EEC on pollution of the aquatic environment by certain dangerous substances

Legal basis in the treaties

The directive was adopted under Articles 100 and 235 of the Treaty of Rome.

Scope and structure of the directive

The aim of the Dangerous Substances Directive (DSD) is to eliminate, or to reduce, pollution of waters by dangerous substances listed in the Annex. The directive covers both diffuse and point source discharges. It applies to inland surface waters, territorial waters, and internal coastal waters (referred to as 'waters'). Groundwater is currently regulated through Directive 80/68/EEC and is not anymore covered by this directive.

The DSD sets requirements to eliminate pollution of certain individual substances of 'List I' on Community level whereas the substances and groups of substances of 'List II' have to be reduced through pollution reduction programmes. The Community level measures for the seventeen List I substances are set in daughter directives¹.

The Community measures of DSD will be repealed and substituted by the Water Framework Directive (WFD) fairly soon (see below). Contrary to that, the national provisions remain in force until the end of 2013. In the further implementation of national measures under DSD the principles and procedures laid in the WFD may be used. The whole of DSD will be repealed after 13 years of the date of entry into force of the WFD (Art. 21(2)). Provisions related to Community wide measures will, however, be repealed and revised already earlier:

- Art. 6 of Directive 76/464/EEC (which authorises the Council to lay down limit values for emission standards for various dangerous substances) was repealed on the date of entry into force of the WFD (Art. 21(2) of the WFD).
- The list of priority substances adopted under the WFD will replace the list of substances in Commission Communication to the Council of 22 June 1982 (Art. 21(3a) of the WFD).

¹ The daughter directives are:

- Council Directive 82/176/EEC on Limit Values and Quality Objectives for Mercury Discharges by the Chlor-alkali Electrolysis Industry (OJ L 81, 27.3.82);
- Council Directive 83/513/EEC on Limit Values and Quality Objectives for Cadmium Discharges (OJ L 291, 24.10. 83);
- Council Directive 84/156/EEC on Limit Values and Quality Objectives for Mercury Discharges by Sectors other than the Chlor-Alkali Electrolysis Industry (OJ L 74, 17.3.84);
- Council Directive 84/491/EEC on Limit Values and Quality Objectives for Discharges of Hexachlorocyclohexane (OJ L 274, 17.10.84); and
- Council Directive 86/280/ EEC on Limit Values and Quality Objectives for Discharges of Certain Dangerous Substances included in List I of the Annex to Directive 76/464/EEC (OJ L 181, 4.7.86), as amended by Directive 88/347/EEC and Directive 90/415/EEC.

- The Commission will within two years of the date of entry into force of the WFD review the daughter directives under Directive 76/464/EEC. The provisions for controlling water pollution by substances on the priority list under the WFD will need to be revised. The review will consider the repeal of controls for all other substances (Art. 16(10) of the WFD).
- Member States may apply the principles and procedures laid down in the WFD for the purpose of implementing Article 7 of the DSD (which obliges Member States to establish programmes to reduce water pollution caused by List II substances) (Art. 21(3b) of the WFD).

Measures, procedures and time frame for applying the tool to additional substances

A basic obligation in the DSD is that discharges of list I and II substances require authorisation. List I, for which Community emission limit values (ELVs) and environmental quality objectives (EQOs) have been set in daughter directives, includes 17 substances². These ELVs and EQOs are rather loose and, therefore do not serve as a guidance on setting emission limit values in plant-by-plant permits. The ELVs and EQOs for these 17 substances will be revised under the WFD.

In the following the description concentrates on article 7 of the DSD which includes provisions concerning national measures. More information on the Commission view on the implementation of the national provisions under the DSD is to be found in the Commission guidance document³ and report on assessment of programmes⁴.

Article 7 sets obligations to the Member States to reduce pollution of waters by the substances within list II. List II includes both individual substances and large groups of substances. Furthermore list II covers all substances belonging to the groups of substances in list I for which Community measures have not been established (that is all other substances but those 17 covered by the daughter directives). Communication from the Commission to the Council on dangerous substances which might be included in List I of the DSD (OJ C 176, 14.7.1982) establishes a list of 132 substances. 99 of these substances for which there are no Daughter Directives or proposals for Community measures are regarded as List II substances. In addition to those there may also be other nationally relevant pollutants which belong to list II. The methodology for identifying the relevant pollutants is not specified in the DSD. The WFD states that measures laid down in article 16 (2) may be used for identification of national substances under the DSD.

According to Article 7 of the DSD the Member States have to establish programmes, substance by substance, including environmental quality objectives. Discharges of substances require prior authorisation in which emission standards have to be set. The programmes may also include specific provisions concerning the composition and use of substances and

² Hexachlorocyclohexane, DDT, aldrin, dieldrin, endrin, isodrin, trichlorobenzene, hexachlorobenzene, hexachlorobutadiene, carbonchloride, pentachlorophenol, chloroform, 1,2-dichloroethane, trichloroethylene, perchloroethylene, mercury and cadmium

³ European Commission (DG ENV.E.1), Guidance Document on elements for pollution reduction programmes under Article 7 of Council Directive 767464/EEC.

⁴ European Commission (DG ENV) Assessment of programmes under Article 7 of Directive 767464/EEC, WRc Ref: CO 5033, November 2001.

products. The requirements for establishing national measures in the DSD are to large extent same as in the WFD.

Applicability in reducing the risks from chemicals

Article 7 of the DSD provides a framework for defining and establishing emission reduction targets for both diffuse and point sources. EQOs can be used to follow up the efficiency of the measures taken and the need to take additional measures. A comprehensive approach introduced in the DSD gives the national authorities good opportunities to tackle discharges of substances into waters.

It is to large extent left to the national authorities to decide on which substances programmes are made. Furthermore, it is up to the national authorities to decide on the pollution reduction targets, measures taken and their implementation. In practise, the recommendation to use article 7 of DSD will probably lead to varying levels of protection in different Member States.

[2001-12-21]

Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of *water policy*

Legal basis in the treaties

The Water Framework Directive (WFD) is based on article 175 of the Treaties.

The scope and structure of the directive

The directive aims at maintaining and improving the aquatic environment. The directive covers inland surface waters, transitional waters, coastal waters and groundwater. In other words, it covers all other parts of the aquatic environment than the open sea. The aquatic environment of surface waters includes water column, sediment and biota.

The core objective of the directive is to prevent deterioration of the status of surface and groundwater. In addition, for surface waters the aim is to achieve good status within 15 years. For groundwater, in addition to the requirements of good status, any significant and sustained upward trend in the concentration of any pollutant should be identified and reversed.

The directive recognises that individual substances or groups of substances may present a significant risk to or via the aquatic environment and that this requires action against pollution by these substances. Enhanced protection and improvement of the aquatic environment will be achieved, inter alia, through specific measures for the progressive reduction of discharges, emissions and losses of priority substances, and the cessation or phasing-out of discharges, emissions and losses of priority hazardous substances.

Measures and procedures at Community level

Substances which present significant risks to or via the aquatic environment will be prioritised for action on the basis of risk (priority substances). Risk may be identified e.g. by risk assessment carried out under the Existing Substances Regulation (ESR). The directive allows also the use of a simplified risk-based assessment procedure which takes into account the intrinsic properties of substances, evidence from monitoring of widespread environmental contamination, and other factors indicating exposure.

Priority hazardous substances will be identified among these priority substances. The Commission will propose a list of priority substances and an identification of priority hazardous substances. The list of priority substances shall be reviewed at least every four years.

The Commission shall submit proposals for

- the environmental quality standards (EQSs) applicable to concentrations of the priority substances in surface water, sediments or biota
- product and process controls for point and diffuse sources

For the priority substances the proposed controls shall aim at progressive reduction of discharges, emissions and losses and for the priority hazardous substances cessation of discharges, emissions and losses within 20 years.

The Commission shall submit these proposals for EQSs and control measures within 2 years of the inclusion of the substance on the list of priority substances. The proposed product and process controls will be established under the relevant Community or national legislation. In the absence of agreement on EQSs and control measures at Community level 6 years after the date of entry into force of the Water Framework Directive, the Member States have to establish EQSs and controls for principal sources.

The Commission shall make proposals for specific measures to prevent and control groundwater pollution within 2 years after entry into force of the directive. These measures shall include criteria for assessing good groundwater chemical status, criteria for the identification of significant and sustained upward trends and for definition of starting points for trend reversals.

Measures at national level

Member States shall prepare at the latest 4 years after entry into force of the Water Framework Directive a review of the impact of human activity on the status of surface waters and groundwater. That includes identification and estimation of significant point and diffuse source pollution, in particular substances listed in Annex VIII. Annex VIII includes i.a. persistent and bioaccumulable organic toxic substances.

Member States shall establish for each river basin district a programme of measures at the latest 9 years after entry into force of the WFD. These programmes shall include measures needed to progressively reduce pollution by other substances than priority substances. The measures have to be operational at the latest 12 years after entry into force. These other substances are identified nationally and are those that may cause pollution and are discharged in significant quantities into the body of water. The aim for the reduction is to achieve at least good surface water status that is the status of a body of surface water in which concentrations of pollutants do not exceed the environmental quality standards. Member States have to establish quality standards for these other pollutants. Standards may be set for water, sediment or biota.

Concentrations of pollutants are used as parameters for the determination of groundwater chemical status. "Pollutant" is defined as "any substance liable to cause pollution in particular those listed in Annex VIII". There is no further guidance in the Water Framework Directive on which substances should be dealt with when defining groundwater chemical status.

Member States have to monitor surface water, including concentrations of priority substances and nationally identified pollutants. Groundwater monitoring will include concentrations of pollutants. The monitoring programmes shall be operational at the latest 6 years after entry into force of the directive.

Applicability in reducing the risks from chemicals

According to article 16.2 (a) substances shall be prioritised for action on the basis of risk to or via the aquatic environment identified, e.g., by risk assessment carried out under the Existing Substances Regulation (ESR). For these substances the Commission shall submit proposals of

controls of discharges, emissions and losses. On the other hand, the ESR already requires preparation of a risk reduction strategy for limiting the identified risks.

These two proposals for measures are at least partly overlapping even if the scope and partly the aims of measures are different. Measures proposed under the WFD cover only risks to or via the aquatic environment while proposals under the ESR cover all identified risks to the environment and human health. The aim of the WFD measures for the priority substances is to progressively reduce discharges, emissions and losses and to achieve at least good surface water chemical status. For the priority hazardous substances the aim under the WFD is cessation or phasing out of discharges, emissions and losses. The ESR measures aim at limiting the identified risks. For the aquatic environment that in practice means reducing the discharges, emissions and losses at least to the level where the predicted non-effect concentration (PNEC) in the receiving water body is not exceeded.

The WFD requires that EQSs are set up for the priority substances. Good surface water chemical status requires that concentrations of a priority substance do not exceed the defined EQS. In practice EQS will probably be set at PNEC-level. Hence, the aim of the WFD and ESR will differ only for those substances which are under the WFD selected as priority hazardous substances.

Actual control measures will in both cases, the WFD and ESR, be established under other relevant Community or national legislation. Here the main difference is that the WFD requires always setting up the EQSs. The WFD can also be seen as a tool for setting Community wide EQSs when deemed necessary in the ESR RRS.

The WFD list of priority substances will be reviewed at least every 4 years. The Commission has to make proposals for measures, including for EQSs, within 2 years of the inclusion of the substance on the list. The time frame of actions under the WFD for the substances for which the ESR risk assessment identifies risk to or via the aquatic environment remains to be seen. These substances could be included in the WFD priority list immediately after completion of the risk assessment and Community wide EQS could be established quickly on the basis of the work done during the risk assessment. In the worst case inclusion to the priority list will take 4 years, and agreement on EQSs at Community level 5 years (together 9 years).

Concerning other measures than setting EQSs (which actually are not risk reduction measures but a way to follow up the effectivity of measures taken) a close cooperation and coordination of the work of the relevant Commission services and the rapporteur MS for the ESR risk assessment and risk reduction is needed. Or: The Commission can utilise RRS prepared by the rapporteur MS.

If the risk assessment under the ESR concludes that there is a risk to or via the aquatic environment but the substance in question is not selected for a list of priority substances, the ESR RRS could propose measures under the WFD. Such a case could be, for instance, if the risk is identified only for one country or otherwise limited geographical area. Risk reduction measure could be national measures under the WFD. Means to communicate this to relevant MSs as well as means to ensure that sufficient measures are taken at a national level have to be clarified.

[2000-06-15]

Council Directive 80/68/EEC of 17 December 1979 on the protection of *groundwater* against pollution caused by certain dangerous substances

Legal basis for the directive

The Council Directive 80/68/EEC (Groundwater Directive) was adopted under article 100 of the treaty of Rome, now article 95. According to the Water Framework Directive (WFD) the Groundwater Directive will be repealed with effect from 13 years after the date of entry into force of the WFD, that is 22.12.2013.

Scope and structure

The purpose of the Groundwater Directive is to prevent the pollution of groundwater by groups of substances in lists I and II in the Annex and as far as possible to check or eliminate the consequences of pollution which have already occurred.

List I includes the following substances: organohalogen, organophosphorous and organotin compounds, CMR substances, mercury and cadmium and their compounds, cyanides and mineral oils and hydrocarbons. List II includes: 20 metals and their compounds, biocides, organic silicon compounds, inorganic phosphorous compounds, fluorides, ammonia and nitrites and substances, which have a deleterious effect on the taste or odour of groundwater.

Domestic effluents from isolated dwellings are excluded from the scope of the Directive. Discharges containing list I or II substances in very small quantities and concentrations are also excluded from the scope on account of the low pollution risk and the difficulty of controlling such discharges. The Directive does not provide any further guidance on what is small quantity or concentration.

Measures and procedures

The Directive obliges the Member States to take necessary steps to prevent introduction into groundwater of substances in list I and to limit the introduction of substances in list II so as to avoid pollution.

Direct discharges of list I substances into groundwater are prohibited. 'Indirect discharge' means discharge into groundwater after percolation through the ground or subsoil. Any disposal of list I substances which may lead to indirect discharges into groundwater need prior investigation and authorisation. All direct discharges of list II substances need an authorisation. Furthermore, Member States have to take the appropriate measures they deem necessary to limit all indirect discharges of list II substances. The directive specifies the content of the authorisation and requires monitoring of the compliance with the conditions set in the authorisations.

A proposed Groundwater Action programme (COM (96) 315 final of 10. July 1996) recommends that Member States should establish national action programmes aiming at protection of groundwater against pollution from diffuse and point sources. The proposal

includes main lines of action programme, i.a. monitoring to provide information on development of quantitative and qualitative aspects of groundwater resources.

Applicability in reducing the risks from chemicals

The Directive provides a framework to eliminate or reduce direct or indirect discharges of substances included in list I and II into groundwater. Although lists I and II include fairly large groups of substances, they do not cover all hazardous substances. Furthermore, lack of monitoring obligation can be regarded as a major shortcoming of the directive. However, even if the Groundwater Directive will still remain in force until 2013, the WFD obliges Member States to prepare a review of the impact of human activity on the status of groundwater already by 22.12.2004. Furthermore, monitoring programmes for groundwater have to be operational by 22.12.2006.

[2000-06-15]

Council Directive 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to *detergents*

Today, the EU legislation concerning detergents comprises of this framework directive, four amending Directives (73/405/EEC, 82/242/EEC, 82/243/EEC, 86/94/EEC) and a Commission Recommendation (89/542/EEC). The Commission has started to update this existing legislation and draft proposals to a new directive have been discussed.

Legal basis for the directive

The legal basis for these directives is article 100a of the Treaty of Rome, which corresponds to article 95 of the present treaty.

Structure and scope

The purpose is to prevent sale of detergents resulting in foaming of rivers and to ensure free trade within the Community of detergents that comply with the directive in relation to biodegradability and labelling. Each MS is obliged to provide the necessary laws, regulations and administrative provisions to comply with the regulations.

The directive lays down the main regulations concerning detergents. The directive prohibits the placing on the market and use of detergents containing anionic, cationic, non-ionic and/or ampholytic surfactants with an average level of biodegradability less than 90 %. The directive also provides that the surfactants being used under normal condition must not be harmful to human or animal health. The biodegradability requirement applies only on surfactants in detergents. The directive also set up requirements for certain information that must be put on the packaging of products sold to consumers. According to the directive compliance with the biodegradability requirements shall be established by methods of testing provided for in other directives.

Council Directive 73/405/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to *methods of testing the biodegradability of anionic surfactants*

This directive specifies five testing methods for anionic surfactants including one reference method, which is fully described in the Annex to the Directive. The member states shall prohibit the placing on the market if the level of biodegradability is less than 80 % determined in accordance with one of the methods described.

Council Directive 82/243/EEC of 31 March 1982 on the approximation of the laws of the Member States relating to *methods of testing the biodegradability of anionic surfactants*

This directive amends Directive 73/405/EEC and replaces the reference method for anionic surfactants. A new testing method is also added and a procedure for updating methods according to technical progress is introduced.

The directive makes it clear that the test method described in directive 73/405 applies only to surfactants used in detergents and that the level of biodegradability is for the surfactants that is used in the detergent and not the detergent itself.

Council Directive 82/242/EEC of 31 March 1982 on the approximation of the laws of the Member States relating to *methods of testing the biodegradability of non-ionic surfactants*

This directive specifies five testing methods for the biodegradability of non-ionic surfactants. One of the methods is a reference method, which is described in an annex. The directive also contains derogation from directive 73/404. For a limit period the use of certain non-ionic surfactants not satisfying the biodegradability requirements of 90 % provided for in directive 73/404/EEC, is permitted. The directive also introduces a procedure for updating methods according to technical progress.

Council Directive 86/94/EEC of 10 March 1986 on the approximation of the laws of the Member States relating to *detergents*

This directive extends the period (given in directive 82/242) available for exemption of certain products from the minimum biodegradability of 90 %. This exemption expired at the end of 1989.

Commission Recommendation 89/542 of 13 September 1989 for the *labelling of detergents and cleaning products*

This recommendation lays down detailed labelling requirements for detergents and cleaning products. The labelling shall indicate the content of the constituents defined in the recommendation according to percentage ranges. The packaging of detergents and cleaning products intended for use by the general public as laundry detergents should bear information on the recommended quantities and/or dosage instructions.

Proposal for a new directive

The Commission has started an update of the existing legislation and draft proposal to a new directive has been discussed. The following description is based on a working document of 24 January 2000.

The proposal is to replace existing directives on detergents and biodegradability of surfactants in detergents and the recommendation for labelling of detergents and cleaning products.

The proposal is to be based on article 95 of the Treaty of the European Community and aim at the approximation of the laws, regulation and administrative provisions of the MS concerning the free movement of detergents in relation to biodegradability of surfactants in detergents and labelling of detergents. The measures should ensure a high level of environmental protection.

The proposed definition for detergents enlarges the scope of the existing legislation. The proposal also contains a definition for surfactants, which is lacking in the existing legislation. The new biodegradability tests proposed are applicable to all kinds of surfactants in detergents

As a first requirement for marketing permission, the proposal introduces that the surfactant has to pass a test based on ready biodegradability. In case of failing these tests the existing primary biodegradability tests are to be performed. If the surfactant also fails this test the marketing is to be banned, but if it pass these tests it need in order to be marketed a specific Decision by Committee procedure on the basis of data related to risk assessment. It is the manufacturer's responsibility not to market substances not complying with the provisions by the directive.

The technical Annexes to the directive are to be adapted to scientific and technical progress by committee procedure.

[2000-06-15]

E. Emissions to air

Council Directive 96/61/EC of 24 September 1996 concerning *integrated pollution prevention and control*

(see D above)

Council Directive 1999/13/EC of 11 March 1999 on the limitation of *emissions of volatile organic* compounds due to the use of organic solvents in certain activities and installations

Legal basis for the directive

The directive is based on article 130 s of the Treaty of Rome corresponding to article 175 of the present Treaty.

Scope and structure

The purpose of the directive is to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds (VOC) into the environment, mainly to the air, and the potential risk to human health due to the use of organic solvents within certain processes and industrial installation. Also fugitive emissions are covered, including emissions to soil, water and, in most cases, solvents contained in products. The activities covered by the directive are defined in Annex I to the directive. The directive shall apply to these activities in so far as they are operated above the solvent consumption threshold limits defined in Annex II A. This annex also contains emissions limit values for each activity, both limit values for waste gas emission, fugitive emission and in some case limit value for the total emission. Both the consumption limit and emission limit values differ from one activity to another.

Measures and procedures

The Member States shall take appropriate measures, either by specifications in the conditions of authorisation or by general binding rules to ensure that the requirements in the directive are complied with. Laws, regulations and administrative provisions necessary to comply by the directive shall be brought into force not later than April 2001.

All new installations shall meet the requirement of the directive. New installations that are not covered by the IPPC-directive (96/61) shall be registered or undergo authorisation before being put into operation. All existing installations shall be registered or undergo authorisation and comply with the requirement not later than 31 October 2007.

All installation and activities covered by the directive shall comply with the emission limit values, or other requirements laid down in Annex II A of the directive or the requirements of the reduction scheme specified in Annex II B.

Without prejudice to directive 96/61/EC, Member States may define and implement national plans for reducing emission from existing activities and industrial installation covered by the directive with some exception. These plans shall result in a reduction of annual emissions of VOC from existing installations by at least the same amount and within the same time frame as would have been achieved by applying the emission limits.

The directive also lays down requirements for the monitoring of emissions to demonstrate compliance with the emission limits.

The directive requires that substances or preparation which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction under directive 67/548, shall be replaced as far as possible by less harmful ones within shortest possible time. There are also specific requirements for the emission of volatile halogenated organic compounds which are assigned the risk phrase R40.

Applicability in reducing the risks from chemicals

The directive will be an appropriate instrument for limiting the risks from the emission to air of volatile organic compounds from those industrial installations and activities covered by the directive. The applicability in reducing risks of individual compounds can however be restricted due to following constraints:

- certain activities, like oil and petrochemical industry, are not covered by the directive
- for some activities the thresholds for solvent consumption are quite high. Therefore, the directive does not apply to the manufacturing of e.g. varnishes and adhesives, where less than 100 tonnes of solvents is used per year
- emission limit values are generally established for the sum of all VOCs used in an activity and not to individual substances
- emission limit values are expressed as mg/Nm³, as percentages of solvent use or as kg/ton of product. Thus the emitted quantities may rise if for instance the production is increased.

According to article 5 p. 13 of the directive, the Commission is required to take appropriate measures, if a risk assessment carried out under regulation 793/93 indicates that a VOC substance should be labelled R40, R60 or R61.

[2001-12-21]

F. Waste management

Council Directive 96/61/EC of 24 September 1996 concerning *integrated pollution prevention and control*

(see D above)

Council Directive 91/689/EEC of 12 December 1991 on *hazardous waste*

Scope and structure

The scope of the directive is to improve the management of hazardous waste and to ensure that disposal and recovery of hazardous waste is monitored in the fullest manner possible. The directive is laid down under article 130 s of the Treaty of Rome or article 175 of the present Treaty. The object of the directive is to approximate the law of the Member States on the control and management of hazardous waste.

General rules applying to waste management are laid down by directive 75/442/EEC on waste as amended by directive 91/156/EEC. This directive has general requirement for waste which also applies on the management of hazardous waste. According to directive 75/442 article 2, specific rules on the management of particular categories of waste may be laid down by means of individual directives. The Directive also requires that any installation handling waste on the behalf of third parties must obtain a permit from the component authority.

Directive 91/686 is worked out in accordance with article 2 in directive 75/442 and replaces directive 78/319/EEC on hazardous waste.

According to the directive a list of "hazardous waste" should be worked out. The list should be drawn up in accordance with the procedure laid down in directive 75/447 and on the basis of annexes I and II of 91/689. The waste must have one or more of the properties listed in annex III to the directive. The directive also require that the Member States shall take necessary measures relating to recording and identifying sites where tipping of hazardous waste take place, to require that mixing of different categories of hazardous waste does not take place and to ensure that in the course of collection, transport and temporary storage, waste is properly packaged and labelled.

A list of hazardous waste pursuant to directive 91/686 is laid down in Council Decision 94/904, updated by Commission Decision 2000/532/EC. The definition of hazards largely use the criteria of the Substances Directive.

Applicability in reducing the risks from chemicals

The directive can be a useful instrument for risk reduction if the chemical represents a special risk as waste. To do this, the substance must be placed on the list for hazardous waste.

[2000-06-15]

Council Directive 88/609/EEC of 24 November 1988 on the limitation of emission of certain pollutants into the air from *large combustion plants*, as amended by directive 94/66/EEC of 15 December 1994

Scope and legal basis

The directive is based on article 130 s of the Treaty of Rome, article 175 of the present Treaty. The purpose of the directive is to reduce and control the air pollution from new and existing large combustion plants. "Large combustion plants" means plants with a rated thermal input of, which is equal to or greater than 50 MW, irrespective of the type of fuel used. The directive shall apply only to plants designed for production of energy with the exception of those, which makes direct use of products for combustion in manufacturing processes. Special plants the directive shall not apply on are mention.

Measures and procedures

The directive sets overall objectives for a gradual and staged reduction of total annual emission of SO₂ and NO_x from existing plants. Before 1 of July 1990 the Member States should draw up appropriate program for progressive reduction of total annual emission with timetables and implementing procedures. Special reduction requirements are stipulated for each Member State based on the emission in 1980.

For new plants the directive fix emission limit values for SO₂, NO_x and dust for the different type of fuel that can be used. The Member States should take appropriate measures to ensure compliance whit these emission limit values

Methods of measurement of emission to air are described in an annex to the directive.

Applicability in reducing the risks from chemicals

The directive is not useful in the reduction of risk from specific chemical substances.

[2000-06-15]

Council Directive 89/369/EEC of 8 June 1989 on the prevention of air pollution from new municipal waste incineration plants*Scope and legal basis*

The directive is based on article 130 s of the Treaty of Rome, article 175 of the present Treaty. The scope of the directive is "new municipal waste-incineration plants". With "new plant" means a plant for which authorisation to operate is granted as from 1 December 1990. The aim of the directive is to ensure an effective protection of environment.

Measures/requirements

All new municipal waste- incineration plants shall have a prior authorisation from the authority. The Member States shall take all necessary measures to ensure that the condition laid down in the directive are attached to the prior authorisation. The directive fix emission limit values for dust, heavy metals, HCl, HF and SO₂ as a function of the nominal capacity of the plant. The authorities shall lay down emission values for other pollutants when they consider this to be appropriate because of the composition of the waste to be incinerated and of the characteristics of the incineration plant, in particular emission limit values for dioxins and furans.

The directive also fixes specific requirement for how the plant shall be equipped and operated, and how to measure the emission of air pollutants.

Applicability in reducing the risks from chemicals

The directive is not seen as a useful instrument in the reduction of risk from the use of specific chemical substances.

Note: A new general directive (2000/76/EC) on the incineration of waste was laid down on 4 December 2000. For new plants this directive shall apply as from 28 December 2002. For existing plants it shall apply as from 20 December 2005 and directive 89/369/EEC shall be repealed as from the same date.

Council Directive 89/429/EEC of 21 June 1989 on the reduction of air pollution from existing municipal waste-incineration plants*Scope and legal basis*

The directive is based on article 130 s of the Treaty of Rome, article 175 of the present Treaty. The scope of the directive is "existing municipal waste-incineration plants". With "existing plant" is meant a plant for which the first authorisation to operate is granted before 1 December 1990.

Measures and procedures

In accordance with directive 84/360 Member States shall take appropriate measures to ensure that the operation of existing municipal waste-incineration plants complies with specific requirement within defined time limits.

Directive 89/429 requires that plants with a nominal capacity equal to or more than 6 tonnes waste pr hour shall by 1 December 1996, be subject to the same condition as those imposed on new incineration plants of the same capacity laid down by Directive 89/369. Requirement relating to combustion condition should however be as stipulated in this directive. Other plants should comply with specific requirements fix in the directive before 1 December 1995. Before 1 December 2000 they should comply with the requirements for new municipal waste-incineration plants in directive 89/369/EEC.

The requirements also comprise measurements and verification at the incineration plant.

Applicability in reducing the risks from chemicals

The directive is not seen as a useful instrument in the reduction of risk from the use of specific chemical substances.

Note: A new general directive (2000/76/EC) on the incineration of waste was laid down on 4 December 2000. For new plants this directive shall apply as from 28 December 2002. For existing plants it shall apply as from 20 December 2005 and directive 89/369/EEC shall be repealed as from the same date.

[2001-12-21]

Council Directive 94/67/EC of 16 December 1994 on the *incineration of hazardous waste*

Legal basis of the directive

The directive is based on article 130s of the Treaty of Rome, article 175 of the present Treaty.

Scope and structure

The aim of the directive is to prevent or reduce as far as possible the negative effects on the environment and the resulting risk to human health from the incineration of hazardous waste.

By hazardous waste is meant any solid or liquid waste defined in article 1 of directive 91/686/EEC on hazardous waste with some specified exceptions. The term "incineration plant" is defined and followed by a specification of which plants are not covered by the directive. The directive also covers co-incineration of hazardous waste.

The provisions of the directive are minimum requirements and do not prevent MS from maintaining or introduce more stringent measures for the protection of the environment.

Measures and procedures

According to directive 75/442/EEC on waste as complemented by directive 91/689 on hazardous waste and directive 84/360 on combating of air pollutants from industrial plants, any installation or undertaking treating waste must obtain a permit from the authority.

According to directive 94/67/EC permit should only be granted if the application shows that the incineration plant is designed, equipped and will be operated in such a manner that the requirement in the directive would be met.

The directive has provisions concerning:

- delivery and reception of waste
- design, equipment and operation of the plant
- air emission limit values for several pollutants, such as dust, TOC, SO₂, HCl, HF, heavy metals and dioxins and furans
- residues resulting from the incineration
- measurements requirements in order to demonstrate compliance with the operation requirements and air emission limit values

The MS should bring into force the laws, regulations and administrative provisions necessary to comply with the directive before 31 December 1996. For existing incineration plants the provisions of the directive should apply within three years and 6 month from that date.

Applicability in reducing the risks from chemicals

The directive is not an appropriate instrument for limiting the risk from use and emission of specific chemical substances.

Note: A new general directive (2000/76/EC) on the incineration of waste was laid down on 4 December 2000. For new plants this directive shall apply as from 28 December 2002. For existing plants it shall apply as from 20 December 2005 and directive 89/369/EEC shall be repealed as from the same date.

[2001-12-21]

Council and Parliament Directive 2000/76/EC of 4 December 2000 on the *incineration of waste**Legal basis*

The directive is based on article 175 of the Treaty of the European Community.

Scope and structure

The aim of the Directive is to prevent or to limit negative effects on the environment, in particular pollution by emission into air, soil, surface water and ground water, and the resulting risk to human health, from the incineration and co-incineration of waste. The directive covers all incineration and co-incineration plants with some specified exceptions. The directive shall apply on the incineration of both "waste" as defined in Directive 75/442/EEC, "hazardous waste" as defined in Directive 91/689/EEC with some exceptions and "mixed municipal waste" as defined in the annex to Decision 94/3/EC.

Measures and procedures

The Directive states that all incineration and co-incineration plants shall have a permit from the competent authority to carry out their activities. The application for a permit shall include a description of the measures which are envisaged to guarantee that the requirements in the Directive will be fulfilled. A permit shall be granted only if the application shows that the proposed measurements techniques for emissions into the air and water comply with the established emission limit values set out in annexes to the Directive. The Directive also has provisions concerning delivery and reception of waste, operating conditions, handling of residues, control and monitoring, measurement requirements and abnormal operating conditions.

The MS shall bring into force the laws, regulations and administrative provisions necessary to comply with the Directive no later than 28 December 2002. For new plants the Directive shall apply as from the same date and for existing plants as from 28 December 2005. The existing Directives on incineration of hazardous waste and municipal waste, Directive 89/369/EEC, Directive 89/429/EEC and Directive 94/67/EC shall be repealed as from 28 December 2005.

Applicability in reducing the risks from chemicals

The Directive is not seen as an appropriate instrument for limiting the risks from the use of specific chemical substances.

[2001-12-21]

G. Other directives

"New-approach" directives

Scope and structure

The directives on safety of personal protective equipment (89/656/EEC), toys (88/378/EEC), medical devices (93/42/EEC), medical devices to in-vitro diagnostics (98/79/EEC) and building materials (89/166) are all part of a group of directives called "new approach-directives". There are today at least ten other directives within this group, e.g for machinery, lifts, pleasure boats, and the number of directives is expected to rise steadily.

The aim of such directives is primarily to eliminate technical barriers to trade and to guarantee the free movement of goods. The directives are based on article 100a of the treaty of Rome or article 95 of the present treaty. A secondary aim may be to provide a sufficient level of protection for workers or consumers.

Measures and procedures

The idea of the "new approach" is that authority approvals as far as possible are substituted by producer responsibility and certification by bodies of civil law. The directives lay down the essential and general conditions, but leave the details to be set up by European standardisation bodies.

References (number and title) of all adopted European standards (EN, European Norm) that are linked to the directives are published in The Official Journal. Also, relevant national standards that may be used during a transition period while awaiting a European Standard should be published.

Applicability in reducing the risks from chemicals

These directives could be of importance when trying to reduce the risks by general restrictions on the use of a hazardous substance. The structure of the directives where the details are to be found in numerous linked standards, makes it very difficult to get a clear picture of the importance of each directive in relation to risk management.

Standards that require the use of a certain hazardous substance (e.g. mercury in thermometers) may create special problems.

[2001-02-03]