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provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (repealed)

Article 1

Objectives and scope

1 This Directive aims at the approximation of the laws, regulations and administrative provisions of the Member States relating to:

— the classification, packaging and labelling of dangerous preparations, and to

— the approximation of specific provisions for certain preparations which may present hazards, whether or not they are classified as dangerous within the meaning of this Directive,

when such preparations are placed on the market of the Member States.

2 This Directive shall apply to preparations which:

— contain at least one dangerous substance within the meaning of Article 2,

and

— are considered dangerous within the meaning of Article 5, 6 or 7.

3 The specific provisions set out:

— in Article 9 and defined in Annex IV,

— in Article 10 and defined in Annex V, and

— in Article 14

shall also apply to preparations which are not considered dangerous within the meaning of Articles 5, 6 or 7 but may nevertheless present a specific hazard.

4 Without prejudice to Directive 91/414/EEC, the articles on classification, packaging, labelling and safety data sheets of this Directive shall apply to plant protection products.

5 This Directive shall not apply to the following preparations in the finished state, intended for the final user:

a medicinal products for human or veterinary use, as defined in Directive 65/65/EEC[(1)];

b cosmetic products as defined in Directive 76/768/EEC[(2)];

c mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC[(3)] and 78/319/EEC[(4)];

d foodstuffs;

e animal feedingstuffs;

f preparations containing radioactive substances as defined by Directive 80/836/Euratom[(5)];

g medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as this Directive.

6 This Directive shall not apply to:

— the carriage of dangerous preparations by rail, road, inland waterway, sea or air,

— preparations in transit which are under customs supervision, provided they do not undergo any treatment or processing.

Article 2

Definitions

1 For the purposes of this Directive:

a ‘substances’ means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

b ‘preparations’ means mixtures or solutions composed of two or more substances;

c ‘polymer’ means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a ‘monomer unit’ means the reacted form of a monomer in a polymer;

d (……);

e ‘placing on the market’ means making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive;

f ‘scientific research and development’ means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

g ‘process-orientated research and development’ means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance;

h ‘Einecs’ means the European Inventory of Existing Commercial Chemical Substances. This inventory contains the definitive list of all chemical substances deemed to be on the Community market on 18 September 1981.

2 The following are ‘dangerous’ within the meaning of this Directive:

a explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

b oxidising substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

c extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

d highly flammable substances and preparations:
- — substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
- — solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
- — liquid substances and preparations having a very low flash-point, or
- — substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;

e flammable substances and preparations: liquid substances and preparations having a low flash-point;

f very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

g toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

h harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

i corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;

j irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

k sensitising substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance of preparation, characteristic adverse effects are produced;

l carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

m mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

n substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

o substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment.

Article 3

Determination of dangerous properties of preparations

1 The evaluation of the hazards of a preparation shall be based on the determination of:

— physico-chemical properties,

— properties affecting health,
— environmental properties.

These different properties shall be determined in accordance with the provisions laid down in Articles 5, 6 and 7.

Where laboratory tests are conducted, they shall be carried out on the preparation as placed on the market.

2 Where the determination of dangerous properties is carried out in accordance with Articles 5, 6 and 7, all dangerous substances within the meaning of Article 2 and in particular those which:

— are listed in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures**]**(6),
— are listed in Elincs in accordance with Article 21 of Directive 67/548/EEC,
— are classified and labelled provisionally by the person responsible for the placing on the market in accordance with Article 6 of Directive 67/548/EEC,
— are classified and labelled in accordance with Article 7 of Directive 67/548/EEC and are not yet included in Elincs,
— are covered by Article 8 of Directive 67/548/EEC,
— are classified and labelled in accordance with Article 13 of Directive 67/548/EEC.

shall be taken into consideration in accordance with the provisions laid down in the method used.

3 For preparations covered by this Directive, dangerous substances as referred to in paragraph 2 which are classified as dangerous on the basis of their health and/or environmental effects, whether they are present as impurities or additives, shall be taken into consideration when their concentrations are equal to, or greater than, those defined in the following table unless lower values are given in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]**, or in Part B of Annex II to this Directive or in Part B of Annex III thereto, unless otherwise specified in Annex V to this Directive.

Category of danger of the substance	**Concentration to take into consideration for**	
	gaseous preparations% vol/vol	**other preparations% w/w**
Very toxic	≥ 0,02	≥ 0,1
Toxic	≥ 0,02	≥ 0,1
Carcinogenic Category 1 or 2	≥ 0,02	≥ 0,1
Mutagenic Category 1 or 2	≥ 0,02	≥ 0,1
Toxic for reproduction Category 1 or 2	≥ 0,02	≥ 0,1
Harmful	≥ 0,2	≥ 1
Corrosive	≥ 0,02	≥ 1
Irritant	≥ 0,2	≥ 1

Sensitising	≥ 0,2	≥ 1
Carcinogenic Category 3	≥ 0,2	≥ 1
Mutagenic Category 3	≥ 0,2	≥ 1
Toxic for reproduction Category 3	≥ 0,2	≥ 1
Dangerous for the environment N Dangerous for the environment N		≥ 0,1
Dangerous for the environment ozone	≥ 0,1	≥ 0,1
Dangerous for the environment		≥ 1

Textual Amendments

F1 Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

Article 4

General principles of classification and labelling

1 The classification of dangerous preparations according to the degree and specific nature of the hazards involved shall be based on the definitions of categories of danger laid down in Article 2.

2 The general principles of the classification and labelling of preparations shall be applied in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC, save where alternative criteria referred to in Article 5, 6, 7 or 10 and the relevant Annexes of this Directive are applied.

Article 5

Evaluation of the hazards deriving from physico-chemical properties

1 The hazards of a preparation deriving from its physico-chemical properties shall be assessed by determining, by means of the methods specified in Part A of Annex V to Directive 67/548/EEC, the physico-chemical properties of the preparation necessary for appropriate classification and labelling in accordance with the criteria laid down in Annex VI to that Directive.

2 By way of derogation from paragraph 1:

the determination of the explosive, oxidising, extremely flammable, highly flammable, or flammable properties is not necessary provided that:

— none of the constituents possesses such properties and that, on the basis of the information available to the manufacturer, the preparation is unlikely to present hazards of this kind,

— in the event of a change in the composition of a preparation of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification,

— preparations placed on the market in the form of aerosols satisfy the provisions of Article 9a of Directive 75/324/EEC[7].

3 For certain cases for which the methods laid down in Part A of Annex V to Directive 67/548/EEC are not appropriate, alternative calculation methods are laid down in Part B of Annex I to this Directive.

4 Certain exemptions from the application of the methods laid down in Part A of Annex V to Directive 67/548/EEC are referred to in Part A of Annex I to this Directive.

5 The hazards deriving from the physico-chemical properties of a preparation covered by Directive 91/414/EEC shall be assessed by determining the physico-chemical properties of the preparation necessary for appropriate classification in accordance with the criteria set out in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part A of Annex V to Directive 67/548/EEC unless other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

Article 6

Evaluation of health hazards

1 The health hazards of a preparation shall be assessed by one or more of the following procedures:

a by a conventional method described in Annex II;

b by determining the toxicological properties of the preparation necessary for appropriate classification in accordance with the criteria in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part B of Annex V to Directive 67/548/EEC, unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

2 Without prejudice to the requirements of Directive 91/414/EEC, only where it can be scientifically demonstrated by the person responsible for placing the preparation on the market that the toxicological properties of the preparation cannot correctly be determined by the method outlined in paragraph 1(a), or on the basis of existing test results on animals, the methods outlined in paragraph 1(b) may be used, provided they are justified or specifically authorised under Article 12 of Directive 86/609/EEC.

When a toxicological property is established by the methods outlined in paragraph 1(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their

applications for tests on chemical substances[8] and the provisions of Directive 86/609/EEC, in particular Articles 7 and 12 thereof.

Subject to the provisions of paragraph 3, where a toxicological property has been established on the basis of both the methods outlined in paragraphs 1(a) and (b), the results from the methods outlined in paragraph 1(b) shall be used for classifying the preparation, except in the case of carcinogenic, mutagenic or toxic effects for reproduction for which only the method outlined in 1(a) shall be used.

Any of the toxicological properities of the preparation which are not assessed by the method outlined in paragraph 1(b) shall be assessed in accordance with the method outlined in paragraph 1(a).

3 Furthermore, where it can be demonstrated:

— by epidemiological studies, by scientifically valid case studies as specified by Annex VI to Directive 67/548/EEC or by statistically backed experience, such as the assessment of data from poison information units or concerning occupational diseases, that toxicological effects on man differ from those suggested by the application of the methods outlined in paragraph 1, then the preparation shall be classified according to its effects on man,

— that, owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation,

— that, owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

4 For preparations of a known composition, with the exception of those covered by Directive 91/414/EEC, classified in accordance with paragraph 1(b), a new evaluation of health hazard by the methods outlined in either paragraph 1(a) or (b) shall be performed whenever:

— changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	**Permitted variation in initial concentration of the constituent**
≤ 2,5 %	± 30 %
> 2,5 ≤ 10 %	± 20 %
> 10 ≤ 25 %	± 10 %
> 25 ≤ 100 %	± 5 %

— changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions set out in Article 2, are introduced by the manufacturer.

This new evaluation will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Article 7

Evaluation of environmental hazards

1 The hazards of a preparation for the environment shall be assessed by one or more of the following procedures:

a by a conventional method described in Annex III to this Directive;

b by determining the hazardous properties of the preparation for the environment necessary for appropriate classification in accordance with the criteria set out in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part C of Annex V to Directive 67/548/EEC unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC. Without prejudice to the testing requirements set out in Directive 91/414/EEC, the conditions for application of the test methods are described in Part C of Annex III to this Directive.

2 Where an ecotoxicological property is established by one of the methods outlined in paragraph 1(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.

Where the environmental hazards have been assessed in compliance with both the procedures mentioned above, the results of the methods referred to in paragraph 1(b) shall be used for classifying the preparation.

3 For preparations of a known composition, with the exception of those covered by Directive 91/414/EEC, classified in accordance with the method outlined in paragraph 1(b), a new evaluation of environmental hazard either by the method outlined in paragraph 1(a) or that outlined in paragraph 1(b) shall be performed whenever:

— changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	**Permitted variation in initial concentration of the constituent**
≤ 2,5 %	± 30 %
> 2,5 ≤ 10 %	± 20 %
> 10 ≤ 25 %	± 10 %
> 25 ≤ 100 %	± 5 %

— changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions set out in Article 2, are introduced by the manufacturer.

This new evaluation will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Article 8

Obligations and duties of the Member States

1 Member States shall take all necessary measures to ensure that the preparations covered by this Directive cannot be placed on the market unless they comply with it.

2 In order to ensure compliance with this Directive, the authorities of the Member States may request information on the composition of the preparation and any other pertinent information from any person responsible for placing the preparation on the market.

3 Member States shall take all necessary measures to ensure that those responsible for placing the preparation on the market hold at the disposal of the authorities of the Member States:

— the data used for the classification and labelling of the preparation,

— any pertinent information relating to packaging requirements in accordance with Article 9(1.3), including the test certificate issued in accordance with Part A of Annex IX to Directive 67/548/EEC,

— the data used for establishing the safety data sheet, in accordance with Article 14.

4 Member States and the Commission shall exchange information concerning the name and full address of the national authority (authorities) responsible for communicating and exchanging information relating to the practical application of this Directive.

Article 9

Packaging

1. Member States shall take all necessary measures to ensure that:

1.1 preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) cannot be placed on the market unless their packaging satisfies the following requirements:

— it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed,

— the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents,

— packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling,

— containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping.

1.2 containers which contain preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) offered or sold to the general public do not have:

— either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or

— a presentation and/or a designation used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products.

1.3 containers which contain certain preparations offered or sold to the general public covered by Annex IV to this Directive:

— are fitted with child-resistant fastenings,

and/or

— carry a tactile warning of danger.

The devices must conform to the technical specifications given in Parts A and B of Annex IX to Directive 67/548/EEC.

2. The packaging of preparations shall be deemed to satisfy the requirements of paragraph 1.1, first, second and third indents, if it complies with the requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air.

Article 10

Labelling

1.1 Member States shall take all necessary measures to ensure that:

(a) preparations within the meaning of Article 1(2) cannot be placed on the market unless the labelling on their packaging satisfies all the requirements of this Article and the specific provisions of Part A and B of Annex V;

(b) preparations within the meaning of Article 1(3) as defined in Parts B and C of Annex V cannot be placed on the market unless the labelling on their packaging satisfies the requirements of paragraphs 2.1 and 2.2 and the specific provisions of Parts B and C of Annex V.

1.2 With respect to plant protection products subject to Directive 91/414/EEC, the labelling requirements in accordance with this Directive shall be accompanied by the following wording: ‘To avoid risks to man and the environment, comply with the instructions for use.’

This labelling shall be without prejudice to the information required in accordance with Article 16 of, and Annex V to, Directive 91/414/EEC.

2. The following information shall be clearly and indelibly marked on any package:

2.1 the trade name or designation of the preparation;

2.2 the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;

2.3 the chemical name of the substance or substances present in the preparation in accordance with the following detailed rules:

2.3.1 for preparations classified T^+, T, X_n in accordance with Article 6, only the substances T^+, T, X_n present in concentrations equal to, or greater than, the lowest limit (limit X_n) for each of them laid down in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or, failing that, Part B of Annex II to this Directive have to be taken into consideration;

2.3.2 for preparations classified C in accordance with Article 6, only C substances present in concentrations equal to, or greater than, the lowest limit (limit X_i) laid down in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or, failing that, Part B of Annex II to this Directive have to be taken into consideration;

2.3.3 the name of the substances which have given rise to the classification of the preparation in one or more of the following danger categories:

— carcinogen category 1, 2 or 3,

— mutagen category 1, 2 or 3,

— toxic for reproduction category 1, 2 or 3,
— very toxic, toxic or harmful due to non-lethal effects after a single exposure,
— toxic or harmful due to severe effects after repeated or prolonged exposure,
— sensitising;

shall be mentioned on the label.

The chemical name shall be one of the designations listed in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or an internationally recognised chemical nomenclature if no corresponding designation is yet listed in that Annex.

2.3.4 As a consequence of the above provisions the name of any substance which led to the classification of the preparation in the following danger categories:
— explosive,
— oxidising,
— extremely flammable,
— highly flammable,
— flammable,
— irritant,
— dangerous for the environment,

need not be mentioned on the label unless the substance has to be mentioned pursuant to paragraphs 2.3.1, 2.3.2 or 2.3.3.

2.3.5 As a general rule, a maximum of four chemical names shall suffice to identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding phrases referring to the risk involved. In some cases, more than four chemical names may be necessary.

The danger symbol(s) and indication(s) of danger

2.4 The danger symbols, where specified in this Directive, and indications of the dangers involved in the use of the preparation, shall be in accordance with the wording of Annexes II and VI to Directive 67/548/EEC and shall be applied in accordance with the evaluation of the hazards carried out in accordance with Annexes I, II and III to this Directive.

Where more than one danger symbol must be assigned to a preparation the obligation to apply the symbol:
— T shall make the symbols C and X optional unless otherwise specified in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]**,
— C shall make the symbol X optional,
— E shall make the symbols F and O optional,
— X_n shall make the symbol X_i optional.

The symbol(s) shall be printed in black on an orange-yellow background.

The risk phrases (R phrases)

2.5 The indications concerning special risks (R phrases) shall comply with the wording in Annexes III and VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II, and III to this Directive.

As a general rule, a maximum of six R phrases shall suffice to describe the risks; for this purpose, the combined phrases listed in Annex III to Directive 67/548/EEC shall

be regarded as single phrases. However, if the preparation falls within more than one danger category, those standard phrases shall cover all the principal hazards associated with the preparation. In some cases more than six R phrases may be necessary.

The standard phrases 'extremely flammable' or 'highly flammable' need not be used where they describe an indication of danger used in accordance with 2.4.

The safety advice (S phrases)

2.6 The indications giving safety advice (S phrases) shall comply with the wording in Annex IV and with Annex VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II and III to this Directive.

As a general rule, a maximum of six S phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in Annex IV to Directive 67/548/EEC shall be regarded as single phrases. However, in some cases more than six S phrases may be necessary.

Where it is physically impossible to include the advice on the label or package itself, the package shall be accompanied by safety advice on the use of the preparation.

2.7 The nominal quantity (nominal mass or nominal volume) of the contents in the case of preparations offered or sold to the general public.

3. **[**[F2]In relation to certain preparations classified as dangerous within the meaning of Article 7, by way of derogation from points 2.4, 2.5 and 2.6 of paragraph 2 of this Article, the Commission may determine exemptions to certain provisions on environmental labelling or specific provisions in relation to environmental labelling, where it can be demonstrated that there would be a reduction in the environmental impact. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20a(3).**]** These exemptions or specific provisions are defined and laid down in Part A or B of Annex V.

4. If the contents of the package do not exceed 125 ml:

— in the case of preparations that are classified as highly flammable, oxidising, irritant, with the exception of those assigned R41, or dangerous for the environment and assigned the N symbol it shall not be necessary to indicate the R phrases or the S phrases,

— in the case of preparations that are classified as flammable or dangerous for the environment and not assigned the N symbol it shall be necessary to indicate the R phrases but it shall not be necessary to indicate the S phrases.

5. Without prejudice to Article 16(4) of Directive 91/414/EC, indications such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statement indicating that the preparation is not dangerous or likely to lead to underestimation of the dangers of the preparation in question shall not appear on the packaging or labelling of any preparation subject to this Directive.

Textual Amendments

F1 Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

F2 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 11

Implementation of the labelling requirements

1 Where the particulars required by Article 10 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that those particulars can be read horizontally when the package is set down normally. The dimensions of the label are laid down in Annex VI to Directive 67/548/EEC and the label is intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety information.

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

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

4 The information required on the label under Article 10 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

Specific provisions regarding the presentation and format of this information shall be laid down in Annex VI to Directive 67/548/EEC.

5 Member States may make the placing on the market of preparations covered by this Directive within their territories subject to use of their official language or languages in respect of the labelling thereof.

6 For the purposes of this Directive, labelling requirements shall be deemed to be satisfied:

a in the case of an outer package containing one or more inner packages, if the outer package is labelled in accordance with international rules on the transport of dangerous goods and the inner package or packages are labelled in accordance with this Directive;

b in the case of a single package:

— if such a package is labelled in accordance with international rules on the transport of dangerous goods and with Article 10(2.1), (2.2), (2.3), (2.5) and (2.6); for preparations classified according to Article 7, the provisions of Article 10(2.4) shall additionally apply with respect to the property in question when it has not been so identified on the label, or

— where appropriate, for particular types of packaging such as mobile gas cylinders, if the specific requirements referred to in Annex VI to Directive 67/548/EEC are complied with.

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

Article 12

Exemptions from the labelling and packaging requirements

1 Articles 9, 10 and 11 shall not apply to explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2 For certain dangerous preparations within the meaning of Article 5, 6 or 7 defined in Annex VII which, in the form in which they are placed on the market, do not present any physico-chemical risk, or risk to health or to the environment, Articles 9, 10 and 11 shall not apply.

3 Member States may also:

a permit the labelling required by Article 10 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 11(1) and (2);

b by way of derogation from Articles 10 and 11 permit the packaging of dangerous preparations which are classified as harmful, extremely flammable, highly flammable, flammable, irritant or oxidising to be unlabelled or to be labelled in some other way, if they contain such small quantities that there is no reason to fear any danger to persons handling such preparations or to other persons;

c by way of derogation from Articles 10 and 11, for preparations classified according to Article 7, permit the packaging of dangerous preparations to be unlabelled or labelled in some other way if they contain such small quantities that there is no reason to fear any dangers to the environment;

d by way of derogation from Articles 10 and 11 permit the packaging of dangerous preparations which are not mentioned in (b) or (c) above to be labelled in some other appropriate way, if the packages are too small for the labelling provided for in Articles 10 and 11 and there is no reason to fear any danger to persons handling such preparations or to other persons.

Where this paragraph is applied, the use of symbols, indications of danger, risk (R) phrases or safety (S) phrases different to those laid down in this Directive shall not be permitted.

4 If a Member State makes use of the options provided for in paragraph 3, it shall forthwith inform the Commission and Member States thereof. **[**[F2]Where appropriate, the Commission may decide upon measures in the framework of Annex V. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20a(3).**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 13

Distance selling

Any advertisement for a preparation within the meaning of this Directive which enables a member of the general public to conclude a contract for purchase without first having sight of the label for that preparation must make mention of the type or types of hazard indicated on the label. This requirement is without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts[9].

[X1]Article 14

[[F3][X1]Safety data sheet]]

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Editorial Information

X1 Deleted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

Textual Amendments

F3 Deleted by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance).

Article 15

Confidentiality of chemical names

Where the person responsible for placing the preparation on the market can demonstrate that the disclosure on the label or safety data sheet of the chemical identity of a substance which is exclusively classified as:

— irritant with the exception of those assigned R41 or irritant in combination with one or more of the other properties mentioned in point 2.3.4 of Article 10, or

— harmful or harmful in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 presenting acute lethal effects alone

will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Annex VI, be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of

an alternative name. This procedure may not be applied where the substance concerned has been assigned a Community exposure limit.

Where the person responsible for placing a preparation on the market wishes to take advantage of confidentiality provisions, he shall make a request to the competent authority of the Member State in which the preparation is to be first placed on the market.

This request must be made in accordance with the provisions of Annex VI and must provide the information required in the form in Part A of that Annex. The competent authority may nevertheless request further information from the person responsible for placing the preparation on the market if such information appears necessary in order to evaluate the validity of the request.

The authority of the Member State receiving a request for confidentiality shall notify the applicant of its decision. The person responsible for placing the preparation on the market shall forward a copy of this decision to each of the Member States where he wishes to market the product.

Confidential information brought to the attention of the authorities of a Member State or of the Commission shall be treated in accordance with Article 19(4) of Directive 67/548/EEC.

Article 16

Rights of Member States regarding safety of workers

This Directive shall not affect the right of Member States to specify, in compliance with the Treaty, the requirements they deem necessary to ensure that workers are protected when using the dangerous preparations in question, provided that this does not mean that the classification, packaging, and labelling of dangerous preparations are modified in a way not provided for in this Directive.

Article 17

Bodies responsible for receiving information relating to health

Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in case of emergency.

Member States shall ensure that the information is not used for other purposes.

Member States shall ensure that the appointed bodies have at their disposal all the information required from the manufacturers or persons responsible for marketing to carry out the tasks for which they are responsible.

Article 18

Free movement clause

Without prejudice to the provisions set out in other Community legislation, Member States may not prohibit, restrict or impede the placing on the market of preparations because of their classification, packaging, labelling or safety data sheets if such preparations comply with the provisions laid down in this Directive.

Article 19

Safeguard clause

1 Where a Member State has detailed evidence that a preparation, although satisfying the provisions of this Directive, constitutes a hazard for man or the environment on grounds relating to the provisions of this Directive, it may provisionally prohibit the placing on the market of that preparation or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2 In the case referred to in paragraph 1, the Commission shall consult the Member States as soon as possible.

[F2 3 The Commission shall take a decision in accordance with the regulatory procedure referred to in Article 20a(2).**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

*[*F2 *Article 20*

The Commission shall adapt to technical progress the Annexes to this Directive. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20a(3).**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

*[*F4 *Article 20a*

1 The Commission shall be assisted by the committee established by Article 29(1) of Council Directive 67/548/EEC[10]

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F4 Inserted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 21

Repeal of Directives

1 The Directives listed in Part A of Annex VIII are hereby repealed, without prejudice to the obligation of the Member States concerning the deadlines for transposition into national law and for application of the Directives indicated in Part B of Annex VIII.

2 The Directives listed in Part A of Annex VIII shall apply to Austria, Finland and Sweden subject to provisions laid down in Part C of that Annex and pursuant to the Treaty.

3 References to the repealed Directives shall constitute references to this Directive and should be read in accordance with the correlation table set out in Annex IX.

Article 22

Transposition

1 Member States shall adopt and publish before 30 July 2002 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

2 Member States shall apply the laws, regulations and administrative provisions referred to in paragraph 1:

a to preparations not within the scope of Directive 91/414/EEC or Directive 98/8/EC as from 30 July 2002; and

b to preparations within the scope of Directive 91/414/EEC or Directive 98/8/EC as from 30 July 2004.

3 When Member States adopt such measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by Member States.

Article 23

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 21(2) shall apply from 1 January 1999.

Article 24

Addressees

This Directive is addressed to the Member States.

(**1**) OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

(**2**) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Directive 97/18/EC (OJ L 114, 1.5.1997, p. 43).

(**3**) OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).

(**4**) OJ L 84, 31.3.1978, p. 43.

(**5**) OJ L 246, 17.9.1980, p. 1. Directive as amended by Directive 84/467/Euratom (OJ L 265, 5.10.1984, p. 4).

(**6**) **[**[F1]OJ L 353, 31.12.2008, p. 1.**]**

(**7**) OJ L 147, 9.6.1975, p. 40. Directive as last amended by Directive 94/1/EC (OJ L 23, 28.1.1994, p. 28).

(**8**) OJ L 15, 17.1.1987, p. 29.

(**9**) OJ L 144, 4.6.1997, p. 19.

(**10**) **[**[F4]OJ 196, 16.8.1967, p. 1.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

F4 Inserted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.