STATUTORY INSTRUMENT

S.I. No. 624 of 2001

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EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND LABELLING OF PLANT PROTECTION PRODUCTS AND BIOCIDE PRODUCTS) REGULATIONS, 2001

Pn. No. 10982

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EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND LABELLING OF PLANT PROTECTION PRODUCTS AND BIOCIDE PRODUCTS) REGULATIONS, 2001

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S.I. No. 624 of 2001

EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND LABELLING OF PLANT PROTECTION PRODUCTS AND BIOCIDE PRODUCTS) REGULATIONS, 2001

I, Joe Walsh, Minister for Agriculture, Food and Rural Development, in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 [1] and Commission Directive 2001/60/EC of 7 August 2001 [2],

taking account of Council Directive 67/548/EEC of 27 June 1967 [3], Council Directive 92/32/EEC of 30 April 1992 [4], Council Directive 96/56/EEC of 3 September 1996 [5], Commission Directive 88/302/EEC of 18 November 1987 [6], the corrigendum to Commission Directive 88/302/EEC of 18 November 1987 [7], Commission Directive 91/410/EEC of 22 July 1991 [8], Commission Directive 92/69/EEC of 31 July 1992 [9], Commission Directive 93/21/EEC of 27 April 1993 [10], Commission Directive 93/72/EEC of 1 September 1993 [11], Commission Directive 93/105/EC of 25 November 1993 [12], Commission Directive 93/101/EC of 11 November 1993 [13], Commission Directive 94/69/EC of 19 December 1994 [14], Commission Directive 96/54/EC of 30 July 1996 [15], Commission Directive 97/69/EC of 5 December 1997 [16], Commission Directive 98/73/EC of 18 September 1998 [17], the corrigendum to Commission Directive 98/73/EC of 18 September 1998 [18], Commission Directive 98/98/EC of 15 December 1998 [19], the corrigendum to Commission Directive 98/98/EC of 15 December 1998 [20], Commission Decision of 19 May 2000 correcting Commission Directive 98/98/EC of 15 December 1998 [21], Commission Directive 2000/32/EC of 19 May 2000 [22], Commission Directive 2000/33/EC of 25 April 2000 [23], Commission Directive 2001/59/EC of 6 August 2001 [24],

taking account of Council Directive 91/414/EEC of 15 July 1991 [25],

and further taking account of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 [26], hereby make the following Regulations:

Citation

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[1] O.J. No. L 200/1 30/7/1999
[2] O.J. No. L 226/5 22/8/2001
[3] O.J. No. L 196/1 16/8/1967
[4] O.J. No. L 154/1 5/6/1992
[5] O.J. No. L 236/35 18/9/1996
[6] O.J. No. L 133/1 30/5/1988
[7] O.J. No. L 136/20 2/6/1988
[8] O.J. No. L 228/67 17/8/1991
[9] O.J. No. L 383/113 29/12/1992 and O.J. No. L 383A/1 29/12/1992
[10] O.J. No. L 110/20 4/5/1993 and O.J. No. L 110A/1 4/5/1993
[11] O.J. No. L 258/29 16/10/1993 and O.J. No. L 258A/1 16/10/1993
[12] O.J. No. L 294/21 30/11/1993
[13] O.J. No. L 13/1 15/1/1994
[14] O.J. No. L 381/1 31/12/1994
[15] O.J. No. L 248/1 30/9/1996
[16] O.J. No. L 343/19 13/12/1997
[17] O.J. No. L 305/1 16/11/1998
[18] O.J. No. L 285/1 8/11/1999
[19] O.J. No. L 355/1 30/12/1998
[20] O.J. No. L 293/1 15/11/1999
[21] O.J. No. L 136/108 8/6/2000
[22] O.J. No. L 136/1 8/6/2000
[23] O.J. No. L 136/90 8/6/2000
[24] O.J. No. L 225/1 21/8/2001
[25] O.J. No. L 230/1 19/8/1991
[26] O.J. No. L 123/1 24/4/1998

1 (1) These Regulations may be cited as the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001.

(2) These Regulations shall come into operation on the 28th day of December 2001.

Interpretation

2 (1) In these Regulations -

"Annex I" means Annex I to the Directive of 1967, as last amended by Commission Directive 2001/59/EC of 6 August 2001 [24];

"Annex II" (which is set out in the First Schedule) means Annex II to the Directive of 1967, as amended by the Directive of 1992 and Commission Directive 2001/59/EC of 6 August 2001[24];

"Annex III" (which is set out in the First Schedule) means Annex III to the Directive of 1967, as amended by the Directive of 1992 and Commission Directive 2001/59/EC of 6 August 2001[24];

"Annex IV" (which is set out in the First Schedule) means Annex IV to the Directive of 1967, as amended by the Directive of 1992 and Commission Directive 2001/59/EC of 6 August 2001[24];

"Annex V" means Annex V to the Directive of 1967, as amended by the Directive of 1992, Commission Directive 88/302/EEC of 18 November 1987 [6], Commission Directive 92/69/EEC of 31 July 1992 [9], Commission Directive 93/21/EEC of 27 April 1993 [10], Commission Directive 96/54/EC of 30 July 1996 [15], Commission Directive 98/73/EC of 18 September 1998 [17], the corrigendum to Commission Directive 98/73/EC of 18 September 1998 [18], Commission Directive 2000/32/EC of 19 May 2000 [22], Commission Directive 2000/33/EC of 25 April 2000 [23] and Commission Directive 2001/59/EC of 6 August 2001[24];

"Annex VI" (which is set out in the First Schedule) means Annex VI to the Directive of 1967, as amended by the Directive of 1992 and Commission Directive 2001/59/EC of 6 August 2001[24];

"Annex VII" means Annex VII set out in the Second Schedule, comprising additional safety advice in accordance with Article 16 (5) of the Directive of 1991;

"Annex VIII" (which is set out in the Third Schedule) means Annex I to the Directive of 1999;

"Annex IX" (which is set out in the Third Schedule) means Annex II to the Directive of 1999 as amended by Commission Directive 2001/60/EC of 7 August 2001 [2];

"Annex X" (which is set out in the Third Schedule) means Annex III to the Directive of 1999;

"Annex XI" (which is set out in the Third Schedule) means Annex IV to the Directive of 1999, supplemented by the technical specifications comprising Annex IX to the Directive of 1967 as amended by the Directive of 1992, Commission Directive No.

91/410/EEC of 22 July 1991 [7], and Commission Directive 2000/32/EC of 19 May 2000 [21];

"Annex XII" (which is set out in the Third Schedule) means Annex V to the Directive of 1999 as amended by Commission Directive 2001/60/EC of 7 August 2001 [2];

"Annex XIII" (which is set out in the Third Schedule) means Annex VI to the Directive of 1999;

"Annex XIV" means Annex XIV set out in the Fourth Schedule, comprising a list of preparation (formulation) types and codes;

"aircraft" includes hovercraft;

"approval" means acceptance by the Minister that, following examination, the record of studies conducted and the information, documentation, materials, labelling and packaging submitted in relation to a plant protection product or biocide product, are in compliance with the requirements of these Regulations and cognate words shall be construed accordingly;

"authorised officer" means an officer of the Minister appointed in writing by the Minister to be an authorised officer for the purpose of these Regulations;

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

“clearance” means clearance to market or use a plant protection product or biocide product for which the record of studies conducted, and the information, documentation, materials, labelling and packaging submitted have been approved by the Minister in accordance with the requirements of these Regulations and cognate words shall be construed accordingly;

“corrosive substances and preparations” means substances and preparations which may on contact with living tissues, destroy them;

“dangerous for the environment” means 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;

“dangerous substances and preparations” means substances and preparations which are flammable, highly flammable, extremely flammable, explosive, oxidising, very toxic, toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction and / or dangerous for the environment;

“designated analyst” means any appropriately qualified officer of the Minister who is authorized in writing by the Minister for the purposes of these Regulations;

"Directive of 1967" means Council Directive 67/548/EEC of 27 June 1967 [3];

"Directive of 1978" means Council Directive 78/631/EEC of 26 June 1978 [27];

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[27] O.J. No. L206/13 29/7/1978

"Directive of 1991" means Council Directive 91/414/EEC of 15 July 1991 [25];

"Directive of 1992" means Council Directive 92/32/EEC of 30 April 1992 [4];

"Directive of 1998" means Directive 98/8/EC of the European Parliament and the Council of 16 February 1998 [26];

"Directive of 1999" means Directive 1999/45/EC of the European Parliament and the Council of 31 May 1999 [1];

“explosive substances and preparations” means 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;

“extremely flammable substances and preparations” means 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;

“flammable substances and preparations” means liquid substances and preparations having a low flash-point;

“harmful substances and preparations” means substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed *via* the skin;

“highly flammable substances and preparations” means:

- 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;

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

"Minister" means the Minister for Agriculture, Food and Rural Development;

“mutagenic substances and preparations” means 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;

"notified" in the case of a plant protection product to which Regulation 3 (1) (a) applies means the packaging, including any label or container used with the package, and basic information as to the nature and composition of any such plant protection product on the market on or before the second day of December 1985, and as to the manufacturer or manufacturers of each such plant protection product, has been submitted and approved by the Minister and cognate words shall be construed accordingly,

and

in the case of a biocide product to which Regulation 3 (1) (b) applies means the packaging, including any label or container used with the package of any such biocide product on the market on or before the first day of February 2002, and basic documentation and information as to the nature and composition and product type of any such biocide product, and as to the manufacturer or manufacturers of each such biocide product as set out in the Fifth Schedule, has been submitted and approved by the Minister and cognate words shall be construed accordingly,

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

"sensitising substances and preparations" means 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 or preparation, characteristic adverse effects are produced;

" State Chemist" means the Head of the State Laboratory or a member of the staff of the State Laboratory authorized by the State Chemist in writing to perform functions assigned to the State Chemist under paragraph 5 of Regulation 19;

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

"toxic for reproduction" means 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;

"very toxic substances and preparations" means 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.

(2) In these Regulations, unless otherwise indicated -

(a) a reference to a Regulation is a reference to a Regulation of these Regulations,

(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision, in which the reference occurs,

(c) a reference to a Schedule is a reference to a Schedule to these Regulations.

(3) A word or expression that is used in any Council Directive of the European Communities or in any Directive of the European Parliament and of the Council mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive concerned.

Application

3 (1) Subject to paragraph (2), these Regulations apply to plant protection products and biocide products, being:

(a) any plant protection product mentioned in paragraph (1) of Article 2 of the Directive of 1991; or

(b) any biocide product mentioned in subparagraph (1) (a) of Article 2 of the Directive of 1998.

(2) These Regulations shall not apply to preparations in the finished state intended for the final user, that are -

(a) medicinal products for human or veterinary use, as defined in Directive 65/65/EEC [28];

(b) cosmetic products as defined in Directive 76/768/EEC [29];

(c) mixtures of substances which in the form of waste are covered by Directives 75/442/EEC [30] and 78/319/EEC [31];

(d) foodstuffs;

(e) animal feedingstuffs;

(f) preparations containing radioactive substances as defined in Directive 80/836/Euratom [32]; or

(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 the Directive of 1999.

[28] O.J. No. L 22/369 9/2/1965
[29] O.J. No. L 262/169 27/9/1976
[30] O.J. No. L 194/39 25/7/1975
[31] O.J. No. L 84/43 31/3/1978
[32] O.J. No. L 246/1 17/9/1980

(3) These Regulations shall not apply to -

(a) the carriage of plant protection products or biocide products by rail, road, inland waterway, sea or air; or

(b) any plant protection product or biocide product that is under customs supervision, that does not undergo any treatment or processing.

National Authorities

4 (1) The Pesticide Control Service of the Department of Agriculture, Food and Rural Development is hereby designated the national authority responsible for communicating and exchanging information concerning the practical application of the Directive of 1999 in relation to plant protection products and biocide products.

(2) The Poisons Information Centre, Beaumont Hospital, Dublin 9 is hereby designated the national authority for the purposes of receiving information, including chemical composition, in relation to plant protection products and biocide products placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects, for use solely for medical purposes in relation to formulating preventative and curative measures and in particular in case of emergency. The Poisons Information Centre shall ensure the confidentiality of information received and shall not use it for other purposes.

General requirements for placing on the market

5 (1) The placing on the market of a plant protection product or biocide product to which these Regulations apply in the form in which it is supplied to the user and intended for use as such is hereby prohibited unless, in relation to it, the requirements of these Regulations regarding notification, clearance, classification, packaging and labelling and the provision of information, test and study reports, supporting documentation and other materials in relation to classification, packaging and labelling, are complied with.

(2) The placing on the market of a plant protection product or biocide product to which these Regulations apply is hereby prohibited if the packaging or any label used in relation to it has such indications as “non-toxic”, “non-harmful”, “non-polluting”, “ecological” or other similar indications.

(3) (a) Subject to subparagraph (c), a plant protection product on the market on or before the second of December, 1985, to which Regulation 3 (1) (a) applies, shall no longer be placed on the market or used unless the package (including any label or container used with the package), and basic information as to the nature and composition of the plant protection product and as to its manufacturer or manufacturers, have been submitted for approval at a time specified by the Minister and have been approved by him, that is, the plant protection product has been duly notified.

(b) Subject to subparagraph (c), a biocide product on the market on or before the first of February, 2002, to which Regulation 3 (1) (b) applies, shall no longer be placed on the market or used unless the package (including any label or container used with the package), and basic information as to the nature and

composition and product type of the biocide product and as to its manufacturer or manufacturers, as set out in the Fifth Schedule, have been submitted for approval by the Minister on or before the first of February 2002 and have been approved by him, that is, the biocide product has been duly notified.

(c) Persons responsible for placing plant protection products and biocide products notified in accordance with subparagraphs (a) and (b) on the market shall ensure that each such plant protection product and biocide product is classified, packaged and labelled in compliance with these Regulations.

(4) The placing on the market of a plant protection product or biocide product to which these Regulations apply in the form in which it is supplied to the user and intended for use as such is hereby prohibited if: -

(a) the net quantity in any container of such plant protection product or biocide product is less than the quantity stated thereon; or

(b) the fastenings or containers used to package such plant protection product or biocide product have been tampered with.

(5) Persons responsible for placing plant protection products and biocide products on the market shall ensure that for each such plant protection product and biocide product, the following information is provided to the national authority specified in paragraph (2) of Regulation 4, in the form specified from time to time by that authority: –

(a) its chemical composition;

(b) its physico-chemical effects;

(c) its health effects;

(d) target organs and mode of toxic action;

(e) the symptoms and time-course of poisoning;

(f) estimated threshold dose for toxic effects;

(g) diagnostic measures;

(h) therapeutic regimes and their effectiveness, including information on the use of antidotes, where available;

(i) contact person or persons (name, address and telephone number):

- for further information; and
- for use in emergency situations.

Dangerous properties to be assessed and dangerous substances to be considered in the evaluation of hazards

6 (1) Evaluation of the hazards associated with plant protection products and biocide products shall be based upon determination of their –

(a) physico-chemical properties as provided for in Regulation 8;

(b) properties affecting health as provided for in Regulation 9; and

(c) environmental properties as provided for in Regulation 10.

(2) Evaluation of the hazards associated with plant protection products and biocide products shall include consideration of the dangerous properties of all dangerous substances identified pursuant to the Directive of 1967 in accordance with the provisions of Regulations 8, 9 and 10.

(3) Dangerous substances referred to in paragraph (2) that have been classified as being dangerous on the basis on their health and / or environmental effects, whether present as impurities or additives, shall be taken into consideration when their concentrations are equal to, or greater than those specified hereunder, unless –

(a) lower values are given in Annex I;

(b) lower values are given in Part B of Annex IX;

(c) lower values are given in Part B of Annex X; or

(d) otherwise specified in Annex XII.

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
Sensitizing	≥ 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		≥ 0.1
Dangerous for the environment ozone	≥ 0.1	≥ 0.1
Dangerous for the environment		≥ 1

General principles of classification and labelling

7 (1) The classification of plant protection products and biocide products according to the degree and specific nature of the hazards involved shall be based upon the following categories of danger – flammable; highly flammable; extremely flammable; explosive; oxidising: corrosive; irritant: sensitising; harmful; toxic; very toxic; carcinogenic; mutagenic; toxic for reproduction; and dangerous for the environment.

(2) The criteria set out in Annex VI shall be applied for the purposes of the classification and labelling of plant protection products and biocide products, save where alternative criteria are specified in accordance with Regulations 8, 9 and 10.

Evaluation of hazards deriving from physico-chemical properties

8 (1) Subject to paragraph (3), the hazards associated with a plant protection product or biocide product deriving from its physico- chemical properties shall be assessed by determining, by means of the test methods specified in Part A of Annex V, the physico-chemical properties necessary for appropriate classification and labelling in accordance with the criteria laid down in Annex VI.

(2) Notwithstanding paragraph (1):

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

- none, of the constituents have such properties and on the basis of the information available, the plant protection product or biocide product is unlikely to present such hazards,
- in the event of a change in the composition of a plant protection product or biocide product of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification,
- in the case of a plant protection product or biocide product placed on the market in the form of an aerosol, it satisfies the provisions of Article 9 (a) of Directive 75/324/EEC [33];

(b) in certain cases for which the methods laid down in Part A of Annex V are not appropriate, alternative calculation methods are laid down in Part B of Annex VIII; and

(c) certain exemptions from the application of the methods laid down in Part A of Annex V are referred to in Part A of Annex VIII.

(3) The hazards deriving from the physico-chemical properties of a plant protection product regulated in accordance with the Directive of 1991 shall be assessed by determining its physico-chemical properties necessary for classification in accordance with the criteria set out in Annex VI. These properties shall be determined by means of the test methods laid down in Part A of Annex V unless other internationally recognised test methods are acceptable in accordance with the provisions of Annex II and Annex III to the Directive of 1991.

[33] O.J. No. L 147/40 9/6/1975 Directive as last amended by Directive 94/1/EC O.J. No. L 23/280 28/1/1994

Evaluation of health hazards

9 (1) Subject to paragraphs (2) to (6) the health hazards associated with a plant protection product or biocide product shall be assessed by use one or more of the following procedures:

(a) a conventional method described in Annex IX; or

(b) the determination of the toxicological properties necessary for appropriate classification in accordance with the criteria in Annex VI. These properties shall be determined by means of the test methods laid down in Part B of Annex V, unless, in the case of plant protection products, other internationally recognised test methods are acceptable in accordance with the provisions of Annexes II and III to the Directive of 1991.

(2) Without prejudice to the requirements of the Directive of 1991, only where it can be scientifically demonstrated that the toxicological properties of a plant protection product or biocide product cannot be determined correctly using the conventional method specified in subparagraph (1) (a), or on the basis of existing test results on animals, the test methods specified in subparagraph (1) (b) may be used.

(3) When a toxicological property is established using the test methods specified in subparagraph (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 the 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 [34], provided that each such test is justified or specifically authorised in accordance with the provisions of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental purposes [35].

(4) (a) Subject to the provisions of paragraph (5), where a toxicological property has been established using the methods specified in both subparagraphs (1) (a) and (b), the results of testing using the test methods specified in subparagraph (1) (b) shall be used for classifying the plant protection product or biocide product, except in the case of carcinogenic, mutagenic or toxic effects for reproduction for which only the method specified in subparagraph (1) (a) shall be used.

(b) Any of the toxicological properties of a plant protection product or biocide product not assessed on the basis of the test methods specified in subparagraph (1) (b) shall be assessed in accordance with the method specified in subparagraph (1) (a).

(5) Furthermore, where for any particular plant protection product or biocide product it can be demonstrated:

- on the basis of epidemiological studies, scientifically valid case studies as specified in Annex VI, or on the basis of statistically verified experience, such as the assessment of Poison Information Centre data or occupational health surveillance

[34] O.J. No. L 15/29 17/1/1987
[35] O.J. No. L 385/1 18/12/1986

data, that toxicological effects on man differ from those suggested by the application of the methods outlined in paragraph (1), the plant protection product or biocide product shall, be classified according to its effects on man,

- that due to effects such as potentiation, a conventional assessment in accordance with subparagraph (1) (a) would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation,
- that due to effects such as antagonism, a conventional assessment in accordance with subparagraph (1) (a) would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

(6) For plant protection products and biocide products of known composition, with the exception of plant protection products, classified in accordance with paragraph (1) (b), a new evaluation of health hazard shall be undertaken using the methods specified in either subparagraph (1) (a) or (b) whenever:

- changes in composition, as a weight/weight or volume/volume percentage of the plant protection product or biocide product are proposed in relation to one or more dangerous constituents, greater than the permitted variation specified in 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 in composition involving the substitution or addition of one or more constituents, which may or may not be dangerous.

Evaluation of environmental hazards

10 (1) Subject to paragraphs (2) to (4) the hazards of a plant protection product or biocide product for the environment shall be assessed using one or more of the following procedures:

(a) a conventional method described in Annex X; or

(b) the determination of the hazardous properties for the environment necessary for appropriate classification in accordance with the criteria in Annex VI. These properties shall be determined by means of the test methods laid down in Part C of Annex V, unless, in the case of plant protection products, other internationally recognised test methods are acceptable in accordance with the provisions of Annexes II and III to the Directive of 1991.

(2) Where an ecotoxicological property is established using the test methods specified in subparagraph (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 [34] and in compliance with the provisions of Directive 86/609/EEC [35].

(3) Where the environmental hazards of a plant protection product or biocide product have been established using the methods specified in both subparagraphs (1) (a) and (b), the results of testing using the methods specified in paragraph (1) (b) shall be used for classifying the plant protection product or biocide product.

(4) For plant protection products and biocide products of known composition, with the exception of plant protection products, classified in accordance with paragraph (1) (b), a new evaluation of environmental hazard shall be undertaken using the methods specified in either subparagraph (1) (a) or (b) whenever:

- changes in composition, as a weight/weight or volume/volume percentage of the plant protection product or biocide product are proposed in relation to one or more dangerous constituent, greater than the permitted variation specified in 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 in composition involving the substitution or addition of one or more constituents, which may or may not be dangerous.

Data, information, supporting documentation and materials

11 (1) Where a plant protection product or biocide product is classified in accordance with these Regulations, the person on whose behalf the classification is made shall, whenever requested, send to the designated national authority specified in paragraph (1) of Regulation 4 for approval, an accurate record of the studies conducted and information used to support such classification or classifications and to establish the nature and extent of foreseeable risks which the handling or use of the plant protection product or biocide product entails, together with relevant supporting documentation and materials, as may be specified from time to time by the Minister, together with the particulars of any safety precautions or other recommendations and the conclusions reached as a result of the studies, information and materials.

(2) (a) In the case of a plant protection product to which Regulation 3 (1) (a) applies that was placed on the market on or before the second day of December 1985, the plant protection product shall not be cleared and shall no longer be placed on the market or used unless the record of the studies conducted and the information, documentation and materials to which it relates are submitted for approval at a time to be specified by the Minister and are approved by him.

(b) In the case of a plant protection product to which Regulation 3 (1) (a) applies that was not placed on the market on or before the second day of December 1985, the plant protection product shall not be cleared and placed on the market or used unless the record of the studies conducted and the information, documentation and materials to which it relates have been approved by the Minister.

(c) In the case of a biocide product to which Regulation 3 (1) (b) applies that was placed on the market on or before the first day of February 2002, the biocide product shall not be cleared and shall no longer be placed on the market or used unless the record of the studies conducted and the information, documentation and materials to which it relates are submitted for approval at a time to be specified by the Minister and are approved by him.

(d) In the case of a biocide product to which Regulation 3 (1) (b) applies that was not placed on the market on or before the first day of February 2002, the biocide product shall not be cleared and placed on the market or used unless the record of the studies conducted and the information, documentation and materials to which it relates have been approved by the Minister.

(e) In the case of a plant protection product or biocide product in relation to which the record of the studies conducted and the information, documentation and materials have neither been approved nor submitted for approval by the Minister in accordance with subparagraphs (a), (b), (c) or (d), notwithstanding non-compliance with the provisions of this Regulation, an authorised officer acting on behalf of the Minister, where there is no apparent risk to man or to the environment through the placing on the market or use of such a plant protection product or biocide, product may, by a notice in writing given to the owner or person in apparent charge or control, permit the controlled placing on the market or use of existing stocks of the plant protection product or biocide product subject to specified conditions.

(f) The Minister may, on a request being made to him in that behalf by a person who had been granted clearance in respect of a plant protection product or biocide product, revoke any clearance granted in respect of that plant protection product or biocide product.

(3) Notwithstanding paragraph (2) and subject to paragraph (4), in the case of a biocide product to which Regulation 3 (1) (b) applies, that was not placed on the market on or before the first day of February 2002, that contains one or more active substances not yet included in Annex I or IA of the Directive of 1998 for that product type, and that only contains active substances of biocidal products on the market on or before 14 May 2000 in a Member State of the European Union for purposes other than scientific research and development or process-oriented research and development, the biocide product may be placed on the market or used where the package (including any label or container used with the package), and basic information as to the nature and composition and product type of any such biocide product and as to its manufacturer or manufacturers, as set out in the Fifth Schedule, have been submitted for approval by the Minister and have been approved by him, that is, the biocide product has been duly notified.

(4) Persons responsible for placing biocide products notified in accordance with paragraph (3) on the market shall ensure that each such biocide product is classified, packaged and labelled in compliance with these Regulations.

Packaging

12 (1) Subject to paragraph (5), the packaging of a plant protection product or biocide product, together with the fastenings or containers used in such packaging and the materials constituting such packaging or fastenings, shall -

(a) be so designed and constructed that its contents cannot escape;

(b) not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents;

(c) be strong and solid throughout such that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) in the case of containers fitted with replaceable fastening devices, be so designed that the packaging can be refastened repeatedly without the contents escaping.

(2) The packaging of a plant protection product or biocide product shall not have -

(a) either a shape and / or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers; or

(b) a presentation and / or a designation used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products.

(3) The packaging of a plant protection product or biocide product that is offered or sold to the general public, shall -

(a) be fitted with a child-resistant fastening conforming with the technical specifications provided in Part A of Annex XI; and / or

(b) carry a tactile warning of danger conforming to the technical specifications provided in Part B of Annex XI;

where the criteria specified in Annex XI are satisfied or although not dangerous it may nevertheless present a specific hazard.

(4) Packaging containing a plant protection product or biocide product shall be closed with a distinctive seal in such a way that when the package is opened for the first time the seal is irreparably damaged.

(5) Subparagraphs (a), (b) and (c) of paragraph (1) shall be deemed satisfied where the packaging of a plant protection product or biocide product to which these Regulations apply complies with the requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air.

Labelling

13 (1) The following information shall be stated clearly and in an indelible form on all packaging that is packaging mentioned in Regulation 12 (1) or on a label on or attached to such packaging in the Irish language or in the English language or in both the Irish and English languages:

(a) the phrases and inscriptions specified in Annex XII;

(b) in the case of plant protection products, the inscription - “To avoid risks to man and the environment, comply with the instructions for use”;

(c) the trade name or designation of the plant protection product or biocide product;

(d) the name, full address and telephone number of the person established in the European Union who is responsible for placing the plant protection product or biocide product on the market, whether it be the manufacturer, the importer or the distributor;

(e) the common name of each active substance contained in the plant protection product or biocide product according to the International Standards Organisation, or, if a common name is not available, the chemical name according to rules of the International Union of Pure and Applied Chemistry;

(f) the amount of each active substance so contained expressed:-

(i) for solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pas at 20 °C), as a percentage by weight;

(ii) for other liquids, as a percentage by weight and in grams per litre at 20 °C;

(iii) for gases, as a percentage by volume;

(iv) for acids, their amides, esters and salts, on an acid equivalent basis;

(g) the chemical name of each substance present in the preparation, in accordance with the designations listed in Annex I or in an internationally recognised chemical nomenclature if no corresponding designation is included in Annex I, in accordance with the following detailed rules:-

(i) for preparations classified as very toxic, toxic or harmful in accordance with Regulation 9 and subject to subparagraph (v), the name of every very toxic, toxic or harmful substance present in concentrations equal to, or greater than, the lowest limit (limit Xn) laid down for the substances concerned in Annex I, or failing that in Part B of Annex IX;

(ii) for preparations classified as corrosive in accordance with Regulation 9 and subject to subparagraph (v), the name of every corrosive substance present in concentrations equal to, or greater than, the lowest limit (limit Xi) laid down for the substances concerned in Annex I, or failing that in Part B of Annex IX;

(iii) subject to subparagraph (v), the name of every substance that has 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;

(iv) the name of every substance that has given rise to the classification of the preparation in one or more of the following danger categories, where the name of the substance must be included on the label in accordance with subparagraphs (i), (ii) or (iii):

- explosive,
- oxidising,
- extremely flammable,
- highly flammable,
- flammable
- irritant,
- dangerous for the environment;

(v) unless more are necessary to identify the substances primarily responsible for the major health hazards that gave rise to the classification and choice of corresponding phrases in accordance with subparagraphs (i) to (iv), a maximum of four chemical names shall suffice;

(h) (i) subject to subparagraphs (ii) and (iii), the danger symbols and indications of the dangers specified in Annex II and VI, selected following application of the methods for evaluation of the physico-chemical properties specified in Annex VIII, application of the methods for evaluation of the health hazards specified in Annex IX, and application of the methods for evaluation of environmental hazards specified in Annex X;

(ii) where more than one danger symbol must be assigned to a preparation the obligation to apply the symbol:

- T shall make use of the symbols C and X optional unless otherwise specified in Annex I,
- C shall make use of the symbol X optional,
- E shall make use of the symbols F and O optional,
- Xn shall make use of the symbol Xi optional;

(iii) the danger symbols shall be printed in black on an orange-yellow background;

(i) (i) subject to subparagraphs (ii), (iii) and (iv), risk phrases (R phrases) selected from those included in Annex III and VI, assigned following application of the methods for evaluation of the physico-chemical properties specified in Annex VIII, application of the methods for evaluation of the health hazards specified in Annex IX, and application of the methods for evaluation of environmental hazards specified in Annex X;

(ii) unless more are necessary to identify the principal hazards, a maximum of six R phrases shall suffice to describe the risks - for this purpose, the combined phrases listed in Annex III shall be regarded as single phrases;

(iii) in the case of plant protection products and biocide products classified dangerous in more than one danger category, the R phrases selected shall cover all of the principal hazards identified;

(iv) the R phrases “extremely flammable” or “highly flammable” need not be used where they describe an indication of danger, used in accordance with subparagraph (h);

(j) (i) subject to subparagraphs (iii) and (iv), safety phrases (S phrases) selected from those included in Annex IV and VI, assigned following application of the methods for evaluation of the physico-chemical properties specified in Annex VIII, application of the methods for evaluation of the health hazards specified in Annex IX, and application of the methods for evaluation of environmental hazards specified in Annex X;

(ii) additional safety advice (additional safety phrases) selected as appropriate from the advice included in Annex VII;

(iii) unless more are necessary to provide appropriate safety advice, a maximum of six S phrases shall suffice - for this purpose, the combined phrases listed in Annex IV shall be regarded as single phrases;

(iv) 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 plant protection product or biocide product;

(k) the nominal quantity (nominal mass or nominal volume) of the contents;

(l) the batch number of the formulation;

(m) an indication of the nature of the formulation, using the appropriate code selected from those listed in Annex XIV; and

(n) the reference number allocated by the national authority specified in paragraph (1) of Regulation 4.

(2) Where the information specified in paragraph (1) appears 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.

(3) The colour and presentation of each label or packaging where the information specified in paragraph (1) is printed on the package, shall be such that the danger symbol and its background stand out clearly from it.

(4) The information specified in paragraph (1) shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

(5) Notwithstanding subparagraphs (h), (i) and (j) of paragraph (1), where it can be demonstrated that there would be a reduction in environmental impact for plant protection products and biocide products classified as dangerous for the environment in accordance with Regulation 10, they shall be labelled in accordance with provisions to be included in Parts A or B of Annex XII.

(6) Notwithstanding subparagraphs (i) and (j) of paragraph (1), where the contents of a package do not exceed 125 millilitres:

- in the case of plant protection products or biocide products classified as highly flammable, oxidising or irritant, with the exception of those assigned the phrase

R41, or classified as dangerous for the environment and assigned the symbol N, the labelling need not include the relevant R and S phrases, and

- in the case of plant protection products and biocide products classified as flammable, or dangerous for the environment but not assigned the N symbol, the labelling need not include the relevant S phrases.

(7) Notwithstanding paragraph (1), the requirements in relation to information to be included on packaging or on a label attached to such packaging shall 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 paragraph (1);

(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 the requirements specified in subparagraphs (c), (d), (g), (i) and (j) of paragraph (1) - for plant protection products and biocide products classified in accordance with Regulation 10, the provisions specified in subparagraph (h) of paragraph (1) of Regulation 13 shall also apply in relation 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, the specific requirements referred to in Annex XIII are complied with.

(8) Subject to paragraph (9), where packaging -

(a) is either too small or is unsuitable to enable all the information required by paragraph (1) to be shown on the container itself or on a label on or attached thereto;

(b) containing a plant protection product or biocide product classified pursuant to these Regulations as being harmful, extremely flammable, highly flammable, flammable, irritant or oxidising and the quantity so contained is small and presents no danger to persons handling the plant protection product or biocide product or who are otherwise concerned;

(c) containing a plant protection product or biocide product classified pursuant to these Regulations as being dangerous for the environment in such small quantities that there is no reason to fear any danger to the environment; or

(d) containing a plant protection product or biocide product not mentioned in subparagraph (b) or (c) and the quantity so contained is small and presents no danger to persons handling the plant protection product or biocide product or who are otherwise concerned;

the labelling required by paragraph (1) shall be in a manner that for the time being stands approved of for the purposes of this paragraph by the Minister and which he/she considers appropriate, subject to the symbols, indications of danger, risk phrases (R phrases) and safety phrases (S phrases) used being those specified in accordance with paragraph (1).

(9) Where paragraph (8) is relied upon for the labelling of a plant protection product or biocide product, the national authority specified in paragraph (1) of Regulation 4 shall forthwith inform the European Commission and the Member States of the European Union thereof.

Distance selling

14 Any advertisement for a plant protection product or biocide product to which these Regulations apply, that enables a member of the general public to conclude a contract for purchase without first having sight of the label for that plant protection product or biocide product 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 [36].

Safety data sheets

15 (1) Safety data sheets intended principally for use by professional users shall be prepared by the person responsible for placing a plant protection product or biocide product on the market. Safety data sheets are intended to enable professional users to take necessary measures as regards the protection of health, safety and the environment at the place of work, and shall comply with Commission Directive 91/155/EEC [37].

(2) Persons responsible for placing a plant protection product or biocide product on the market shall ensure that a safety data sheet in accordance with paragraph (1) is supplied on request made by any professional user of a plant protection product or biocide product, where the plant protection product or biocide product:

(a) contains at least one dangerous substance;

(b) is classified as dangerous in accordance with Regulation 8, 9 or 10; or

(c) although not classified as dangerous in accordance with Regulation 8, 9 or 10, contains in an individual concentration of 1 % or more by weight in the case of non-gaseous preparations and 0.2 % or more by volume for gaseous preparations at least:

- one substance posing health or environmental hazards, or
- one substance for which there is one or more EU workplace exposure limit or acceptable operator exposure level (AOEL).

(3) Safety data sheets may be supplied on paper or in electronic form, provided that the addressee has the necessary means of receiving it.

Confidentiality of chemical names

16 (1) Subject to paragraph (2), where the person responsible for placing a plant protection product or biocide product on the market can demonstrate that disclosure on the label or safety data sheet of the chemical identity of a substance that is classified as -

- irritant but not assigned the phrase R41,
- irritant and in addition, explosive, oxidising, extremely flammable, highly flammable, flammable, or dangerous for the environment,
- harmful presenting only acute lethal effects,

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[36] O.J. No. L 144/19 4/6/1997

[37] O.J. No. L 76/35 22/3/1991 Directive as last amended by Commission Directive 2001/58/EC O.J. No. L 212/24 7/8/2001

- harmful presenting only acute lethal effects, and in addition, explosive, oxidising, extremely flammable, highly flammable, flammable, or dangerous for the environment,

would put at risk his/her intellectual property, he/she may, in accordance with the procedures specified in Annex XIII, be permitted to refer to that substance either by means of a name that identifies its most important functional groups and chemical element or by means of an alternative name. This procedure may not be applied where the substance concerned has been assigned an EU workplace exposure limit or an acceptable operator exposure level (AOEL).

(2) (a) Where the person responsible for placing a plant protection product or biocide product on the market wishes to take advantage of the provisions of paragraph (1), a request shall be made to the competent authority of the Member State in which the preparation is to be first placed on the market. Where any such plant protection product or biocide product is first placed on the market in the territory of the State, the request shall be made to the national authority specified in paragraph (1) of Regulation 4.

(b) Any request made pursuant to subparagraph (a) shall comply with the provisions of Annex XIII and must include the information specified in Part A of that Annex. The national authority specified in paragraph (1) of Regulation 4 may in addition request further information from the person responsible for placing on the market a plant protection product or biocide product to which paragraph (1) applies, if such information appears necessary in order to evaluate the validity of the request.

(3) The national authority specified in paragraph (1) of Regulation 4 shall notify the applicant of its decision in relation to any request made for confidentiality. The person responsible for placing the plant protection product or biocide product on the market shall forward a copy of this decision to the national authority of each of the Member States of the European Union where he/she wishes to market the product.

(4) Confidential information brought to the attention of the national authority specified in paragraph (1) of Regulation 4, shall be kept secret, but nevertheless may be divulged to persons directly involved in administrative or legal proceedings involving sanctions undertaken for the purpose of controlling substances, plant protection products or biocide products placed on the market and to persons who are to participate or be heard in legislative proceedings.

Emergency measures

17 (1) Where the Minister is satisfied on the basis of detailed evidence that a plant protection product or biocide product to which these Regulations apply constitutes a hazard for man or for the environment on grounds embraced by these Regulations, he/she may either prohibit the placing on the market of such plant protection product or biocide product or permit its being so placed only if conditions specified by him/her are complied with.

(2) Where the Minister takes action pursuant to paragraph (1), the national authority specified in paragraph (1) of Regulation 4 shall forthwith inform the European Commission and the Member States of the European Union thereof.

Notification of imports and exports

18 Persons that import plant protection products or biocide products to which these Regulations apply into the State or export such plant protection products or biocide products from the State, shall by the 1 June of each year, provide an annual return of all such imports and exports during the previous calendar year to the national authority specified in paragraph (1) of Regulation 4. Annual returns of imports and exports provided shall include the following information for each plant protection product and biocide product: –

(a) the brand name of the plant protection product or biocide product;

(b) the reference number allocated to the plant protection product or biocide product by the national authority specified in paragraph (1) of Regulation 4;

(c) the number of packages of each size (specify package size by reference to volume or weight of contents); and

(d) the total quantity (specify quantity by reference to volume or weight) imported and exported for the year for which returns are provided.

Inspections, sampling, tests and examinations

19 (1) Subject to paragraph (7) an authorised officer may at any reasonable time enter: -

(a) any place or premises, in which he/she has reasonable grounds for believing that a plant protection product or biocide product is being manufactured, placed on the market, stored or used;

(b) any railway wagon, vehicle, ship, vessel, aircraft, container or other thing in which he/she has reasonable grounds for believing that a plant protection product or biocide product is being either transported, stored or used;

(c) any premises in which he/she has reasonable grounds for believing that there are any books, documents or records relating to any business whose activities consist of or include the manufacture, placing on the market, storage, transport or use of a plant protection product or biocide product;

and there or at any other place: -

(i) make such examinations, tests and inspections; and

(ii) take samples in accordance with the methods described in the manual on the development and use of FAO specifications for plant protection products (Food and Agriculture Organisation of the United Nations, FAO Plant Production and Protection Paper 149, Fifth Edition), as updated from time to time, of any plant protection product or biocide product which he/she finds in the course of his/her inspection and which he/she believes is or may be a plant protection product or biocide product to which these Regulations apply; and

(iii) take samples in accordance with Commission Directive 79/700/EEC [38], or the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, recommended method of sampling for the determination of Pesticide Residues (Volume 2a, Codex Alimentarius, Food and Agriculture Organisation of the United Nations, World Health Organisation, "Pesticide Residues in Food, Methods of Analysis and Sampling" 2nd edition, Rome 2000), where relevant, and in accordance with other internationally accepted procedures in other cases, of any plant, plant product, food, food product, soil, compost, or take samples from or of any other thing, which he/she finds in the course of an inspection and which he/she believes may have been treated or contaminated with a plant protection product or biocide product to which these Regulations apply;

as he/she may consider appropriate and provided the quantity which a sample taken pursuant to this Regulation comprises is reasonable.

(2) A person who has in any place, on any premises or in any railway wagon, vehicle, ship, vessel, aircraft, container or other thing a plant protection product or biocide product to which these Regulations apply shall at all reasonable times: -

(a) afford to an authorised officer such facilities and assistance as are reasonably necessary for an inspection and taking of samples pursuant to this Regulation;

(b) give an authorised officer any information which he/she may reasonably require regarding the purchase, importation, sale or use of any such plant protection product or biocide product and which is within the person's knowledge or procurement; and

(c) produce to an authorised officer any document relating to the raw materials used in the formulation of any plant protection product or biocide product which the authorised officer may reasonably require and when produced permit the officer to inspect and take extracts from the document.

(3) In addition to the foregoing any person who carries on the business of manufacturing, formulating, packaging, processing or marketing a plant protection product or biocide product to which these Regulations apply, shall: -

(a) keep records of all transactions regarding the plant protection product or biocide product;

(b) produce at the request of an authorised officer any records, books or other documents relating to such business which are in his possession or under his control;

(c) permit such an officer to inspect and take extracts from such records, books or other documents and give to the officer any information which is within his knowledge or under his control and which such officer may reasonably require in relation to any entries therein;

(d) afford to any such an officer such facilities and assistance as are reasonably necessary for inspecting the stock of any plant protection product or biocide product on any premises on which such person carries on such a business; and

[38] O.J. No. L207/26 15/8/1979

(e) give to such an officer any information he/she may reasonably require in relation to such transactions, including, in particular, information which he/she may reasonably require regarding any plant protection product or biocide product specified by him/her.

(4) Where a sample is taken pursuant to this Regulation, the authorised officer concerned shall: -

(a) either: –

- divide the sample into three or more parts, each of which he/she shall seal and mark, or
- identify 3 or more packages or containers containing product of the same formulation batch, each package or container of which shall constitute a part which he/she shall seal and mark;

(b) give one part thereof to a designated analyst for analysis in accordance with paragraph (5);

(c) leave with, deliver to, or send by registered post to, the defendant or his/her agent, a second part thereof;

(d) where there is more than one defendant, leave with, deliver to, or send by registered post to such defendant or agent of such defendant, a further part thereof; and

(e) give the remaining part thereof to the State Chemist for analysis in accordance with paragraph 5.

(5) Where a designated analyst or the State Chemist receives a sample from an authorized officer in pursuance of these Regulations he/she shall make analyses thereof using appropriate analytical methods.

(6) (a) In any proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or any report on, a sample taken pursuant to this Regulation shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided (as required by paragraph (4)) was left with, delivered to or sent by registered post to, the defendant or his/her agent.

(b) In any proceedings for an offence under these Regulations, evidence of the presence of a residue of a plant protection product or biocide product to which these Regulations apply, in or on agricultural produce, in or on food or food products, in or on soil or compost or in or on surfaces or other materials which may have been treated with or exposed to the plant protection product or biocide product, shall be evidence, until the contrary is proved, of the use of the plant protection product or biocide product by the owner, occupier or person in possession, as the case may be.

(c) In any proceedings for an offence under these Regulations, a certificate in the form set out in the Sixth or Seventh Schedule showing the results of an analysis shall, until the contrary is shown, be sufficient evidence of the facts certified to therein in relation to the presence in a plant protection product or biocide product of any substance, impurity or formulating ingredient, and the level of

such presence and a document purporting to be such a certificate shall be deemed, until the contrary is shown, to be such a certificate.

(d) In any proceedings for an offence under these Regulations, each of the documents referred to in subparagraphs (1) (ii) and (iii) may be proved by a production of a copy thereof purporting to have been published in the Official Journal of European Communities, by the Food and Agriculture Organisation of the United Nations, by the World Health Organisation, as appropriate.

(e) For the purpose of these Regulations, the presence of a plant protection product or biocide product, to which these Regulations apply, on any premises (including any stores), shall, until the contrary is shown, be sufficient evidence that the plant protection product or biocide product in question is or was being placed on the market by the owner and by the occupier of such premises.

(7) An authorised officer shall be furnished with a certificate of his/her appointment as an authorised officer and when exercising any power conferred on him/her by these Regulations, shall if requested by any person affected, produce the certificate to that person.

(8) A designated analyst shall be furnished with a warrant of his/her appointment by the Minister to carry out analyses as required by these Regulations.

Seizure, retention, removal and disposal

20 (1) An authorised officer may seize and retain, or seize, remove and retain any plant protection product or biocide product which he/she believes is a plant protection product or biocide product to which these Regulations apply and in relation to which the authorised officer has reasonable grounds for suspecting that there is or has been a failure to comply with any provision of these Regulations.

(2) An authorised officer may by a notice in writing given to the owner or to the person in apparent charge or control of a plant protection product or biocide product that has been seized under this Regulation: -

(a) require things specified in the notice to be done in relation to the plant protection product or biocide product before it is released by an authorised officer;

(b) either: -

(i) require the disposal of the plant protection product or biocide product by the person to whom the notice is given, in a manner specified in the notice and at the expense of the owner; or

(ii) indicate the authorised officer's intention of disposing of the plant protection product or biocide product at the expense of the owner;

such disposal to be, in either case, such as will prevent the said plant protection product or biocide product from being placed on the market or used;

and in case a notice given under this paragraph requires specified things to be done in relation to a plant protection product or biocide product, the authorised officer shall

retain control of the plant protection product or biocide product to which the notice relates until the requirements of the notice have been complied with.

(3) Where a notice is given under this Regulation, a person shall not, without the consent of the authorised officer by whom the notice was given sell, move, dispose of or otherwise interfere with the plant protection product or biocide product in any way pending compliance with the requirements of the notice.

(4) Any person who is aggrieved by a notice given under paragraph (2) that either requires the plant protection product or biocide product to which it relates to be disposed of or indicates an intention to dispose of such plant protection product or biocide product may, not later than the expiration of a period of seven days beginning on the date of the notice, appeal against the notice to the District Court in the District Court District in which the notice has been served.

(5) Disposal of a plant protection product or biocide product pursuant to a notice given under paragraph (2) shall not take place until: -

(a) the period during which an appeal under paragraph (4) may be taken against the notice has expired; or

(b) an appeal under that paragraph is determined or withdrawn.

(6) (a) Where an appeal is made to the District Court under paragraph (4) that court, if it is satisfied that: -

(i) the plant protection product or biocide product to which the relevant notice under this Regulation relates is one to which Regulation 3 (1) applies; and

(ii) there has been a failure to comply with the provisions of these Regulations;

shall order that the plant protection product or biocide product be disposed of in the manner specified in the notice, or in such other manner as may be specified in the court's order and which, in the opinion of the court, will prevent the plant protection product or biocide product from being used or placed on the market.

(b) Where an order made by the District Court under this paragraph requires the plant protection product or biocide product to which it relates to be disposed of by an authorised officer, the cost of such disposal shall be recoverable by the Minister as a simple contract debt in any court of competent jurisdiction from the person who was the owner of the product at the time of its seizure under this Regulation.

(7) Notwithstanding paragraph (2) and the requirements of these Regulations in relation to classification, packaging and labelling, the method of disposal specified in a notice given under paragraph (2) may include its use subject to such conditions as the authorized officer may specify in the notice, provided that the officer is not aware of any apparent risk to man or the environment by such use.

(8) In the case of a notice given under paragraph (2) which indicates an intention to dispose of a plant protection product or biocide product, the ownership of such plant protection product or biocide product shall, in the absence of an appeal by the owner against the notice to the District Court, vest in the Minister on the expiration of a period

of seven days beginning on the date of the notice. In the event of an appeal by the owner against the notice to the District Court, ownership of the plant protection product or biocide product shall vest in the Minister if the court makes an order under paragraph (6) which requires the plant protection product or biocide product to be disposed of by an authorised officer.

(9) In the case of a notice under paragraph (2) which requires the disposal at the expense of the owner of a plant protection product or biocide product that has been seized under this Regulation and where there has been a failure to pay, the cost of such disposal shall be recoverable by the Minister as a simple contract debt in any court of competent jurisdiction from the person who was the owner of the plant protection product or biocide product at the time of its seizure under this Regulation.

General offences

21 (1) A person who contravenes Regulation 5 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €1,905, or to imprisonment for a term not exceeding six months, or to both.

(2) If any person -

(a) tampers with any plant protection product or biocide product so as to procure that any sample of it taken pursuant to Regulation 19 does not correctly represent the plant protection product or biocide product; or

(b) tampers or interferes with any sample taken pursuant to Regulation 19,

he/she shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €1,905 or to imprisonment for a term not exceeding six months or to both.

(3) A person who: -

(a) fails to comply with the requirements of Regulation 11, paragraph (1) of Regulation 17, Regulation 18, paragraphs (2) and (3) of Regulation 19, or paragraph (3) of Regulation 20;

(b) obstructs or interferes with an authorised officer in the course of exercising a power conferred on him by Regulation 19, 20 or 26; or

(c) gives false information when requested to provide information under Regulation 26;

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €1,905, or to imprisonment for a term not exceeding six months, or to both.

(4) Where an offence under these Regulations has been committed by a body corporate and is proved to have been so committed with the consent, or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished as if he/she were guilty of the first mentioned offence.

Prosecutions and specific rules of evidence

22 (1) An offence under these Regulations may be prosecuted by the Minister.

(2) In proceedings for an offence under Regulation 21 (1), evidence that claims have been made that a substance or preparation -

(a) destroys organisms harmful to plants or to plant products or protects plants and plant products form such organisms;

(b) improves or regulates plant production, with the exception of fertilizers and soil conditioners;

(c) preserves plant products;

(d) destroys undesired plants;

(e) destroys parts of plants, checks or prevents undesired growth of plants; or

(f) renders harmless, destroys, deters, gives protection against, or prevents the action of, or otherwise exerts a controlling effect on any harmful organisms by chemical or biological means,

shall, until the contrary is shown, be sufficient evidence that it is a plant protection product or biocide product to which these Regulations apply.

Referee analysis

23 (1) Where an appeal is made to the District Court concerning the results of any analysis made by a designated analyst under Regulation 19 (5), the results of analysis of the third part of the sample made by the State Chemist, in the form of a certificate set out in the Seventh Schedule, shall if either the District Court or the defendant so requests, be made available by the State Chemist.

(2) Where in accordance with paragraph (1), the State Chemist is requested to make the results of an analysis carried out by him/her available, copies of the certificate in the form set out in the Seventh Schedule shall be provided to the defendant and to the designated analyst concerned.

24 The defendant shall be liable for the cost of the analysis carried out by the State Chemist under Regulation 19 (5) where a request is made by the defendant in accordance with paragraph (1) of Regulation 23 and the results of that analysis confirm that there has been a breach of these Regulations.

Fees

25 (1) Every application for approval of documentation and materials for clearance of a plant protection product or biocide product shall be subject to the payment at the time application is made of the following fees, that is to say -

(a) for each active substance contained in the plant protection product or biocide product, the fee set out in column (2) of Part 1A of the Eight Schedule payable to the Minister in respect of the appropriate type of clearance in relation to a category set out in column (1) of the said Part 1A;

(b) in relation to each preparation, the fee set out in column (2) of Part 1B of the Eight Schedule payable to the Minister in respect of the appropriate type of clearance in relation to a category set out in column (1) of the said Part 1B;

(c) a fee of €190 shall be payable in each case where application is made for minor amendment to the packaging and labelling or to the documentation and materials submitted in accordance with subparagraphs (2) (a), (b), (c) or (d) of Regulation 11, where it is considered that an evaluation of the risks arising for man, animals or the environment is not involved or required.

(2) Every application for approval of documentation and materials, in relation to the notification of a biocide product in accordance with paragraph (3) of Regulation 11 shall be subject to the payment at the time application is made of a fee of €254.

(3) (a) Every grant of a clearance of a plant protection product or biocide product pursuant to paragraph (2) of Regulation 11 and every notification of a biocide product accepted pursuant to paragraph (3) of Regulation 11, shall be for 12 months from the date of such grant or acceptance and shall be renewable at the discretion of the Minister for further periods of 12 months on an application being made in that behalf to the Minister and shall be accompanied by the appropriate annual fee set out in Part 2 of the Eight Schedule. In the event of a failure to pay the annual fee set out in Part 2 of the Eight Schedule, within 30 days of the annual fee falling due, renewal of clearance or notification, as

appropriate, may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 3 of the Eight Schedule.

(b) Plant protection products notified as being on the market on or before the second of December 1985, in accordance with the provisions of the subparagraph (3) (a) of Regulation 5, may continue to be placed on the market and used if the annual fee set out in Part 2 of the Eight Schedule has been paid to the Minister, within 30 days of the fee falling due. Where for a particular plant protection product, the annual fee has not been paid by the date due, the notification concerned shall be revoked, but renewal of the notification may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 3 of the Eight Schedule.

(c) Biocide products notified as being on the market on or before the first of February 2002, in accordance with the provisions of the subparagraph (3) (b) of Regulation 5, may continue to be placed on the market and used if the annual fee set out in Part 2 of the Eight Schedule has been paid to the Minister, within 30 days of the fee falling due. Where for a particular biocide product, the annual fee has not been paid by the date due, the notification concerned shall be revoked, but renewal of the notification may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 3 of the Eight Schedule.

(d) The annual fees payable in accordance with subparagraphs (a), (b) and (c) shall be paid by 1 September of each year.

(e) In the case of a plant protection product or biocide product already on the market for a period of one year or more prior to the calendar year for which the annual fee is payable, the Minister may reduce the level of the annual fee payable to the Minister in accordance with this paragraph, where, on the basis of an auditor's certificate furnished to him/her, he/she is satisfied that the wholesale sales of such plant protection product or biocide product during the previous calendar year did not exceed: -

(i) in the case of a plant protection product or biocide product for household, home garden or other amateur use, € 6,350; and

(ii) in the case of any other plant protection product or biocide product, €19,050.

In all such cases, the minimum fee payable for each such plant protection product or biocide product shall be €65.

(f) In the case of a plant protection product or biocide product on the market for less than one year prior to the calendar year for which an annual fee is payable, the Minister may refund part of the annual fee payable in accordance with this paragraph, on a request being made to him/her in that behalf, where, on the basis of an auditor's certificate furnished to him/her, he/she is satisfied that the wholesale sales of the such plant protection product or biocide product during the year for which the annual fee was paid, did not exceed -

(i) in the case of a plant protection product or biocide product for household, home garden or other amateur use, € 6,350, and

(ii) in the case of any other plant protection product or biocide product, €19,050.

In all such cases, any refund made shall be such that for each such plant protection product or biocide product, the minimum annual fee payable shall be €65.

(4) In the case of a plant protection product or biocide product already on the market for a period of three years or more prior to the calendar year in which the fee is payable and which is placed on the market exclusively for a specialised use or specialised uses, the fee or fees payable in accordance with paragraph (1) (a) and (b) shall be reduced by the amount specified in column (2) of Part 1C of the Eight Schedule, on a request being made to the Minister in that behalf, where, on the basis of an auditor's certificate furnished to him/her, he/she is satisfied that the wholesale sales of the plant protection product or biocide product during each of the three calendar years immediately prior to the year in which the fee or fees are payable, did not exceed the amounts specified in column (1) of the said Part 1C.

(5) In the case of a plant protection product or biocide product on the market for a period of less than three years prior to the calendar year in which the fee is payable and which is placed on the market exclusively for a specialised use or specialised uses, the fee or fees payable in accordance with paragraph (1) (a) and (b) shall be reduced by the amount specified in column (2) of Part 1D of the Eight Schedule, on a request being made to the Minister in that behalf, where, on the basis of a market survey report provided by the applicant, he/she is satisfied that the potential annual wholesale sales of the plant protection product or biocide product do not exceed the amounts specified in column (1) of the said Part 1D. In cases, where the plant protection product or biocide product has been on the market for one or two years immediately prior to the calendar year in which the fee is payable, any application made for a reduction in fees must be supported by an auditor's certificate relating to the wholesale sales of such plant protection product or biocide product during each such year.

(6) Each clearance of a plant protection product or biocide product and each notification accepted for a plant protection product or biocide product in accordance with the requirements of these Regulations shall be withdrawn if, in each case where such a plant protection product or biocide product continues to be placed on the market, there is a failure to pay the annual renewal fee set out in Part 2 of the Eight Schedule within 30 days of the fee falling due but an application for a renewal of clearance of a plant protection product or biocide product, or of a notification for a plant protection product or biocide product, as appropriate, may be made more than 30 but not more than 60 days after the renewal fee fell due on payment to the Minister of the late annual renewal fee set out in Part 3 of the Eight Schedule.

(7) In the case of an application to alter the type of clearance where a clearance has been approved, the fee, or fees, payable in respect of any subsequent clearance shall be reduced by the amount already paid in accordance with paragraph (1) (a) and (b).

(8) A fee payable under these Regulations may be recovered by the Minister as a simple contract debt in any court of competent jurisdiction.

26 A person who makes a claim for a reduction or a refund of fees in accordance with paragraphs (3), (4) or (5) of Regulation 25 shall, at all reasonable times -

(a) produce, at the request of an authorised officer, any records, books or other documents which are in his possession or under his control which substantiate such a claim,

(b) permit the officer to inspect and take extracts from such records, books or other documents and give to the officer any information which is within his knowledge or under his control and which such officer may reasonably require for the purpose of verifying the claim,

(c) afford to such an officer such facilities and assistance as are reasonably necessary for inspecting the stock of the relevant plant protection product or biocide product if the officer considers such inspection is necessary for the purpose of verifying the claim.

Statutory instruments revoked

27 The following are hereby revoked -

(a) the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994 (S.I. No. 138 of 1994);

(b) the European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 1999 (S.I. No. 463 of 1999); and

(c) the European Communities (Classification, Packaging and Labelling of Pesticides) (Amendment) Regulations, 2001 (S.I. No. 140 of 2001).

FIRST SCHEDULE

Annex I

LIST OF THE DANGEROUS SUBSTANCES FOR WHICH CLASSIFICATION AND LABELLING HAVE BEEN AGREED

Comprising Annex I to the Directive of 1967, as last amended by Commission Directive 2001/59/EC of 6 August 2001 [24]

Annex II

(Annex II to the Directive of 1967 as amended by the Directive of 1992 and adapted by Commission Directive 2001/59/EC of 6 August 2001 [24])

SYMBOLS AND INDICATIONS

Note: The letters E, O, F, F+, T, T+, C, Xn, Xi and N do not form part of the symbol.

E

Explosive

O

Oxidizing

F

Highly flammable

F+

Extremely flammable

T

Toxic

T+

Very Toxic

C

Corrosive

Xn

Harmful

Xi

Irritant

N

Dangerous for the environment

Annex III

(Annex III to the Directive of 1967 as amended by the Directive of 1992 and adapted by Commission Directive 2001/59/EC of 6 August 2001 [24])

NATURE OF SPECIAL RISKS

R1	Explosive when dry
R2	Risk of explosion by shock, friction, fire or other sources of ignition
R3	Extreme risk of explosion by shock, friction, fire or other sources of ignition
R4	Forms very sensitive explosive metallic compounds
R5	Heating may cause an explosion
R6	Explosive with or without contact with air
R7	May cause fire
R8	Contact with combustible material may cause fire
R9	Explosive when mixed with combustible material
R10	Flammable
R11	Highly flammable
R12	Extremely flammable
R14	Reacts violently with water
R15	Contact with water liberates extremely flammable gases
R16	Explosive when mixed with oxidising substances
R17	Spontaneously flammable in air
R18	In use, may form flammable/explosive vapour-air mixture
R19	May form explosive peroxides
R20	Harmful by inhalation
R21	Harmful in contact with skin
R22	Harmful if swallowed

R23	Toxic by inhalation
R24	Toxic in contact with skin
R25	Toxic if swallowed
R26	Very toxic by inhalation
R27	Very toxic in contact with skin
R28	Very toxic if swallowed
R29	Contact with water liberates toxic gas
R30	Can become highly flammable in use
R31	Contact with acids liberates toxic gas
R32	Contact with acids liberates very toxic gas
R33	Danger of cumulative effects
R34	Causes burns
R35	Causes severe burns
R36	Irritating to eyes
R37	Irritating to respiratory system
R38	Irritating to skin
R39	Danger of very serious irreversible effects
R40	Limited evidence of a carcinogenic effect
R41	Risk of serious damage to eyes
R42	May cause sensitization by inhalation
R43	May cause sensitization by skin contact
R44	Risk of explosion if heated under confinement
R45	May cause cancer
R46	May cause heritable genetic damage
R48	Danger of serious damage to health by prolonged exposure
R49	May cause cancer by inhalation
R50	Very toxic to aquatic organisms

R51	Toxic to aquatic organisms
R52	Harmful to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees
R58	May cause long-term adverse effects in the environment
R59	Dangerous for the ozone layer
R60	May impair fertility
R61	May cause harm to the unborn child
R62	Possible risk of impaired fertility
R63	Possible risk of harm to the unborn child
R64	May cause harm to breastfed babies
R65	Harmful: May cause lung damage if swallowed
R66	Repeated exposure may cause skin dryness or cracking
R67	Vapours may cause drowsiness and dizziness
R68	Possible risk of irreversible effects

Combination of R-Phrases

R14/15	Reacts violently with water, liberating extremely flammable gases
R15/29	Contact with water liberates toxic, extremely flammable gas
R20/21	Harmful by inhalation and in contact with skin
R20/22	Harmful by inhalation and if swallowed
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R21/22	Harmful in contact with skin and if swallowed
R23/24	Toxic by inhalation and in contact with skin

R23/25	Toxic by inhalation and if swallowed
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R24/25	Toxic in contact with skin and if swallowed
R26/27	Very toxic by inhalation and in contact with skin
R26/28	Very toxic by inhalation and if swallowed
R26/27/28	Very toxic by inhalation, in contact with skin and if swallowed
R27/28	Very toxic in contact with skin and if swallowed
R36/37	Irritating to eyes and respiratory system
R36/38	Irritating to eyes and skin
R36/37/38	Irritating to eyes, respiratory system and skin
R37/38	Irritating to respiratory system and skin
R39/23	Toxic: danger of very serious irreversible effects through inhalation
R39/24	Toxic: danger of very serious irreversible effects in contact with skin
R39/25	Toxic: danger of very serious irreversible effects if swallowed
R39/23/24	Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/26	Very toxic: danger of very serious irreversible effects through inhalation
R39/27	Very toxic: danger of very serious irreversible effects in contact with skin
R39/28	Very toxic: danger of very serious irreversible effects if swallowed
R39/26/27	Very toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/26/28	Very toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/27/28	Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed

R39/26/27/28	Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R42/43	May cause sensitization by inhalation and skin contact
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation
R48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed
R48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation
R48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed
R48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R68/20	Harmful: possible risk of irreversible effects through inhalation
R68/21	Harmful: possible risk of irreversible effects in contact with skin

R68/22	Harmful: possible risk of irreversible effects if swallowed
R68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin
R68/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed
R68/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed
R68/20/21/22	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed

Annex IV

(Annex IV to the Directive of 1967 as amended by the Directive of 1992 and adapted by Commission Directive 2001/59/EC of 6 August 2001 [24])

SAFETY ADVICE (PHRASES)

S1	Keep locked up
S2	Keep out of the reach of children
S3	Keep in a cool place
S4	Keep away from living quarters
S5	Keep contents under ...(*appropriate liquid to be proposed by the manufacturer*)
S6	Keep under ... (*inert gas to be proposed by the manufacturer*)
S7	Keep container tightly closed
S8	Keep container dry
S9	Keep container in a well-ventilated place
S12	Do not keep the container sealed
S13	Keep away from food, drink and animal feeding stuffs
S14	Keep away from .... (*incompatible materials to be indicated by the manufacturer*)
S15	Keep away from heat
S16	Keep away from sources of ignition - No smoking
S17	Keep away from combustible material
S18	Handle and open container with care
S20	When using do not eat or drink
S21	When using do not smoke
S22	Do not breathe dust
S23	Do not breathe gas/fumes/vapour/spray (*appropriate wording to be proposed by the manufacturer*)

S24	Avoid contact with skin
S25	Avoid contact with eyes
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S27	Take off immediately all contaminated clothing
S28	After contact with skin, wash immediately with plenty of ... (*to be proposed by the manufacturer*)
S29	Do not empty into drains
S30	Never add water to this product
S33	Take precautionary measures against static discharges
S35	This material and its container must be disposed of in a safe way
S36	Wear suitable protective clothing
S37	Wear suitable gloves
S38	In case of insufficient ventilation, wear suitable respiratory equipment
S39	Wear eye/face protection
S40	To clean the floor and all objects contaminated by this material, use ... (*to be proposed by the manufacturer*)
S41	In case of fire and/or explosion do not breathe fumes
S42	During fumigation/spraying wear suitable respiratory equipment (*appropriate wording to be proposed by the manufacturer*)
S43	In case of fire, use ... (*indicate in the space the precise type of fire-fighting equipment. If water increases risk, add* - Never use water)
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S46	If swallowed, seek medical advice immediately and show this container or label
S47	Keep at temperature not exceeding ... °C (*to be proposed by the manufacturer*)
S48	Keep wetted with ... (*appropriate material to be proposed by the manufacturer*)
S49	Keep only in the original container
S50	Do not mix with ... (*to be proposed by the manufacturer*)

S51	Use only in well ventilated areas
S52	Not recommended for interior use on large surface areas
S53	Avoid exposure - obtain special instructions before use
S56	Dispose of this material and its container to hazardous or special waste collection point
S57	Use appropriate containment to avoid environmental contamination
S59	Refer to manufacturer/supplier for information on recovery/recycling
S60	This material and its container must be disposed of as hazardous waste
S61	Avoid release to the environment. Refer to special instructions/Safety data sheets
S62	If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label
S63	In case of accident by inhalation: remove casualty to fresh air and keep at rest
S64	If swallowed, rinse mouth with water (only if the person is conscious)

Combination of S-Phrases

S1/2	Keep locked up and out of the reach of children
S3/7	Keep container tightly closed in a cool place
S3/9/14	Keep in a cool, well ventilated place away from ..... (*incompatible materials to be indicated by the manufacturer*)
S3/9/14/49	Keep only in the original container in a cool, well ventilated place away from ..... (*incompatible materials to be indicated by the manufacturer*)
S3/9/49	Keep only in the original container in a cool, well ventilated place
S3/14	Keep in a cool place away from ..... (*incompatible materials to be indicated by the manufacturer*)
S7/8	Keep container tightly closed and dry
S7/9	Keep container tightly closed and in a well ventilated place
S7/47	Keep container tightly closed and at a temperature not exceeding ..... °C (*to be proposed by the manufacturer*)
S20/21	When using do not eat, drink or smoke

S24/25 Avoid contact with skin and eyes

S27/28 After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of ….. (*to be specified by the manufacturer*)

S29/35 Do not empty into drains, dispose of this material and its container in a safe way

S29/56 Do not empty into drains, dispose of this material and its container to hazardous or special waste collection point

S36/37 Wear suitable protective clothing and gloves

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection

S36/39 Wear suitable protective clothing and eye/face protection

S37/39 Wear suitable gloves and eye/face protection

S47/49 Keep only in the original container at temperature not exceeding .....ºC (*to be proposed by the manufacturer*)

Annex V

TEST METHODS

Comprising Annex V to the Directive of 1967, as amended by the Directive of 1992, Commission Directive 88/302/EEC of 18 November 1987 [6], Commission Directive 92/69/EEC of 31 July 1992 [9], Commission Directive 93/21/EEC of 27 April 1993 [10], Commission Directive 96/54/EC of 30 July 1996 [15], Commission Directive 98/73/EC of 18 September 1998 [17], the corrigendum to Commission Directive 98/73/EC of 18 September 1998 [18], Commission Directive 2000/32/EC of 19 May 2000 [22], Commission Directive 2000/33/EC of 25 April 2000 [23] and Commission Directive 2001/59/EC of 6 August 2001 [24]

Annex VI

(Annex VI to the Directive of 1967 as amended by the Directive of 1992 and adapted by Commission Directive 2001/59/EC of 6 August 2001 [24])

CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES AND PREPARATIONS

CONTENTS

1 GENERAL INTRODUCTION

1.1 The object of classification is to identify all the physico-chemical, toxicological and ecotoxicological properties of substances and preparations that may constitute a risk during normal handling or use. Having identified any hazardous properties the substance or preparation must then be labelled to indicate the hazard(s) in order to protect the user, the general public and the environment.

1.2 This Annex sets out the general principles governing the classification and labelling of substances and preparations. It is addressed to all those concerned with methods of classifying and labelling dangerous substances and preparations (manufacturers, importers, and national authorities).

1.3 The provisions of the Directive of 1967 and of these Regulations are intended to provide the primary means by which the general public and persons at work are given essential information concerning dangerous plant protection products and biocide products. The label draws the attention of persons handling or using such substances and preparations to the inherent danger of certain such materials. The label may also serve to draw attention to more comprehensive product information on safety and use available in other forms.

1.4 The label takes account of all potential hazards that are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, *e.g.*

diluted. The most severe hazards are highlighted using symbols. Such hazards and those arising from other dangerous properties are specified using standard risk phrases. Safety phrases provide advice on necessary precautions.

In the case of substances, the information provided is completed using the name of the substance using an internationally recognised chemical nomenclature, the preferred name being the one used in the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS), the EC number and the name, address and telephone number of the person established in the Community who is responsible for placing the substance on the market.

In the case of preparations, the information provided is augmented by the:

- designation or trade name of the preparation,
- chemical name of the active substance(s) and dangerous substances present in the preparation in accordance Regulation 13, and
- name, address and telephone number of the person established in the European Union who is responsible for placing the preparation on the market.

1.5 Article 6 of Directive of 1967 provides that manufacturers, distributors and importers of dangerous substances that appear in EINECS but which have not yet been introduced into Annex 1 are obliged to carry out an investigation to make themselves aware of the relevant and accessible data that exist concerning the properties of such substances. On the basis of that information, they must package and provisionally label such substances in accordance with the provisions of these Regulations and the criteria specified in this Annex.

1.6 **Data required for classification and labelling**

1.6.1 For substances the data required for classification and labelling may be obtained:

(a) as regards substances for which the information specified in Annex VII of the Directive of 1967 is required, most of the necessary data for classification and labelling appear in the 'base set'. This classification and labelling must be reviewed, if necessary, when further information is available (Annex VIII of the Directive of 1967, Annex II and Annex III of the Directive of 1991 and Annex II, Annex III and Annex IV of the Directive of 1998);

(b) as regards other substances (*e.g.* those referred to in paragraph 1.5 above), the data required for classification and labelling may, if necessary, be obtained from a number of different sources, for example the results of previous tests, information required by international rules on the transport of dangerous substances, information taken from reference works and literature or information derived from practical experience. The results of validated structure-activity relationships and expert judgement may also be taken into account where appropriate.

1.6.2 For preparations, the data required for classification and labelling may be obtained:

(a) if it concerns physico-chemical data, by the application of the test methods specified in Annex V, unless in the case of plant protection products other internationally recognised methods are acceptable in accordance with Annex II and Annex III of the Directive of 1991. For gaseous preparations a calculation method may be used for flammable and oxidising properties (see Chapter 9 of this Annex). For non-gaseous preparations containing organic peroxides a calculation method may be used for oxidising properties (see paragraph 2.2.2.1 of this Annex);

(b) if it concerns data on health effects:

- by the application of the test methods specified in Annex V unless in the case of plant protection products other internationally recognised methods are acceptable in accordance with Annex II and Annex III of the Directive of 1991,
- and / or by the application of the conventional method referred to in Regulation 9, details of which are provided in Annex IX, or,
- in the case of R65, by the application of the rules provided in paragraph 3.2.3,
- however, if it concerns the evaluation of the carcinogenic, mutagenic and reproductive properties, by the application of the conventional method referred to in Regulation 9, details of which are provided in Annex IX;

(c) if it concerns data on ecotoxicological properties:

(i) for aquatic toxicity only:

- by the application of the test methods specified in Annex V, subject to the conditions specified in Part C of Annex X, unless in the case of plant protection products other internationally recognised methods are acceptable in accordance with Annex II and Annex III of the Directive of 1991,
- and / or by the application of the conventional method referred to in Regulation 10, details of which are provided in Annex X.;

(ii) for the calculation of the potential for (or actual) bioaccumulation through the determination of log Pow (or BCF), or the evaluation of degradability, by application of the conventional method referred to in Regulation 10, details of which are provided in Annex X;

(iii) for dangers to the ozone layer by the application of the conventional method referred to in Regulation 10, details of which are provided in Annex X.

Note concerning the performance of animal tests

The performance of animal tests to generate experimental data is subject to the provisions of Directive 86/609/EEC regarding the protection of animals used for experimental purposes [35].

1.7 **Application of the criteria**

Classification must cover the physico-chemical, toxicological and ecotoxicological properties of substances and preparations.

Classification of substances and preparations is made on the basis of the criteria in Chapters 2 to 5 of this Annex. All types of hazard must be considered. For instance, classification in accordance with paragraph 3.2.1 does not imply that the paragraphs such as 3.2.2 or 3.2.4 can be ignored.

The choice of symbol(s) and risk phrase(s) must be made on the basis of the classification to ensure that the specific nature of the potential dangers identified in classification is expressed on the label.

Notwithstanding the criteria specified in paragraphs 2.2.3, 2.2.4 and 2.2.5, substances and preparations in the form of aerosols shall be subject to the provisions of Directive 75/324/EEC[33] as amended and adapted to technical progress.

1.7.1. Definitions

"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 product, and any impurity deriving from the production process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

A substance may be chemically very well defined (*e.g.* acetone) or a complex mixture of constituents of variable composition (*e.g.* aromatic distillates). For certain complex substances, some individual constituents have been identified.

"Preparations" means mixtures or solutions composed of two or more substances.

1.7.2 Application of the criteria for substances

The criteria set out in this Annex are directly applicable when the data in question have been obtained using test methods comparable with those described in Annex V. In other cases, the available data must be evaluated by comparing the test methods employed with those specified in Annex V, following which where appropriate the rules specified in this Annex for determining the appropriate classification and labelling may be applicable.

In some cases there may be doubt over the application of the relevant criteria, especially where these require the use of expert judgement. In such cases the manufacturer, distributor or importer should provisionally classify and label the substance on the basis of an assessment of the evidence by a competent person.

Without prejudice to Article 6 of the Directive of 1967, where the above procedure has been followed and there is concern over possible inconsistencies then a proposal may be submitted for the entry of the provisional classification into Annex I. The proposal should be made to one of the Member States and should be accompanied by appropriate scientific data (see also paragraph 4.1).

A similar procedure may be followed when information is identified which gives cause for concern over the accuracy of an existing entry in Annex I.

1.7.2.1 Classification of substances containing impurities, additives or individual constituents

Where impurities, additives or individual constituents of substances have been identified, they shall be taken into account if their concentration is greater than or equal to the limits specified:

- 0. 1 % for substances classified as very toxic, toxic, carcinogenic (category 1 or 2), mutagenic (category 1 or 2) or toxic to reproduction (category 1 or 2), or dangerous for the environment (assigned the symbol "N" for the aquatic environment, dangerous for the ozone layer),
- 1% for substances classified as harmful, corrosive, irritant sensitising, carcinogenic (category 3), mutagenic (category 3), or toxic to reproduction (category 3), or dangerous for the environment (not assigned the symbol "N", *i.e.* harmful to aquatic organisms, may cause long-term adverse effects),

unless lower values have been specified in Annex I.

With the exception of substances listed specifically in Annex I, classification should be carried out according to the requirements of Regulations 8, 9 and 10 and labelled according to the requirements of Regulation 13.

In the case of asbestos (650-013-00-6) this general rule does not apply until a concentration limit has been fixed in Annex I. Substances in which asbestos is present must be classified and labelled according to the principles laid down in Article 6 of the Directive of 1967.

1.7.3 Application of the criteria for preparations

The criteria set out in this Annex are directly applicable when the data in question have been obtained using test methods comparable with those described in Annex V. In the case of the criteria specified in Chapter 4, the conventional method referred to in Regulation 9 must be applied. In the case of the criteria specified in Chapter 5, a conventional method referred to in Regulation 10 is also applicable, except in the case of aquatic toxicity subject to the conditions specified in Part C of Annex X. For plant protection products, data generated in accordance with the methods specified in Annexes II and III to the Directive of 1991 may be used. In other cases, the available data must be evaluated by comparing the test methods employed with those indicated in Annex V and where appropriate applying the rules specified in this Annex for determining the appropriate classification and labelling.

If the health and environmental hazards are assessed by applying the conventional methods referred to in Regulations 9 and 10, details of which are provided in Annexes IX and X, the individual concentration limits to be used are those set out either:

- in Annex I, or
- in accordance with Annexes IX and X where the substance or substances do not appear in Annex I, or appear in it without concentration limits.

In the case of preparations containing mixtures of gases, classification with respect to health and environmental effects must be established using the calculation method on the basis of the individual concentration limits from Annex I or, when these limits are not in Annex I on the basis of the criteria specified in Annexes IX and X.

1.7.3.1 Preparations or substances described in paragraph 1.7.2.1 used as constituents of another preparation

The labelling of such preparations must be in conformity with the provisions of Regulation 13.

In certain cases, the information on the label of the preparation or substance described in paragraph 1.7.2.1 is insufficient to enable other manufacturers who wish to use it as a constituent of their own preparation(s) to carry out the classification and labelling of their preparation(s) correctly. In these cases, the person established within the Community responsible for placing the original preparation or substance described in paragraph 1.7.2.1 on the market whether it be the manufacturer, the importer or the distributor shall supply upon justified request and as soon as possible all necessary data concerning the dangerous substances present to enable correct classification and labelling of the new preparation. This data is also necessary to enable the person responsible for placing the new preparation on the market to comply with other provisions of these Regulations.

2 CLASSIFICATION ON THE BASIS OF PHYSICO-CHEMICAL PROPERTIES

2.1 Introduction

The test methods relating to explosive, oxidizing and flammable properties included in Annex V serve to give specific meaning to the general definitions provided in paragraph (1) of Regulation 2. Criteria follow directly from the test methods in Annex V as far as they are mentioned.

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

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

In the case of preparations, the criteria referred to in Regulation 8 must be taken into consideration.

2.2.1 *Explosive*

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

R2 Risk of explosion by shock, friction, fire or other sources of ignition

- substances and preparations except those set out below

R3 Extreme risk of explosion by shock, friction, fire or other source of ignition

- substances and preparations which are particularly sensitive such as picric acid salts or PETN

2.2.2 *Oxidizing*

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

R7 May cause fire

- organic peroxides which have flammable properties even when not in contact with other combustible material

R8 Contact with combustible material may cause fire

- other oxidizing substances and preparations, including inorganic peroxides, which may cause fire or enhance the risk of fire when in contact with combustible material

R9 Explosive when mixed with combustible material

- other substances and preparations, including inorganic peroxides, which become explosive when mixed with combustible materials, *e.g.* certain chlorates

2.2.2.1 Remarks concerning peroxides

In relation to explosive properties, an organic peroxide or preparation thereof in the form in which it is placed on the market must be classified according to the criteria in paragraph 2.2.1 on the basis of tests carried out in accordance with the methods specified in Annex V.

In relation to oxidising properties, the methods currently included in Annex V cannot be applied to organic peroxides.

Substances that are organic peroxides and not already classified as explosive are classified as dangerous on the basis of their structure (*e.g.* R-0-0-H; R_1-0-0-R_2).

Preparations not already classified as explosive must be classified using the calculation method based on the percentage of active oxygen shown in paragraph 9.5.

Any organic peroxide or preparation thereof not already classified as explosive is classified as oxidising, if the peroxide or its formulation contains:

- more than 5 % of organic peroxides, or
- more than 0.5 % available oxygen from organic peroxides, and more than 5 % hydrogen peroxide

2.2.3 *Extremely flammable*

Substances and preparations shall be classified as extremely flammable and assigned the symbol "F+" and the indication of danger "extremely flammable" in accordance with the results of the tests specified in Annex V. The risk phrase R12 shall be assigned in accordance with the following criteria:

R12 Extremely flammable

- liquid substances and preparations which have a flash point lower than 0 ºC and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 ºC
- gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure

2.2.4 *Highly flammable*

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

R11 Highly flammable

- solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition
- liquid substances and preparations having a flash point below 21ºC but which are not extremely flammable.

R15 Contact with water liberates extremely flammable gases

- substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities, at a minimum rate of one litre per kilogram per hour

R17 Spontaneously flammable in air

- substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy

2.2.5 *Flammable*

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

R10 Flammable

- liquid substances and preparations having a flash point equal to or greater than 21 ºC, and less than or equal to 55 ºC.

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

2.2.6 *Other physico-chemical properties*

Additional risk phrases shall be assigned to substances and preparations which have been classified in accordance with paragraphs 2.2.1 to 2.2.5 above, or in accordance with Chapters 3, 4 and 5 below, in accordance with the following criteria (based on experience obtained during compilation of Annex I):

R1 Explosive when dry

for explosive substances and preparations put on the market in solution or in a wetted form; *e.g.* nitro-cellulose with more than 12.6 % nitrogen

R4 Forms very sensitive explosive metallic compounds

for substances and preparations which may form sensitive explosive metallic derivatives, *e.g.* picric acid, styphnic acid

R5 Heating may cause an explosion

for thermally unstable substances and preparations not classified as explosive, *e.g.* perchloric acid > 50 %

R6 Explosive with or without contact with air

for substances and preparations which are unstable at ambient temperatures, *e.g.* acetylene

R7 May cause fire

for reactive substances and preparations: *e.g.* fluorine, sodium hydrosulphite.

R14 Reacts violently with water

for substances and preparations which react violently with water, *e.g.* acetyl chloride, alkali metals, titanium tetrachloride

R16 Explosive when mixed with oxidizing substances

for substances and preparations which react explosively with an oxidizing agent, *e.g.* red phosphorus

R18 In use, may form flammable / explosive vapour-air mixture

for preparations not in themselves classified as flammable, which contain volatile components that are flammable in air

R19 May form explosive peroxides

for substances and preparations which may form explosive peroxides during storage, *e.g.* diethyl ether, 1,4-dioxan

R30 Can become highly flammable in use

for preparations not in themselves classified as flammable, which may become flammable due to the loss of non-flammable volatile components

R44 Risk of explosion if heated under confinement

for substances and preparations not in themselves classified as explosive in accordance with paragraph 2.2.1 but which may nevertheless display explosive properties in practice if heated under sufficient confinement. For example, certain substances that would decompose explosively if heated in a steel drum do not show this effect if heated in less-strong containers

For other additional risk phrases see paragraph 3.2.8.

3 CLASSIFICATION ON THE BASIS OF TOXICOLOGICAL PROPERTIES

3.1 Introduction

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

If adequate evidence is available to demonstrate that in practice the toxic effect of substances and preparations on man is, or is likely to be, different from that suggested by the experimental results obtained in animal tests or by the application of the conventional method referred to in Regulation 9, details of which are provided in Annex IX, then such substances and preparations should be classified according to their toxicity in man. The evidence referred to includes epidemiological studies, scientifically valid case studies as specified in this Annex, and statistically backed experience such as the assessment of data from poison information units or concerning occupational diseases. However, tests on man are discouraged and should not normally be used to negate positive animal data.

Directive 86/609/EEC [35] serves to protect animals used for experimental and other scientific purposes. For several endpoints there are validated *in vitro* test methods in Annex V and these should be used where appropriate.

3.1.2 The classification of substances must be made on the basis of the experimental data available in accordance with the following criteria, which take into account the magnitude of these effects:

(a) for acute toxicity (lethal and irreversible effects after a single exposure), the criteria specified in paragraphs 3.2.1 to 3.2.3 are to be used;

(b) for subacute, subchronic or chronic toxicity the criteria specified in paragraphs 3.2.2 to 3.2.4 are to be used;

(c) for corrosive and irritant effects the criteria specified in paragraphs 3.2.5 and 3.2.6 are to be used;

(d) for sensitising effects the criteria specified in paragraph 3.2.7 are to be used;

(e) for specific effects on health (carcinogenicity, mutagenicity and reproductive toxicity), the criteria specified in Chapter 4 are to be used.

3.1.3. For preparations, classification in relation to danger for health must be carried out:

(a) on the basis of the conventional method referred to in Regulation 9, details of which are provided in Annex IX, in the absence of experimental data. Where the conventional method is used, the classification must be based on the individual concentration limits taken from:

- either Annex I,
- or provided for in Annex IX, where the substance or substances do not appear in Annex I, or appear in it without concentration limits; or

(b) when experimental data are available, in accordance with the criteria described in paragraph 3.1.2 – however carcinogenic, mutagenic and toxic to reproduction properties referred to under 3.1.2 (e) must be evaluated using the conventional method specified in Annex IX.

Whichever method is used for the evaluation of the danger of a preparation, all the dangerous effects addressed in Annex IX must be taken into consideration.

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

3.1.5 The acute oral toxicity of substances or preparations placed on the market may be established through use of a method permitting assessment of the LD_{50} value, by determining the discriminating dose (the fixed dose procedure) or by determining the range of exposure where lethality may be expected (the acute toxic class method).

3.1.5.1 The discriminating dose is the dose that causes evident toxicity but not mortality and must be one of the four dosage levels specified in Annex V (5, 50, 500 or 2,000 mg per kg body weight).

The concept "evident toxicity" is used to designate toxic effects, after exposure to the substance tested, which are so severe that exposure to the next highest fixed dose would probably lead to mortality.

The results of testing at a particular dose following the fixed dose method may be either:

- less than 100 % survival,
- 100 % survival, but evident toxicity,
- 100 % survival, but no evident toxicity.

The criteria in paragraphs 3.2.1, 3.2.2 and 3.2.3 only include the final test result. The 2,000 mg/kg dose should be used primarily to obtain information on the toxic effects of substances which are of low acute toxicity and which are not classified on the basis of acute toxicity.

The test method requires in some cases testing at higher or lower doses, if not already tested at the relevant dose level. Refer also to the evaluation table in test method B.1 *bis* of Annex V.

3.1.5.2 The range of exposure where lethality may be expected is derived from the observed absence or presence of substance related mortality where the acute toxic class method has been used. For initial testing one of three fixed starting doses (25, 200 or 2,000 mg/kg body weight) should be used.

3.2 Criteria for classification, choice of symbols, indication of danger, choice of risk phrases

3.2.1 *Very toxic*

Substances and preparations shall be classified as very toxic, and assigned the symbol "T +" and the indication of danger "very toxic" in accordance with the criteria specified below.

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

R28 Very toxic if swallowed

acute toxicity results:

- LD_{50} oral, rat ≤ 25 mg/kg
- less than 100 % survival at 5 mg/kg oral, rat using the fixed dose procedure, or

- high mortality at doses ≤ 25 mg/kg oral, rat, using the acute toxic class method (for test result interpretation see the flow charts in Appendix 2 to test method B.1 *ter* of Annex V)

R27 Very toxic in contact with skin

acute toxicity results:

- LD_{50} dermal, rat or rabbit: ≤ 50 mg/kg

R26 Very toxic by inhalation

acute toxicity results:

- LC_{50} inhalation, rat, for aerosols or particulates: ≤ 0.25 mg/litre/4hr
- LC_{50} inhalation, rat, for gases and vapours: ≤ 0.5 mg/litre/4hr.

R39 Danger of very serious irreversible effects

- strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above mentioned dose range.

In order to indicate the route of administration/exposure one of the following combinations shall be used: R39/26, R39/27, R39/28, R39/26/27, R39/26/28, R39/27/28, R39/26/27/28.

3.2.2 *Toxic*

Substances and preparations shall be classified as toxic and assigned the symbol "T" and the indication of danger "toxic" in accordance with the criteria specified below. Risk phrases shall be assigned in accordance with the following criteria.

R25 Toxic if swallowed

acute toxicity results:

- LD_{50} oral, rat: $25 < LD_{50} \leq 200$ mg/kg
- discriminating dose, oral, rat, 5 mg/kg: 100 % survival but evident toxicity, or
- high mortality at doses < 25 to ≤ 200 mg/kg oral, rat, using the acute toxic class method (for test result interpretation see the flow charts in Appendix 2 to test method B.1 *ter* of Annex V)

R24 Toxic in contact with skin

acute toxicity results:

- LD_{50} dermal, rat or rabbit: $50 < LD_{50} \leq 400$ mg/kg.

R23 Toxic by inhalation

acute toxicity results:

- LC_{50} inhalation, rat, for aerosols or particulates: $0.25 < LC_{50} \leq 1$ mg/litre/4hr
- LC_{50} inhalation, rat, for gases and vapours: $0.5 < LC_{50} \leq 2$ mg/litre/4hr

R39 Danger of very serious irreversible effects

- strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above mentioned dose range

In order to indicate the route of administration/exposure one of the following combinations shall be used: R39/23, R39/24, R39/25, R39/23/24, R39/23/25, R39/24/25, R39/23/24/25.

R48 Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which has toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route

Substances and preparations are classified at least as Toxic when these effects are observed at levels of one order of magnitude lower (*i.e.* 10- fold) than those set out for R48 in paragraph 3.2.3.

In order to indicate the route of administration/exposure one of the following combinations shall be used: R48/23, R48/24, R48/25, R48/23/24, R48/23/25, R48/24/25, R48/23/24/25.

3.2.3 *Harmful*

Substances and preparations shall be classified as harmful and assigned the symbol "Xn" and the indication of danger "harmful" in accordance with the criteria specified below. Risk phrases shall be assigned in accordance with the following criteria:

R22 Harmful if swallowed

acute toxicity results:

- LD_{50} oral, rat: $200 < LD_{50} \leq 2{,}000$ mg/kg
- discriminating dose, oral, rat, 50 mg/kg: 100 % survival but evident toxicity
- less than 100 % survival at 500 mg/kg, rat oral by the fixed dose procedure. Refer to the evaluation table in the test method B1 (a) of Annex V, or
- high mortality at doses <200 to ≤ 2,000 mg/kg oral, rat, using the acute toxic class method (for test result interpretation see the flow charts in Appendix 2 to test method B.1 *ter* of Annex V).

R21 Harmful in contact with skin

acute toxicity results:

- LD_{50} dermal, rat or rabbit: $400 < LD_{50} \leq 2{,}000$ mg/kg

R20 Harmful by inhalation

acute toxicity results:

- LC_{50} inhalation, rat, for aerosols or particulates: $1 < LC_{50} \leq 5$ mg/litre/4hr
- LC_{50} inhalation, rat, for gases or vapours: $2 < LC_{50} \leq 20$ mg/litre/4hr.

R65 Harmful: may cause lung damage if swallowed

liquid substances and preparations presenting an aspiration hazard in humans because of their low viscosity:

(a) for substances and preparations containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration equal to or greater than 10 % and having either

- a flow time of less than 30 sec in a 3 mm ISO cup according to ISO 2431 (April 1996 / July 1999 edition) relating to "Paints and varnishes – Determination of flow time by use of flow cups", or
- a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7 x 10^{-6} m^2 / sec at 40 ºC (ISO 3104, 1994 edition, relating to "Petroleum products – Transparent and opaque liquids – Determination of kinematic viscosity and calculation of dynamic viscosity": ISO 3105, 1994 edition, relating to "Glass capillary kinematic viscometers – Specifications and operating instructions"), or
- a kinematic viscosity derived from measurements of rotational viscometry in accordance with ISO 3219 of less than 7 x 10^{-6} m^2 / sec at 40 ºC (ISO 3219, 1993 edition, relating to "Plastics – Polymers / resins in the liquid state or as emulsions or dispersions – Determination of viscosity using a rotational viscometer with defined shear rate");

> **Note:** substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33mN/m at 25 ºC as measured by the du Nouy tensiometer or by the test methods shown in Annex V Part A.5

(b) for substances and preparations, based on practical experience in humans.

R68 Possible risk of irreversible effects

- strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above mentioned dose range

In order to indicate route of administration/exposure one of the following combinations shall be used: R68/20, R68/21, R68/22, R68/20/21, R68/20/22, R68/21/22, R68/20/21/22.

R48 Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which has toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route

Substances and preparations are classified at least as harmful when these effects are observed at levels of the order of.

- oral, rat ≤ 50 mg/kg (body weight)/day,
- dermal, rat or rabbit ≤ 100mg/kg (body weight)/day,
- inhalation, rat ≤ 0.25 mg/l, 6h/day.

These guide values can apply directly when severe lesions have been observed in a subchronic (90-day) toxicity test. When interpreting the results of a sub-acute (28-day) toxicity test these figures should be increased approximately three fold. If a chronic (2-year) toxicity test is available it should be evaluated on a case-by-case basis. If results of studies of more than one duration are available, then those from the study of the longest duration should normally be used.

In order to indicate route of administration/exposure one of the following combinations shall be used: R48/20, R48/21, R48/22, R48/20/21, R48/20/22, R48/21/22, R48/20/21/22.

3.2.3.1 Comments regarding volatile substances

For certain substances with a high saturated vapour concentration evidence may be available to indicate effects that give cause for concern. Such substances may not be classified under the criteria for health effects in this Annex (paragraph 3.2.3) or not covered by the criteria in paragraph 3.2.8. However, where there is appropriate evidence that such substances may present a risk in normal handling and use then classification on a case-by-case basis in Annex I may be necessary.

3.2.4 Comments regarding the use of R48

Use of this risk phrase refers to the specific range of biological effects as outlined hereunder. For application of this risk phrase serious damage to health is to be considered to include death, clear functional disturbance and morphological changes which are toxicologically significant. It is particularly important when these changes are irreversible. It is also important to consider not only specific severe changes in a single organ or biological system but also generalised changes of a less severe nature involving several organs, or severe changes in general health status.

When assessing whether there is evidence of such effects reference should be made to the following guidelines:

1 evidence indicating that R48 should be applied:

(a) substance-related deaths;

(b) (i) major functional changes in the central or peripheral nervous systems, including sight, hearing and the sense of smell, assessed by clinical observations or other appropriate methods (*e.g.* electrophysiology),

(ii) major functional changes in other organ systems (for example the lung);

(c) any consistent changes in clinical biochemistry, haematology or urinalysis parameters which indicate severe organ dysfunction. Haematological disturbances are considered to be particularly important if the evidence suggests that they are due to decreased bone marrow production of blood cells;

(d) severe organ damage noted on microscopic examination following autopsy,

(i) widespread or severe necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity (*e.g.* liver),

(ii) severe morphological changes that are potentially reversible but are clear evidence of marked organ dysfunction (*e.g.* severe fatty change in the liver, severe acute tubular nephrosis in the kidney, ulcerative gastritis), or

(iii) evidence of appreciable cell death in vital organs incapable of regeneration (*e.g.* fibrosis of the myocardium or dying back of a nerve) or in stem cell populations (*e.g.* aplasia or hypoplasia of the bone marrow).

The above evidence will most usually be obtained from animal experiments. When considering data derived from practical experience special attention should be given to exposure levels.

2 Evidence indicating that R48 should not be applied

The use of this risk phrase is restricted to "serious damage to health by prolonged exposure". A number of substance-related effects may be observed in both humans and animals that would not justify the use of R48. These effects are relevant when attempting to determine a no-effect level for a chemical substance.

Examples of well documented changes which would not normally justify classification with R48, irrespective of their statistical significance, include:

(a) clinical observations or changes in bodyweight gain, food consumption or water intake, which may have some toxicological importance but which do not, by themselves, indicate "serious damage";

(b) small changes in clinical biochemistry, haematology or urinalysis parameters which are of doubtful or minimal toxicological importance;

(c) changes in organ weights with no evidence of organ dysfunction;

(d) adaptative responses (*e.g.* macrophage migration in the lung, liver hypertrophy and enzyme induction, hyperplastic responses to irritants). Local effects on the skin produced by repeated dermal application of a substance which are more appropriately classified with R38 "irritating to skin"; or

(e) where a species-specific mechanism of toxicity (*e.g.* specific metabolic pathways) has been demonstrated.

3.2.5 *Corrosive*

Substances and preparations shall be classified as corrosive and assigned the symbol "C" and the indication of danger "Corrosive" in accordance with the following criteria:

- a substance or a preparation shall be considered corrosive if, when it is applied to healthy intact animal skin, it produces full thickness destruction of skin tissue on at least one animal during the test for skin irritation cited in Annex V or during an equivalent test,

- classification can be based on the results of a validated *in vitro* test such as that cited in Annex V (B.40 Skin corrosion: rat skin transcutaneous electrical resistance assay and human skin model assay),

- a substance or a preparation shall also be considered corrosive if the result can be predicted, for example from strongly acid or alkaline reactions indicated by a pH of 2 or less or 11.5 or greater. Where extreme pH is the basis for classification, alkaline / acidic reserve may also be taken into consideration (J.R. Young, M.J. How, A.P. Walker and W.M.H. Worth (1998), "Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals", Toxic. *In Vitro* 2(1): pp 19-26). If consideration of alkaline or acidic reserve suggests that the substance or preparation may not be corrosive then further testing should be carried out to confirm this, preferably using an appropriate validated *in vitro* test. Consideration of alkaline or acidic reserve should not be used alone to exonerate substances or preparations from classification as corrosive.

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

R35 Causes severe burns

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

R34 Causes burns

- if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to four hours exposure, or if this result can be predicted
- organic hydroperoxides, except where evidence to the contrary is available.

Note: Where classification is based upon the results of a validated *in vitro* test, R35 or R34 should be applied in accordance with the capacity of the test method to discriminate between the suitability of the two phrases.

Where classification is based upon consideration of extreme pH alone, R35 should be applied

3.2.6 *Irritant*

Substances and preparations shall be classified as irritant and assigned the symbol "Xi" and the indication of danger "irritant" in accordance with the criteria specified hereunder.

3.2.6.1 Inflammation of the skin

The following risk phrase shall be assigned in accordance with the criteria specified:

R38 Irritating to skin

- substances and preparations which cause significant inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours determined on the rabbit according to the cutaneous irritation test method cited in Annex V

  Inflammation of the skin is significant if:

  (a) the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is 2 or more, or

  (b) in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of 2 or more calculated for each animal separately has been observed in two or more animals.

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

  Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation time. Particular effects *e.g.* hyperplasia, scaling, discoloration, fissures, scabs and alopecia should be taken into account.

  Relevant data may also be available from non-acute animal studies (see comments on R48). These are considered significant if the effects seen are comparable to those described above.

- substances and preparations that cause significant inflammation of the skin, based on practical observations in humans on immediate, prolonged or repeated contact
- Organic peroxides, except where evidence to the contrary is available.

Paresthesia:

Paresthesia caused in humans by skin contact with pyrethroid pesticides is not regarded as an irritant effect justifying classification as Xi; R38. The S-phrase S24 should however be applied for substances seen to cause this effect.

3.2.6.2 Ocular lesions

The following risk phrases shall also be assigned in accordance with the criteria specified hereunder:

R36 Irritating to eyes

- substances and preparations which, when applied to the eye of the animal, cause significant ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours

  Ocular lesions are significant if the mean scores of the eye irritation test cited in Annex V have any of the following values:

  - cornea opacity equal to or greater than 2 but less than 3
  - iris lesion equal to or greater than 1 but not greater than 1.5
  - redness of the conjunctivae equal to or greater than 2.5
  - oedema of the conjunctivae (chemosis) equal to or greater than 2

  or, in the case where the Annex V test has been completed using three animals if the lesions on two or more animals are equivalent to any of the above values, except that for iris lesion the value should be equal to or greater than 1 but less than 2 and for redness of the conjunctivae the value should be equal to or greater than 2.5

  In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values.
- substances or preparations which cause significant ocular lesions, based on practical experience in humans
- organic peroxides except where evidence to the contrary is available

R41 Risk of serious damage to eyes

- substances and preparations which, when applied to the eye of the animal cause severe ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours

  Ocular lesions are severe if the means of the scores of the eye irritation test in Annex V have any of the values:

  - cornea opacity equal to or greater than 3
  - iris lesion greater than 1.5

  The same shall be taken to be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values:

  - cornea opacity equal to or greater than 3

- iris lesion equal to 2

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

Ocular lesions are also severe when they are still present at the end of the observation time.

Ocular lesions are also severe if the substance or preparation causes irreversible coloration of the eyes.

- substances and preparations that cause severe ocular lesions, based on practical experience in humans

Note: When a substance or preparation is classified "corrosive" and assigned R34 or R35, the risk of severe damage to eyes is considered implicit and R41 is not included in the label.

3.2.6.3 Respiratory system irritation

The following risk phrase shall be assigned in accordance with the criteria specified:

R37 Irritating to respiratory system

- substances and preparations that cause serious irritation to the respiratory system based on:
  - practical observation in humans.
  - positive results from appropriate animal tests

Comments regarding the use of R37

In interpreting practical observations in humans, care should be taken to distinguish between effects which lead to classification with R48 (see paragraph 3.2.4) from those leading to classification with R37. Conditions normally leading to classification with R37 are reversible and usually limited to the upper airways.

Positive results from appropriate animal tests may include data obtained in a general toxicity test, including histopathological data relating to the respiratory system. Data from the measurement of experimental bradypnea may also be used to assess airway irritation.

3.2.7 *Sensitisation*

3.2.7.1 Sensitisation by inhalation

Substances and preparations shall be classified as sensitising and assigned the symbol "Xn", the indication of danger "Harmful" and the risk phrase R42 in accordance with the criteria specified hereunder:

R42 May cause sensitisation by inhalation

- if there is evidence that the substance or preparation can induce specific respiratory hypersensitivity,
- where there are positive results from appropriate animal tests, or
- if the substance is an isocyanate, unless there is evidence that the substance does not cause respiratory hypersensitivity.

Comments regarding the use of R42

Human evidence

Evidence that the substance can induce specific respiratory hypersensitivity will normally be based on human experience. In this context hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis and alveolitis must also be considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms need not be demonstrated.

When considering the evidence following human exposure, it is necessary for a decision on classification to take into account in addition to the evidence from the cases:

- the size of the population exposed, and
- the extent of exposure.

The evidence referred to above could be clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence that may include:

- a chemical structure related to substances known to cause respiratory hypersensitivity;
- *in vivo* immunological test (*e.g.* skin prick test);
- *in vitro* immunological test (*e.g.* serological analysis);
- studies that may indicate other specific, but non-immunological mechanisms of action, *e.g.* repeated low level irritation, pharmacologically mediated effects; or
- data from a positive bronchial challenge test with the substance, conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance or preparation and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood, and smoking history.

The results of positive bronchial challenge tests are considered to provide sufficient evidence on their own for classification. It is however recognised that in practice that many of the examinations listed above will already have been carried out.

Substances that elicit symptoms of asthma by irritation only in people with bronchial hyper-reactivity should not be assigned R42.

Animal Studies

Data from tests that may be indicative of the potential of a substance to cause sensitisation by inhalation in humans may include:

- IgE measurements (*e.g.* in mice), and
- specific pulmonary responses in guinea pigs.

3.2.7.2 Sensitisation by skin contact

Substances and preparations shall be classified as sensitising and assigned the symbol "Xi", the indication of danger "Irritant" and the risk phrase R43 in accordance with the criteria given hereunder:

R43 May cause sensitisation by skin contact

- if practical experience shows the substance or preparation to be capable of inducing sensitisation by skin contact in a substantial number of persons,
- where there are positive results from an appropriate animal test

Comments regarding the use of R43

Human evidence

The following evidence (practical experience) is sufficient to classify a substance or preparation with R43:

- positive data from appropriate patch testing, normally in more than one dermatological clinic;
- epidemiological studies showing allergic contact dermatitis caused by the substance or preparation. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small; or
- positive data from experimental studies in man (see also paragraph 3.1.1).

The following is sufficient to classify a substance with R43 when there is supportive evidence:

- isolated episodes of allergic contact dermatitis; or
- epidemiological studies where chance, bias or confounders have not been ruled out fully with reasonable confidence.

Supportive evidence may include:

- data from animal tests performed according to existing guidelines, with a result that does not meet the criteria given in the section on animal studies but is sufficiently close to the limit to be considered significant;
- data from non-standard methods; or
- appropriate structure-activity relationships.

Animal studies

Positive results from appropriate animal tests are:

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

3.2.7.3 Immunological contact urticaria

Some substances or preparations that meet the criteria for R42 may in addition cause immunological contact urticaria. In these cases, information concerning contact urticaria should be included by the use of appropriate S-phrases, usually S24 and S36/37, and in the Safety Data Sheet.

For substances or preparations, which produce signs of immunological contact urticaria, which do not fulfil the criteria for R42, consideration should be given to classification with R43.

There is no recognised animal model available to identify substances that cause immunological contact urticaria. Therefore, classification is normally based on human evidence similar to that for skin sensitisation (R43).

3.2.8 *Other toxicological properties*

Additional risk phrases shall be assigned in accordance with the following criteria (based on experience obtained during compilation of Annex I) to substances and preparations classified by virtue of paragraphs 2.2.1 to 3.2.7 above and/or chapters 4 and 5:

R29 Contact with water liberates toxic gas

substances and preparations which in contact with water or damp air, evolve very toxic/toxic gases in potentially dangerous amounts, *e.g.* aluminium phosphide, phosphorus pentasulphide

R31 Contact with acids liberates toxic gas

substances and preparations which react with acids to evolve toxic gases in dangerous amounts, *e.g.* sodium hypochlorite, barium polysulphide. For substances used by members of the general public, the use of S50 (do not mix with ... (*to be proposed by the manufacturer*)) would be more suitable

R32 Contact with acids liberates very toxic gas

substances and preparations which react with acids to evolve very toxic gases in dangerous amounts; *e.g.* salts of hydrogen cyanide, sodium azide. For substances used by members of the general public, the use of S50 (do not mix with ... (*to be proposed by the manufacturer*)) would be more suitable

R33 Danger of cumulative effects

substances and preparations likely to accumulate in the human body and may cause some concern which, however, is not sufficient to justify the use of R48

For comments on use for substances of R33 see paragraph 4.2.3.3 and for preparations see paragraph 3 of Part of Annex XII

R64 May cause harm to breastfed babies

substances and preparations absorbed by women and that may interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child

For comments on the use for substances of R64 (and in some cases R33) see paragraph 4.2.3.3 and for preparations see paragraph 4 of Part A of Annex XII.

R66 Repeated exposure may cause skin dryness or cracking

substances and preparations that may cause concern as a result of skin dryness, flaking or cracking but which do not meet the criteria for R38:

based on either:

- practical observation after normal handling and use, or
- relevant evidence concerning their predicted effects on the skin.

See also paragraphs 1.6 and 1.7.

R67 Vapours may cause drowsiness and dizziness

volatile substances and preparations containing such substances which cause clear symptoms of central nervous system depression by inhalation and which are not already classified with respect to acute inhalation toxicity (R20, R23, R26, R68/20, R39/23 or R39/26).

The following evidence may be used:

(a) data from animal studies showing clear signs of CNS depression such as narcotic effects, lethargy, lack of co-ordination (including loss of righting reflex) and ataxia either:

- at concentrations/exposure times not exceeding 20 mg/l/4h or,
- for which the ratio of the effect concentration at ≤ 4 h to the saturated vapour concentration (SVC) at 20ºC is ≤ 1/10.

b) practical experience in humans (*e.g.* narcosis, drowsiness, reduced alertness, loss of reflexes, lack of co-ordination, vertigo) from well-documented reports under comparable exposure conditions to the effects specified above for animals.

See also paragraphs 1.6 and 1.7.

For other supplementary risk phrases see paragraph 2.2.6.

4 CLASSIFICATION ON THE BASIS OF SPECIFIC EFFECTS ON HUMAN HEALTH

4.1 Introduction

4.1.1 This chapter sets out the procedure to be followed for the classification of substances which may have the effects mentioned below. For preparations see paragraph 4.2.4.

4.1.2 If a manufacturer, distributor or importer has information available which indicates that a substance should be classified and labelled in accordance with the criteria in paragraphs 4.2.1, 4.2.2 or 4.2.3, he shall provisionally label the substance in accordance with these criteria, on the basis of the assessment of the evidence by a competent person.

4.1.3 The manufacturer, distributor or importer shall submit as soon as possible a document summarising all relevant information to one Member State in which the substance is placed on the market. Relevant information in this context comprises in particular all available published and unpublished information required for appropriate classification of the substance in question, on the basis of its intrinsic properties and the criteria specified in this Annex. This summary document submitted should include a bibliography containing all relevant references, including any relevant unpublished data.

4.1.4 Furthermore, a manufacturer, distributor or importer who has new data which are relevant to the classification and labelling of a substance in accordance with the criteria in paragraphs 4.2.1, 4.2.2 or 4.2.3, shall submit this data as soon as possible to one Member State in which the substance is placed on the market.

4.1.5 In order to obtain as quickly as possible a harmonised classification for the European Union by means of the procedure defined in Article 28 of the Directive of 1967, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information together with suggestions for classification and labelling, to the European Commission as soon as possible.

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

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

4.2 Criteria for classification, indication of danger, choice of risk phrases

4.2.1 Carcinogenic substances

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

Category 1

Substances known to be carcinogenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2

Substances that should be regarded as if they are carcinogenic to man.

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

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

Category 3

Substances that cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate to make a satisfactory assessment.

There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.

4.2.1.1 The following symbols and specific risk phrases apply:

Categories 1 and 2: **T; R45 May cause cancer**

However for substances and preparations which present a carcinogenic risk only when inhaled, for example, as dust, vapour or fumes, (other routes of exposure *e.g.* by swallowing or in contact with skin do not present any carcinogenic risk), the following symbol and specific risk phrase should be used:

T; R49 May cause cancer by inhalation

Category 3: **Xn; R40 Limited evidence of a carcinogenic effect**

4.2.1.2 Comments regarding the categorisation of carcinogenic substances

The placing of a substance into Category 1 is done on the basis of epidemiological data; placing into Categories 2 and 3 is based primarily on animal experiments.

For classification as a Category 2 carcinogen either positive results in two animal species should be available or clear positive evidence in one species, together with supporting evidence such as genotoxicity data, metabolic or biochemical studies, induction of benign tumours, structural relationship with other known carcinogens, or data from epidemiological studies suggesting an association.

Category 3 actually comprises 2 sub-categories:

(a) substances which are well investigated but for which the evidence of a tumour-inducing effect is insufficient for classification in Category 2. Additional experiments would not be expected to yield further relevant information with respect to classification;

(b) substances which are insufficiently investigated. The available data are inadequate, but they raise concern for man. This classification is provisional; further experiments are necessary before a final decision can be made.

For a distinction between Categories 2 and 3 the arguments listed below are relevant which reduce the significance of experimental tumour induction in view of possible human exposure. These arguments, especially in combination, would lead in most cases to classification in Category 3, even though tumours have been induced in animals:

- carcinogenic effects observed only at very high dose levels exceeding the "maximal tolerated dose". The maximal tolerated dose is characterized by toxic effects which, although not yet reducing lifespan, go along with physical changes such as about 10 % retardation in weight gain;
- appearance of tumours, especially at high dose levels, only in particular organs of certain species known to be susceptible to a high spontaneous tumour formation;
- appearance of tumours, only at the site of application, in very sensitive test systems (*e.g.* ip or sc application of certain locally active compounds), if the particular target is not relevant to man;
- lack of genotoxicity in short-term tests *in vivo* and *in vitro*;
- existence of a secondary mechanism of action with the implication of a practical threshold above a certain dose level (*e.g.* hormonal effects on target organs or on mechanisms of physiological regulation, chronic stimulation of cell proliferation);
- existence of a species-specific mechanism of tumour formation (*e.g.* by specific metabolic pathways) irrelevant for man.

For a distinction between Category 3 and no classification the following arguments are relevant which exclude a concern for man:

- a substance should not be classified in any of the categories if the mechanism of experimental tumour formation is clearly identified, with good evidence that this process cannot be extrapolated to man;
- if the only available tumour data are liver tumours in certain sensitive strains of mice, without any other supplementary evidence, the substance may not be classified in any of the categories;
- particular attention should be paid to cases where the only available tumour data are the occurrence of neoplasms at sites and in strains where they are well known to occur spontaneously with a high incidence.

4.2.2 Mutagenic substances

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

Category 1

Substances known to be mutagenic to man.

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

Category 2

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

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

- appropriate animal studies,
- other relevant information.

Category 3

Substances that cause concern for man owing to possible mutagenic effects.

There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in Category 2.

4.2.2.2 The following symbols and specific risk phrases apply:

Category 1: **T; R46 May cause heritable genetic damage**

Category 2: **T; R46 May cause heritable genetic damage**

Category 3: **Xn; R68 Possible risk of irreversible effects**

4.2.2.3 Comments regarding the categorisation of mutagenic substances

Definition of terms:

A mutation is a permanent change in the amount or structure of the genetic material in an organism, resulting in a change of the phenotypic characteristics of the organism. The alterations may involve a single gene, a block of genes, or a whole chromosome. Effects involving single genes may be a consequence of effects on single DNA bases (point mutations) or of large changes, including deletions, within the gene. Effects on whole chromosomes may involve structural or numerical changes. A mutation in the germ cells in sexually reproducing organisms may be transmitted to the offspring. A mutagen is an agent that gives rise to an enhanced occurrence of mutations.

It should be noted that substances are classified as mutagens with specific reference to inherited genetic damage. However, the type of results leading to classification of chemicals in Category 3: "induction of genetically relevant events in somatic cells", is generally also regarded as an alert for possible carcinogenic activity.

Method development for mutagenicity testing is an ongoing process. For many new tests no standardised protocols and evaluation criteria are presently available. For the evaluation of mutagenicity data the quality of the test performance and the degree of validation of the test method have to be considered.

Category 1

To place a substance in Category 1, positive evidence from human mutation epidemiology studies will be needed. Examples of such substances are not known to date. It is recognised that it is extremely difficult to obtain reliable information from studies on the incidence of mutations in human populations, or on possible increases in their frequencies.

Category 2

To place a substance in Category 2, positive results are needed from assays showing (a) mutagenic effects, or (b) other cellular interactions relevant to mutagenicity, in germ cells of mammals *in vivo*, or (c) mutagenic effects in somatic cells of mammals *in vivo* in combination with clear evidence that the substance or a relevant metabolite reaches the germ cells.

With respect to placement in Category 2, at present the following methods are appropriate:

(a) *in vivo* germ cell mutagenicity assays:

- specific locus mutation test,
- heritable translocation test,
- dominant lethal mutation test.

These assays demonstrate the appearance of affected progeny or a defect in the developing embryo.

(b) *in vivo* assays showing relevant interaction with germ cells (usually DNA):

- assays for chromosomal abnormalities, as detected by cytogenetic analysis, including aneuploidy, caused by malsegregation of chromosomes,
- test for sister chromatid exchanges (SCEs),
- test for unscheduled DNA synthesis (UDS),
- assay of (covalent) binding of mutagen to germ cell DNA,
- assaying other kinds of DNA damage.

These assays provide evidence of a more or less indirect nature. Positive results in these assays would normally be supported by positive results from *in vivo* somatic cell mutagenicity assays, in mammals or in man (see under Category 3, preferably methods as under (a)).

(c) *in vivo* assays showing mutagenic effects in somatic cells of mammals (see under Category 3 (a)), in combination with toxicokinetic test results, or other tests capable of demonstrating that the compound or a relevant metabolite reaches the germ cells.

In the case of the tests at (b) and (c), positive results from host-mediated assays or the demonstration of unequivocal effects *in vitro* can be considered supporting evidence.

Category 3

To place a substance in Category 3, positive results are needed in assays showing (a) mutagenic effects or (b) other cellular interaction relevant to mutagenicity, in somatic cells in mammals *in vivo*. The latter especially would normally be supported by positive results from *in vitro* mutagenicity assays.

For effects in somatic cells *in vivo* at present the following methods are appropriate:

(a) *in vivo* somatic cell mutagenicity assays:

- bone marrow micronucleus test or metaphase analysis,
- metaphase analysis of peripheral lymphocytes,
- mouse coat colour spot test.

(b) *in vivo* somatic cell DNA interaction assays:

- test for SCEs in somatic cells,
- test for UDS in somatic cells,
- assay for the (covalent) binding of mutagen to somatic cell DNA,
- assay for DNA damage *e.g.* by alkaline elution, in somatic cells.

Substances showing positive results only in one or more *in vitro* mutagenicity assays should normally not be classified. Their further investigation using *in vivo* assays, however, is strongly indicated. In exceptional cases *e.g.* for a substance showing pronounced responses

in several *in vitro* assays, for which no relevant *in vivo* data are available, and which shows resemblance to known mutagens / carcinogens, classification in Category 3 could be considered.

4.2.3 Substances toxic to reproduction

4.2.3.1 For the purposes of classification and labelling and having regard to the present state of knowledge, such substances are divided into 3 categories:

Category 1 Substances known to impair fertility in humans

There is sufficient evidence to establish a causal relationship between human exposure to the substance and impaired fertility.

Substances known to cause developmental toxicity in humans

There is sufficient evidence to establish a causal relationship between human exposure to the substance and subsequent developmental toxic effects in the progeny.

Category 2 Substances which should be regarded as if they impair fertility in humans

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of:

- clear evidence in animal studies of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary non-specific consequence of the other toxic effects,
- other relevant information.

Substances which should be regarded as if they cause developmental toxicity to humans:

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in developmental toxicity, generally on the basis of:

- clear results in appropriate animal studies where effects have been observed in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects,
- other relevant information.

Category 3 Substances which cause concern for human fertility

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which is not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,
- other relevant information.

Substances which cause concern for humans owing to possible developmental toxic effects

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-

specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,

- other relevant information.

4.2.3.2 The following symbols and specific risk phrases apply:

Category 1:

For substances that impair fertility in humans:	**T;**	**R60: May impair fertility**
For substances that cause developmental toxicity:	**T;**	**R61: May cause harm to the unborn child**

Category 2:

For substances that should be regarded as if they impair fertility in humans:	**T;**	**R60: May impair fertility**
For substances that should be regarded as if they cause developmental toxicity in: humans	**T;**	**R61: May cause harm to the unborn child**

Category 3:

For substances which cause concern for human fertility:	**Xn;**	**R62: Possible risk of impaired fertility**
For substances which cause concern for humans owing to possible developmental toxic effects:	**Xn;**	**R63: Possible risk of harm to the unborn child**

4.2.3.3 Comments regarding the categorisation of substances toxic to reproduction

Reproductive toxicity includes impairment of male and female reproductive functions or capacity and the induction of non-inheritable harmful effects on the progeny. This may be classified under two main headings of 1) effects on male or female fertility and 2) developmental toxicity.

1) *Effects on male or female fertility*, includes adverse effects on libido, sexual behaviour, any aspect of spermatogenesis or oogenesis, or on hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or the development of the fertilised ovum up to and including implantation.

2) *Developmental toxicity*, is taken in its widest sense to include any effect interfering with normal development, both before and after birth. It includes effects induced or manifested prenatally as well as those manifested postnatally. This includes embrytoxic/foetotoxic effects such as reduced body weight, growth and developmental retardation, organ toxicity, death, abortion, structural defects (teratogenic effects), functional defects, peri-postnatal defects, and impaired postnatal mental or physical development up to and including normal pubertal development.

The classification of chemicals as toxic to reproduction relates to chemicals that have an intrinsic or specific property that produce such toxic effects. Chemicals should not be classified as toxic to reproduction where such effects are solely produced as a non-specific secondary consequence of other toxic effects. Chemicals of most concern are those that are toxic to reproduction at exposure levels which do not produce other signs of toxicity.

The placing of a compound in Category 1 because of effects on fertility and/or developmental toxicity is done on the basis of epidemiological data. Placement into Categories 2 or 3 is done primarily on the basis of animal experimental data. Data from *in vitro* studies, or studies on avian eggs, are regarded as "supportive evidence" and would only exceptionally lead to classification in the absence of *in vivo* data.

In common with most other types of toxic effect, substances demonstrating reproductive toxicity are expected to have a threshold below which adverse effects would not be demonstrated. Even when clear effects have been demonstrated in animal studies the relevance for humans may be doubtful because of the doses administered, for example, where effects have been demonstrated only at high doses, or where marked toxicokinetic differences exist, or the route of administration is inappropriate. For these or similar reasons it may be that classification in Category 3, or even no classification, will be warranted.

It is specified in Annex V that a limit test be used in the case of substances of low toxicity. If a dose level of at least 1,000 mg/kg administered orally produces no evidence of effects of toxicity to reproduction, studies at other dose levels may not be considered necessary. If data are available from studies carried out with doses higher than the above limit dose, this data must be evaluated together with other relevant data. Under normal circumstances it is considered that effects seen only at doses in excess of the limit dose would not necessarily lead to classification as "Toxic to reproduction".

Effects on fertility

For the classification of a substance into Category 2 because of impaired fertility, there should normally be clear evidence in one animal species, with supporting evidence in relation to the mechanism of action or the site of action, or chemical relationship to other known anti-fertility agents or other information from humans which would lead to the conclusion that effects would be likely to be seen in humans. Where there are studies in only one species without other relevant supporting evidence then classification in Category 3 may be appropriate.

Since impaired fertility may occur as a non-specific accompaniment to severe generalised toxicity or where there is severe inanition, classification into Category 2 should only be made where there is evidence that there is some degree of specificity of toxicity for the reproductive system. If it was demonstrated that impaired fertility in animal studies was due to failure to mate, then for classification into Category 2, it would normally be necessary to have evidence on the mechanism of action in order to interpret whether any adverse effect such as alteration in pattern of hormonal release would be likely to occur in humans.

Developmental toxicity

For classification into Category 2 there should be clear evidence of adverse effects in well conducted studies in one or more species. Since adverse effects in pregnancy or postnatally may be a secondary consequence of maternal toxicity, reduced food or water intake, maternal stress, lack of maternal care, specific dietary deficiencies, poor animal husbandry, intercurrent infections, and so on, it is important that the effects observed should occur in well conducted studies and at dose levels which are not associated with marked maternal toxicity. The route of exposure is also important. In particular, the injection of irritant material intraperitoneally may result in local damage to the uterus and its contents, and the results of such studies must be interpreted with caution and on their own would not normally lead to classification.

Classification into Category 3 is based on similar criteria as for Category 2 but may be used where the experimental design has deficiencies which make the conclusions less convincing,

or where the possibility that the effects may have been due to non-specific influences such as generalised toxicity cannot be excluded.

In general, classification into Category 3 or no category would be assigned on an *ad hoc* basis where the only effects recorded are small changes in the incidences of spontaneous defects, small changes in the proportions of common variants such as are observed in skeletal examinations, or small differences in postnatal developmental assessments.

Effects during lactation

Substances that are classified as toxic to reproduction and which also cause concern due to their effects on lactation should in addition be labelled with R64 (see criteria in paragraph 3.2.8.).

For the purpose of classification, toxic effects on offspring resulting only from exposure *via* breast milk, or toxic effects resulting from direct exposure of children will not be regarded as "Toxic to reproduction", unless such effects result in impaired development of the offspring.

Substances that are not classified as toxic to reproduction but which cause concern due to toxicity when transferred to the baby during the period of lactation should be labelled with R64 (see criteria in paragraph 3.2.8.). This R-phrase may also be appropriate for substances that affect the quantity or quality of the milk.

R64: May cause harm to breastfed babies

would normally be assigned on the basis of:

(a) toxicokinetic studies that indicate the likelihood that the substance would be present in potentially toxic levels in breast milk; and/or

(b) on the basis of results of one or two generation studies in animals which indicate the presence of adverse effects on the offspring due to transfer in the milk; and/or

(c) on the basis of evidence in humans indicating a risk to babies during the lactation period.

Substances that are known to accumulate in the body and that subsequently may be released into milk during lactation may be labelled with R33 and R64.

4.2.4 Procedure for the classification of preparations concerning specific effects on health

If a preparation contains one or more substances classified with respect to the criteria laid out above, it must be classified according to the criteria referred to in Regulation 9 (the concentration limits are either in Annex I, or in Annex IX where the substance or substances under consideration do not appear in Annex I or appear in it without concentration limits).

5 CLASSIFICATION ON THE BASIS OF ENVIRONMENTAL EFFECTS

5.1 Introduction

The primary objective of classifying substances dangerous for the environment is to alert the user to the hazards these substances and preparations present to ecosystems. Although the present criteria refer to aquatic ecosystems it is recognised that certain substances and preparations may simultaneously or alternatively affect other ecosystems whose constituents may range from soil microflora and microfauna to primates.

The criteria set out below follow directly from the test methods set out in Annex V in so far as they are mentioned. The test methods required for the "base set" referred to in Annex VII of the Directive of 1967 are limited and the information derived from them may be insufficient for an appropriate classification. Classification may require additional data derived from Level 1 (Annex VIII of the Directive of 1967; Annex II of the Directive of 1991 or Annexes II, III and IV of the Directive of 1998) or other equivalent studies. Furthermore, classified substances may be subject to review in the light of other new data.

For the purposes of classification and labelling and having regard to the current state of knowledge such substances and preparations are divided into two groups according to their acute and/or long-term effects in aquatic systems or their acute and/or long-term effects in non-aquatic systems.

5.1.1 The classification of substances shall generally be made on the basis of experimental data for acute aquatic toxicity, degradation and log P_{ow} (or BCF if available).

5.1.2 The classification of preparations shall normally be made on the basis of a conventional method referred to in Regulation 10 details of which are provided in Annex X. Where the conventional method is used, the classification must be based on the individual concentration limits taken from:

- either Annex I,
- or provided for in Annex X, where the substance or substances do not appear in Annex I, or appear in it without concentration limits.

5.2 Criteria for classification, indication of danger, choice of risk phrases

The classification criteria for substances in paragraph 5.2.1 are only applicable to preparations tested as specified in paragraph 5.1.3.

5.2.1 Aquatic environment

5.2.1.1 Substances shall be classified as dangerous for the environment and assigned the symbol "N" and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R50: Very toxic to aquatic organisms

and

R53: May cause long-term adverse effects in the aquatic environment

acute toxicity:		96 hr LC_{50} (for fish)	≤ 1 mg/l
	or	48 hr EC_{50} (for *Daphnia*)	≤ 1 mg/l

or 72 hr IC_{50} (for algae) ≤ 1 mg/l

and the substance is not readily degradable, or

or the log P_{ow} (log octanol/water partition coefficient) ≥ 3.0 (unless the experimentally determined BCF ≤ 100)

R50: Very toxic to aquatic organisms

acute toxicity:		96 hr LC_{50} (for fish)	≤ 1 mg/l
	or	48 hr EC_{50} (for *Daphnia*)	≤ 1 mg/l
	or	72 hr IC_{50} (for algae)	≤ 1 mg/l

R51: Toxic to aquatic organisms

and

R53: May cause long-term adverse effects in the aquatic environment

acute toxicity:		96 hr LC_{50} (for fish)	1 mg/l < LC_{50} ≤ 10 mg/l
	or	48 hr EC_{50} (for *Daphnia*)	1 mg/l < EC_{50} ≤ 10 mg/l
	or	72 hr IC_{50} (for algae)	1 mg/l < EC_{50} ≤ 10 mg/l

and the substance is not readily degradable, or

the log P_{ow} ≥ 3.0 (unless the experimentally determined BCF ≤ 100)

5.2.1.2 Substances shall be classified as dangerous for the environment in accordance with the criteria set out below. Risk phrases shall also be assigned in accordance with the following criteria

R52: Harmful to aquatic organisms

and

R53: May cause long-term adverse effects in the aquatic environment

acute toxicity:		96 hr LC_{50} (for fish)	10 mg/l < LC_{50} ≤ 100 mg/l
	or	48 hr EC_{50} (for *Daphnia*)	10 mg/l < EC_{50} ≤ 100 mg/l
	or	72 hr IC_{50} (for algae)	10 mg/l < EC_{50} ≤ 100 mg/l

and the substance is not readily degradable

This criterion applies unless additional scientific evidence concerning degradation and/or toxicity exists sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment. Such additional scientific evidence should normally be based on the studies required at Level 1 (Annex VIII of the Directive of 1967, Annex II of the Directive of 1991 or Annexes II, III or IV of the Directive of 1998), or studies of equivalent value, and could include:

(i) a proven potential to degrade rapidly in the aquatic environment,

(ii) absence of chronic toxicity effects at a concentration of 1.0 mg/litre, *e.g.* a no-observed effect concentration of greater than 1.0 mg/litre determined in a prolonged toxicity study with fish or Daphnia.

R52: Harmful to aquatic organisms

substances not falling under the criteria listed above in this chapter, but which on the basis of the available evidence concerning their toxicity may nevertheless present a danger to the structure and/or functioning of aquatic ecosystems.

R53: May cause long-term adverse effects in the aquatic environment

substances not falling under the criteria listed above in this chapter, but which, on the basis of the available evidence concerning their persistence, potential to accumulate, and predicted or observed environmental fate and behaviour may nevertheless present a long-term and/or delayed danger to the structure and/or functioning of aquatic ecosystems.

For example, poorly water-soluble substances, *i.e.* substances with a solubility of less than 1 mg/l will be covered by this criterion if:

(a) they are not readily degradable; and

(b) the log $P_{ow} \geq 3.0$ (unless the experimentally determined BCF ≤ 100)

This criterion applies unless additional scientific evidence concerning degradation and/or toxicity exists sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment.

Such additional scientific evidence should normally be based on the studies required at Level 1 (Annex VIII of the Directive of 1967, Annex II of the Directive of 1991 or Annexes II, III or IV of the Directive of 1998), or studies of equivalent value, and could include:

(i) a proven potential to degrade rapidly in the aquatic environment;

(ii) absence of chronic toxicity effects at the solubility limit *e.g.* a no-observed effect concentration of greater than the solubility limit determined in a prolonged toxicity study with fish or Daphnia.

5.2.1.3 Comments on the determination of IC_{50} for algae and of degradability

- where it can be demonstrated in the case of highly coloured substances and preparations that algal growth is inhibited solely as a result of a reduction in light intensity, then the 72-hour IC_{50} for algae should not be used as a basis for classification,
- substances are considered readily degradable if the following criteria hold true -
  (a) if in 28-day biodegradation studies the following levels of degradation are achieved
    - in tests based upon dissolved organic carbon: 70%,
    - in tests based upon oxygen depletion or carbon dioxide generation: 60 % of the theoretical maximum,

  these levels of biodegradation must be achieved within 10 days of the start of degradation, which point is taken as the time when 10 % of the substance has been degraded;

  or

  (b) if in those cases where only COD and BOD_5 data are available when the ratio of BOD_5/COD is greater than or equal to 0.5;

or

(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of > 70% within a 28-day period.

5.2.2 Non - aquatic environment

5.2.2.1 Substances shall be classified as dangerous for the environment and assigned the symbol "N" and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R54: Toxic to flora

R55: Toxic to fauna

R56: Toxic to soil organisms

R57: Toxic to bees

R58: May cause long-term adverse effects in the environment

substances which on the basis of the available evidence concerning their toxicity, persistence, potential to accumulate and predicted or observed environmental fate and behaviour may present a danger, immediate or long-term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered under paragraph 5.2.1 above. Detailed criteria will be elaborated at a later date.

5.2.2.2 Substances shall be classified as dangerous for the environment and assigned the symbol "N" and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R59: Dangerous for the ozone layer

substances which on the basis of the available evidence concerning their properties and their predicted or observed environmental fate and behaviour may present a danger to the structure and/or the functioning of the stratospheric ozone layer. This includes the substances that are listed in Annex 1 to Council Regulation (EC) No 3093/94 on substances that deplete the ozone layer [39] and its subsequent amendments.

Preparations shall be classified on the basis of the conventional method specified in Regulation 10, details of which are provided in Annex X.

[39] O.J. No. L 333/1 22/12/1994

6 CHOICE OF SAFETY ADVICE PHRASES

6.1 Introduction

Safety advice phrases (S-phrases) shall be assigned to dangerous substances and preparations in accordance with the following general criteria. In addition, for certain preparations, the safety advice listed in Annex XII is mandatory.

Whenever the manufacturer is mentioned in Chapter 6 it refers to the person responsible for placing the substance or preparation on the market.

6.2 Safety phrases for substances and preparations

S1 Keep locked up

Applicability:

- very toxic, toxic and corrosive substances and preparations.

Criteria for use:

- *obligatory* for those substances and preparations mentioned above if sold to the general public.

S2 Keep out of the reach of children

Applicability:

- all dangerous substances and preparations.

Criteria for use:

- *obligatory* for all dangerous substances and preparations sold to the general public, except for those only classified as dangerous for the environment.

S3 Keep in a cool place

Applicability:

- organic peroxides,
- other dangerous substances and preparations having a boiling point ≤ 40° C.

Criteria for use:

- *obligatory* for organic peroxides unless S47 is used,
- *recommended* for other dangerous substances and preparations having a boiling point ≤ 40°C.

S4 Keep away from living quarters

Applicability:

- very toxic and toxic substances and preparations.

Criteria for use:

- normally limited to very toxic and toxic substances and preparations when desirable to supplement S13; for example when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters

S5 Keep contents under ... (*appropriate liquid to be proposed by the manufacturer*)

Applicability:

- spontaneously flammable solid substances and preparations.

Criteria for use:

- normally limited to special cases, *e.g.* sodium, potassium or white phosphorous.

S6 Keep under ... (*inert gas to be proposed by the manufacturer*)

Applicability:

- dangerous substances and preparations which must be kept under an inert atmosphere.

Criteria for use:

- normally limited to special cases, *e.g.* certain organo-metallic compounds.

S7 Keep container tightly closed

Applicability:

- organic peroxides,
- substances and preparations which can give off very toxic, toxic, harmful or extremely flammable gases,
- substances and preparations which in contact with moisture give off extremely flammable gases,
- highly flammable solids.

Criteria for use:

- *obligatory* for organic peroxides,
- recommended for the other fields of application mentioned above.

S8 Keep container dry

Applicability:

- substances and preparations which may react violently with water,
- substances and preparations which on contact with water liberate extremely flammable gases,
- substances and preparations which on contact with water liberate very toxic or toxic gases.

Criteria for use:

- normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R14, R15 in particular, and R29.

S9 Keep container in a well-ventilated place

Applicability:

- volatile substances and preparations which may give off very toxic, toxic or harmful vapours,
- extremely flammable or highly flammable liquids and extremely flammable gases.

Criteria for use:

- recommended for volatile substances and preparations which may give off very toxic, toxic or harmful vapours,
- recommended for extremely flammable or highly flammable liquids or extremely flammable gases.

S12 Do not keep the container sealed

Applicability:

- substances and preparations that by giving off gases or vapours are liable to burst the container.

Criteria for use:

- normally limited to the special cases mentioned above.

S13 Keep away from food, drink and animal feeding stuffs

Applicability:

- very toxic, toxic and harmful substances and preparations.

Criteria for use:

- recommended when such substances and preparations are likely to be used by the general public.

S14 Keep away from ... (*incompatible materials to be proposed by the manufacturer)*

Applicability:

- organic peroxides

Criteria for use:

- *obligatory* for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to product a particular risk

S15 Keep away from heat

Applicability:

- substances and preparations that may decompose or which may react spontaneously under the effect of heat.

Criteria for use:

- normally limited to special cases, *e.g.* monomers, but not assigned if risk phrases R2, R3 and/or R5 have already been applied.

S16 Keep away from sources of ignition - No smoking

Applicability:

- extremely flammable or highly flammable liquids and extremely flammable gases.

Criteria for use:

- recommended for the substances and preparations mentioned above but not assigned if risk phrases R2, R3 and/or R5 have already been applied.

S17 Keep away from combustible material

Applicability:

- substances and preparations which may form explosive or spontaneously flammable mixtures with combustible material.

Criteria for use:

- available for use in special cases *e.g.* to emphasise R8 and R9.

S18 Handle and open container with care

Applicability:

- substances and preparations liable to produce an overpressure in the container,
- substances and preparations which may form explosive peroxides.

Criteria for use:

- normally limited to the above-mentioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely to be used by the general public.

S20 When using do not eat or drink

Applicability:

- very toxic, toxic and corrosive substances and preparations.

Criteria for use:

- normally limited to special cases (*e.g.* arsenic and arsenic compounds; fluoracetates) in particular when any of these are likely to be used by the general public.

S21 When using do not smoke

Applicability:

- substances and preparations which produce toxic products on combustion.

Criteria for use

- normally limited to special cases (*e.g.* halogenated compounds).

S22 Do not breathe dust

Applicability:

- all solid substances and preparations dangerous for health.

Criteria for use:

- *obligatory* for those substances and preparations mentioned above to which R42 is assigned,
- recommended for those substances and preparations mentioned above which are supplied in the form of an inhalable dust and for which the health hazards following inhalation are not known.

S23 **Do not breathe gas/fumes/vapour/spray** (*appropriate wording to be proposed by the manufacturer*)

Applicability:

- all liquid or gaseous substances and preparations dangerous to health.

Criteria for use:

- *obligatory* for those substances and preparations mentioned above to which R42 is assigned,
- *obligatory* for substances and preparations intended for use by spraying. Either S38 or S5I must be ascribed in addition,
- recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have to be ascribed.

S24 **Avoid contact with skin**

Applicability:

- all substances and preparations dangerous for health.

Criteria for use:

- *obligatory* for those substances and preparations to which R43 has been ascribed, unless S36 has also been ascribed,
- recommended when it is necessary to draw the attention of the user to skin contact risks not mentioned in the risk phrases (*e.g.* paresthesia) which have to be ascribed. However, may be used to emphasise such risk phrases.

S25 **Avoid contact with eyes**

Applicability:

- all substances and preparations dangerous to health.

Criteria for use:

- recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be applied. However, may be used to emphasis such risk phrases,
- recommended for substances ascribed R34, R35, R36 or R41 which are likely to be used by the general public.

S26 **In case of contact with eyes, rinse immediately with plenty of water and seek medical advice**

Applicability:

- corrosive or irritant substances and preparations.

Criteria for use:

- *obligatory* for corrosive substances and preparations and those to which R41 has already been ascribed,
- recommended for irritant substances and preparations to which the risk phrase R36 has already been ascribed.

S27 **Take off immediately all contaminated clothing.**

Applicability:

- very toxic, toxic or corrosive substances and preparations.

Criteria for use:

- *obligatory* for very toxic substances and preparations to which R27 has been ascribed and which are likely to be used by the general public,
- recommended for very toxic substances and preparations to which R27 has been ascribed used in industry. However, this safety phrase should not be used if S36 has been ascribed,
- recommended for toxic substances and preparations to which R24 has been ascribed as well as corrosive substances and preparations which are likely to be used by the general public.

S28 After contact with skin, wash immediately with plenty of ... (*to be proposed by the manufacturer*)

Applicability:

- very toxic, toxic or corrosive substances and preparations.

Criteria for use:

- *obligatory* for very toxic substances and preparations,
- recommended for the other substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid.
- recommended for corrosive substances and preparations which are likely to be used by the general public.

S29 Do not empty into drains

Applicability:

- extremely or highly flammable liquids immiscible with water,
- very toxic and toxic substances and preparations,
- substances and preparations dangerous for the environment

Criteria for use:

- *obligatory* for substances and preparations dangerous for the environment and assigned the symbol "N", which are likely to be used by the general public, unless this is the intended use,
- recommended for other substances and preparations mentioned above which are likely to be used by the general public, unless this is the intended use.

S30 Never add water to this product

Applicability:

- substances and preparations which react violently with water.

Criteria for use:

- normally limited to special cases (*e.g.* sulphuric acid) and may be used, as appropriate, to give the clearest possible information, either to emphasise R14 or as an alternative to R14.

S33 Take precautionary measures against static discharges

Applicability:

- extremely or highly flammable substances and preparations.

Criteria for use:

- recommended for substances and preparations used in industry which do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by the general public.

S35 This material and its container must be disposed of in a safe way

Applicability:

- all dangerous substances and preparations

Criteria for use:

- recommended for substances and preparations where special guidance is needed to ensure proper disposal.

S36 Wear suitable protective clothing

Applicability:

- organic peroxides,
- very toxic, toxic or harmful substances and preparations,
- corrosive substances and preparations.

Criteria for use:

- *obligatory* for very toxic and corrosive substances and preparations,
- *obligatory* for those substances and preparations to which either R21 or R24 has been ascribed,
- *obligatory* for category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substance or preparation,
- *obligatory* for organic peroxides,
- recommended for toxic substances and preparations if the LD_{50} dermal value is unknown but the substance or preparation is likely to be toxic through skin contact,
- recommended for substances and preparations used in industry which are liable to damage health by prolonged exposure.

S37 Wear suitable gloves

Applicability:

- very toxic, toxic, harmful or corrosive substances and preparations,
- organic peroxides,
- substances and preparations irritating to the skin or causing sensitisation by skin contact,

Criteria for use:

- *obligatory* for very toxic and corrosive substances and preparations,

- *obligatory* for those substances and preparations to which either R21, R24 or R43 has been ascribed,
- *obligatory* for Category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substances and preparations,
- *obligatory* for organic peroxides,
- recommended for toxic substances and preparations if the LD_{50} dermal value is unknown but the substance or preparation is likely to be harmful by skin contact,
- recommended for substances and preparations irritating to the skin.

S38 In case of insufficient ventilation, wear suitable respiratory equipment

Applicability:

- very toxic or toxic substances and preparations.

Criteria for use:

- normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture.

S39 Wear eye/face protection

Applicability:

- organic peroxides,
- corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes,
- very toxic and toxic substances and preparations.

Criteria for use:

- *obligatory* for those substances and preparations to which R34, R35 or R41 have been ascribed,
- *obligatory* for organic peroxides,
- recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be ascribed,
- normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin.

S40 To clean the floor and all objects contaminated by this material use ... (*to be proposed by the manufacturer*)

Applicability:

- all dangerous substances and preparations.

Criteria for use:

- normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (*e.g.* where absorption by powdered material, dissolution by solvent etc. is necessary) and where it is important for health and/or safety reasons to provide a warning on the label.

S41 In case of fire and/or explosion do not breathe fumes

Applicability:

- dangerous substances and preparations which on combustion give off very toxic or toxic gases.

Criteria for use:

- normally limited to special cases.

S42 **During fumigation/spraying wear suitable respiratory equipment** (*appropriate wording to be proposed by the manufacturer*)

Applicability:

- substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken.

Criteria for use:

- normally limited to special cases.

S43 **In case of fire use ...** (*indicate in the space the precise type of fire-fighting equipment. If water increases the risk add*: Never use water)

Applicability:

- extremely flammable, highly flammable and flammable substances and preparations.

Criteria for use:

- *obligatory* for substances and preparations which, in contact with water or damp air, evolve extremely flammable gases,
- recommended for extremely flammable, highly flammable and flammable substances and preparations, particularly when they are immiscible with water.

S45 **In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)**

Applicability:

- very toxic substances and preparations,
- toxic and corrosive substances and preparations,
- substances and preparations causing sensitisation by inhalation.

Criteria for use:

- *obligatory* for the substances and preparations mentioned above.

S46 **If swallowed, seek medical advice immediately and show this container or label**

Applicability:

- all dangerous substances and preparations other than those which are very toxic, toxic, corrosive or dangerous to the environment.

Criteria for use:

- *obligatory* for all dangerous substances and preparations mentioned above which are likely to be used by the general public, unless there is no reason to fear any danger from swallowing, particularly by children.

S47 **Keep at temperature not exceeding ... ° C** (*to be proposed by the manufacturer*)

Applicability:

- substances and preparations which become unstable at a certain temperature.

Criteria for use:

- normally limited to special cases (*e.g.* certain organic peroxides).

S48 **Keep wetted with** .... (appropriate material to be proposed by the manufacturer)

Applicability:

- substances and preparations which may become very sensitive to sparks, friction or impact if allowed to dry out.

Criteria for use:

- normally limited to special cases, *e.g.* nitro-celluloses.

S49 **Keep only in the original container**

Applicability:

- substances and preparations sensitive to catalytic decomposition.

Criteria for use:

- substances and preparations sensitive to catalytic decomposition *e.g.* certain organic peroxides.

S50 **Do not mix with** ... (*to be proposed by the manufacturer*)

Applicability:

- substances and preparations which may react with the specified product to evolve very toxic or toxic gases,
- organic peroxides.

Criteria for use:

- *obligatory* with certain peroxides which may give violent reaction with accelerators or promoters,
- recommended for substances and preparations mentioned above which are likely to be used by the general public, when it is a better alternative to R31 or R32.

S51 **Use only in well-ventilated areas**

Applicability:

- substances and preparations likely to or intended to produce vapours, dusts, sprays, fumes, mists, *etc.* which give rise to inhalation risks or to a fire or explosion risk

Criteria for use:

- recommended when use of S38 would not be appropriate. Thus important when such substances and preparations are likely to be used by the general public.

S52 **Not recommended for interior use on large surface areas**

Applicability:

- volatile, very toxic, toxic and harmful substances and preparations containing them.

Criteria for use:

- recommended when damage to health is likely to be caused by prolonged exposure to these substances by reason of their volatilization from large treated surfaces in the home or other enclosed places where persons congregate.

S53 Avoid exposure - obtain special instructions before use

Applicability:

- substances and preparations that are carcinogenic, mutagenic and/or toxic to reproduction.

Criteria for use:

- *obligatory* for the above mentioned substances and preparations to which at least one of the following R-phrases has been assigned : R45, R46, R49, R60 or R61.

S56 Dispose of this material and its container to hazardous or special waste collection point.

Applicability:

- all dangerous substances and preparations.

Criteria for use:

- recommended for all dangerous substances and preparations likely to be used by the general public for which special disposal is required.

S57 Use appropriate containment to avoid environmental contamination

Applicability:

- substances and preparations that have been assigned the symbol “N”.

Criteria for use:

- normally limited to substances and preparations not likely to be used by the general public.

S59 Refer to manufacturer for information on recovery/recycling

Applicability:

- all dangerous substances and preparations.

Criteria for use:

- *obligatory* for substances and preparations dangerous for the ozone layer,
- recommended for other substances and preparations for which recovery/recycling is recommended.

S60 This material and its container must be disposed of as hazardous waste

Applicability:

- all dangerous substances and preparations.

Criteria for use:

- recommended for substances and preparations not likely to be used by the general public and where S35 is not assigned.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheet

Applicability:

- substances dangerous for the environment.

Criteria for use:

- normally used for substances that have been assigned the symbol "N",
- recommended for all substances classified dangerous for the environment not covered above.

S62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

Applicability:

- substances and preparations classified as harmful with R65 in accordance with the criteria in paragraph 3.2.3.
- not applicable to substances and preparations which are placed on the market in aerosol containers (or in containers fitted with a sealed spray attachment), see Chapters 8 and 9.

Criteria for use:

- *obligatory* for substances and preparations mentioned above, if sold to, or likely to be used by the general public, except when S45 or S46 are obligatory.
- recommended for the substances and preparations mentioned above when used in industry, except where S45 or S46 are obligatory.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest

Applicability:

- very toxic and toxic substances and preparations (gases, vapours, particulates, volatile liquids),
- substances and preparations causing respiratory sensitisation.

Criteria for use:

- *obligatory* for substances and preparations to which R26, R23 or R42 has been assigned which are likely to be used by the general public in a way which could result in inhalation.

S64 If swallowed, rinse mouth with water (only if the person is conscious)

Applicability:

- corrosive or irritant substances and preparations.

Criteria for use:

- recommended for the above substances and preparations which are likely to be used by the general public and where the above treatment is suitable.

7 LABELLING

7.1 When a substance or preparation has been classified, the appropriate label is determined with reference to the requirements of Article 23 of Directive of 1967 and Regulation 13 for substances and preparations respectively. This chapter provides an explanation as to how the label is determined and, in particular, gives guidance on how to choose the appropriate risk and safety phrases.

The label contains *inter alia* the following information:

(a) for preparations, its trade name or designation;

(b) for substances the name of the substance and for preparations the names of the substances present in accordance with the rules set out paragraph (1) of Regulation 13;

(c) name, full address and telephone number of the person responsible for placing the substance or preparation on the market, whether manufacturer, importer or distributor;

(d) symbols and indication of danger;

(e) phrases indicating particular risks (risk phrases);

(f) phrases indicating safety advice (safety phrases);

(g) for substances, the EC number, and in addition for substances appearing in Annex I, the words "EC label";

(h) for preparations offered or sold to the general public the nominal quantity of the contents unless specified on the package.

Note: Additional labelling requirements are set out in paragraph (1) of Regulation 13

7.1.1 Final choice of risk and safety phrases

Although the final choice of the most appropriate risk and safety phrases is primarily governed by the need to give all necessary information, consideration should also be given to the clarity and impact of the label. With clarity in mind, the necessary information should be expressed in a minimum number of phrases.

In the case of irritant, highly flammable, flammable and oxidising substances, the relevant risk phrases and safety phrases need not be given where the package does not contain more than 125ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

For preparations, if the contents of the package do not exceed 125 ml:

- if classified as highly flammable, oxidising, irritant, with the exception of those assigned the phrase R41, or dangerous for the environment and assigned the symbol "N", it shall not be necessary to include the risk and safety phrases assigned,
- if classified as flammable or dangerous for the environment and not assigned the symbol "N", it shall be necessary to include the risk phrases but not the safety phrases assigned.

7.1.2 Indications such as "non-toxic", "non-harmful", "non-polluting", "ecological"or any other such indication that the preparation is not dangerous or that is likely to lead to underestimation of the dangers of the substance or preparation, must not appear on the label or packaging of any substance or preparation.

7.1.3 For certain preparations, Annex XII contains special provisions concerning labelling.

7.2 Chemical name(s) to be displayed on the label

7.2.1 For substances listed in Annex I the label shall show the name of the substances under one of the designations given in Annex I.

For substances not listed in Annex I, the name must be established according to an internationally recognised chemical nomenclature as specified in paragraph 1.4 above.

7.2.2 For preparations, the choice of names to be displayed on the label follows the rules specified in Regulation 13.

Note: The name of sensitising substances must be chosen in accordance with the requirements specified in paragraph 7.2.1

In the case of concentrate preparations intended for the perfume industry:

- the person responsible for placing them on the market may identify merely the sensitising substance judged by him to be primarily responsible for the sensitisation hazard.
- in the case of a natural substance, the chemical name may be of the type: 'essential oil of ...' 'extract of ...', rather than the name of the constituents of that essential oil or extract

7.3 Choice of danger symbols

The design of the danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II. The symbol shall be printed in black on an orange-yellow background.

7.3.1 For substances appearing in Annex I the danger symbols and indications of danger shall be those shown in the Annex.

7.3.2 For dangerous substances not yet appearing in Annex I and for preparations, the danger symbols and indications of danger shall be assigned according to the rules laid down in this Annex.

Where more than one danger symbol is assigned to a substance or preparation

- the obligation to indicate the symbol E makes the symbols F+, F and O optional.
- the obligation to indicate the symbol T+ or T makes the symbols Xn, Xi and C optional,
- the obligation to indicate the symbol C makes the symbols Xn and Xi optional
- if the symbol Xn is assigned, the symbol Xi is optional.

7.4 Choice of Risk phrases

The wording of the risk phrases shall comply with that laid down in Annex III. The combined risk phrases in Annex III shall be used where applicable.

7.4.1 For substances appearing in Annex I, the risk phrases shall be those shown in the Annex.

7.4.2 For substances not appearing in Annex I, risk phrases will be selected according to the following criteria and priorities:

(a) in the case of dangers which give rise to health effects,

(i) risk phrases corresponding to the category of danger illustrated by a symbol must appear on the label,

(ii) risk phrases corresponding to other categories of danger which are not illustrated by a symbol by virtue of Article 23 of the Directive of 1967;

(b) in the case of dangers arising from physico-chemical properties,

- risk phrases corresponding to the category of danger illustrated by a symbol must appear on the label;

c) in the case of dangers for the environment,

- risk phrases corresponding to the classification category "dangerous for the environment" must appear on the label.

7.4.3 For preparations, risk phrases shall be selected according to the following criteria and priorities:

(a) in the case of dangers which give rise to health effects,

(i) risk phrases that correspond to the category of danger illustrated by a symbol. In certain cases the risk phrases must be adopted according to the criteria specified in Annex IX. More specifically, the risk phrases of the constituent(s) responsible for the assignment to the preparation of a danger category must appear on the label,

(ii) risk phrases which correspond to other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol by virtue of Regulation 13;

(b) in the case of dangers arising from physico-chemical properties,

- the criteria of subparagraph 7.4.3 (a) are applicable, except that the risk phrases "extremely flammable" or "highly flammable" need not be indicated where they repeat the wording of the indication of danger used with a symbol.

(c) in the case of dangers arising for the environment

(i) risk phrases corresponding to the classification category "dangerous for the environment" must appear on the label,

(ii) where the risk phrase R50 has been assigned in addition to the combined risk phrase R51/53 or R52/53 or in addition to the risk phrase R53, the combined risk phrase R50/53 shall be used.

As a general rule, for preparations a maximum of six risk phrases shall suffice to describe the risk; for this purpose the combined phrases listed in Annex III shall be regarded as single phrases. However, if the preparation falls within more than one category of danger, the standard phrases must cover all the principal hazards associated with the preparation. In some cases more than six phrases may be necessary.

7.5 Safety phrases

The wording of safety phrases shall comply with that laid down in Annex IV.

The combined safety phrases in Annex IV shall be used where applicable.

7.5.1 For substances appearing in Annex I, the safety phrases shall be those shown in the Annex. Where no safety phrases are shown, appropriate safety phrase(s) may be included. For preparations, safety phrases shall be selected in accordance with the criteria specified in Chapter 6 of this Annex.

7.5.2 Choice of safety phrases

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

- 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 shall be regarded as single phrases,
- in the case of S-phrases concerning disposal, one S- phrase shall be used, unless it is clear that disposal of the material and its container does not present a danger for human health or the environment. In particular, advice on safe disposal is important for substances and preparations sold to the general public,
- some R-phrases become superfluous if a careful selection is made of S-phrases and *vice versa*; S-phrases which obviously correspond to risk phrases will appear on the label only if it is intended to emphasise a specific warning,
- particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations *e.g.* spraying or other aerosol effects. Phrases should be chosen with the intended use in view,
- the safety phrases S1, S2 and S45 are obligatory for all very toxic, toxic and corrosive substances and preparations sold to the general public,
- the safety phrases S2 and S46 are obligatory for all other dangerous substances and preparations (except those only classified as dangerous for the environment) sold to the general public.

Where the phrases selected according to the criteria specified in accordance with paragraph 6.2 result in redundancy or ambiguity or are clearly unnecessary given the specific product/package, then some phrases may be deleted.

7.6 The EC number

If a substance named on the label is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or in the European List of Notified Substances (ELINCS), the EINECS or ELINCS number of the substances shall be shown on the label. This requirement does not apply to preparations.

7.7 Dimensions of the label for preparations

The dimensions of the label shall be as follows:

Capacity of the package	*Dimensions (in millimeters)*
- not exceeding 3 litres	if possible, at least 52 x 74
- greater than 3 litres but not exceeding 50 litres	at least 74 x 105
- greater than 50 litres but not exceeding 500 litres	at least 105 x 148
- greater than 500 litres	at least 148 x 210

Each symbol shall cover at least one-tenth of the surface area of the label but shall not be less than one square centimetre. The label shall be firmly affixed to one or more surfaces of the packaging immediately containing the preparation.

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

8 SPECIAL CASES: SUBSTANCES

8.1 Mobile gas cylinders

For mobile gas cylinders the requirements concerning labelling are considered to be satisfied when they are in agreement with Article 23 or Article 24 (6) (b) of the Directive of 1967.

However, by way of derogation from Article 24 (1) and (2) of the Directive of 1967, one of the following alternatives can be used for gas cylinders with a water capacity of less than or equal to 150 litres:

- the format and dimensions of the label can follow the prescriptions of the ISO Standard ISO/DP 7225,
- the information specified in Article 23 (2) of the Directive of 1967 may be provided on a durable information disc or label held captive on the cylinder.

8.2 Gas containers intended for propane, butane or liquefied petroleum gas (LPG)

These substances are classified in Annex I. Although classified in accordance with Article 2 of the Directive of 1967, they do not present a danger to human health when they are placed on the market in closed refillable cylinders or in non-refillable cartridges in compliance with EN 417, as fuel gases which are only released for combustion. (EN 417, September 1992 edition, relating to "Non-refillable metallic gas cartridges for liquefied petroleum gases, with or without a valve, for use with portable appliances; construction, inspection, testing and marking")

These cylinders or cartridges must be labelled with the appropriate symbol and the risk and safety phrases concerning flammability. No information concerning effects on human health is required on the label. However, the information concerning effects on human health which should have appeared on the label shall be transmitted to the professional user by the person responsible for placing the substance on the market in the format foreseen in Article 27 of the Directive of 1967 (Safety Data Sheet). For the consumer, sufficient information shall be transmitted to enable them to take all necessary measures for health and safety as foreseen in Article 1 paragraph 3 of Directive 91/155/EEC [37].

8.3 Metals in massive form

These substances are classified in Annex I or shall be classified in accordance with Article 6 of the Directive of 1967. However, some of these substances, although classified in accordance with Article 2 of the Directive of 1967 do not present a danger to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market. Such substances do not require a label according to Article 23 of the Directive of 1967. However, all the information which should have appeared on the label shall be transmitted to the user by the person responsible for placing the metal on the market, in a format foreseen in Article 27 of the Directive of 1967 (Safety Data Sheet).

8.4 Substances classified with R65

Substances classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.

9 SPECIAL CASES: PREPARATIONS

9.1 Gaseous preparations (gas mixtures)

For gaseous preparations, consideration must be given to:

- the evaluation of the physico-chemical properties,
- the evaluation of health hazards,
- the evaluation of environmental hazards.

9.1.1 Evaluation of physico-chemical properties

9.1.1.1 Flammability

The flammable properties of these preparations are determined in accordance with Regulation 8 on the basis of the methods specified in Part A of Annex V.

These preparations will be classified according to the results of the tests carried out in accordance with Annex V and the criteria specified in this annex.

However, by way of derogation, in the case of gaseous preparations produced to order in small amounts, the flammability of these gaseous mixtures can be evaluated by the following calculation method:

the expression of the gaseous mixture $A_1F_1 + . \ . + A_iF_i + . \ . \ A_nF_n + B_1I_1 + . \ . + B_iI_i + . \ . \ B_pI_p$

where: Ai and Bi are the molar fractions
F_i flammable gas
I_i inert gas
n number of flammable gases
p number of inert gases

can be transformed to a form where all the I_i (inert gases) are expressed in terms of a nitrogen equivalent using a coefficient K_i and where the equivalent content of inflammable gas A'_i is expressed as follows:

$$A'_i = A_i \times (100 / (A_i + K_iB_i))$$

Through use of the value of the maximum content of flammable gas which, in a mixture with nitrogen, gives a composition which is not flammable in air (Tci), the following expression can be obtained:

$$\Sigma_i \ A'_i / Tci \leq 1$$

The gas mixture is flammable if the value of the above expression is greater than one. The preparation is classified extremely flammable and, the phrase R12 is assigned.

Coefficients of equivalency (K_i)

The values of the coefficients of equivalency K_i, between the inert gases and nitrogen and the values of the maximum contents of flammable gas (Tci) may be found in Tables 1 and 2 of the ISO Standard ISO 10156 edition 15. 12. 1990 (new: 1996 edition) relating to "Gases and gas mixtures – Determination of fire potential and oxidising ability for the selection of cylinder valve outlets".

Maximum content of flammable gas (Tci)

The value of the maximum content of flammable gas (Tci) may be found in Table 2 of the ISO Standard ISO 10156 edition 15.12.1990 (new: 1996 edition) relating to "Gases and gas mixtures – Determination of fire potential and oxidising ability for the selection of cylinder valve outlets".

When a Tci value for a flammable gas does not appear in the above standard, the corresponding lower explosivity limit (LEL) will be used. If no LEL value exists, the value of Tci will be set at 1 % by volume.

Remarks

- the expression above can be used to select the appropriate labelling of gaseous preparations, however, it should not be regarded as a method for replacing experimentation for the determination of technical safety parameters,
- furthermore, the expression gives no information as to whether a mixture containing oxidizing gases can be prepared safely. When estimating flammability these oxidizing gases are not taken into account.
- the expression above will give reliable results only if the flammable gases do not influence each other as far as their flammability is concerned. This must be considered for example in the case of halogenated hydrocarbons.

9.1.1.2 Oxidizing properties

Since Annex V does not contain a method to determine the oxidizing properties of gaseous mixtures, the evaluation of these properties must be realised according to the following estimation method.

The principle of the method involves comparison of the oxidizing potential of gases in a mixture with that of the oxidizing potential of oxygen in air. The concentrations of gases in the mixture are expressed in % vol.

It is considered that the gas mixture is as oxidant as or more oxidant than air, if the following condition is verified:

$$\Sigma_i \, x_i C_i \geq 21$$

where: x_i is the concentration of gas i in % vol,
Ci is the coefficient of oxygen equivalency.

In this case, the preparation is classified as oxidizing and the phrase R8 must be assigned.

Coefficients of equivalency between oxidizing gases and oxygen

The coefficients used in the calculation to determine the oxidizing capacity of certain gases in a mixture with respect to the oxidizing capacity of oxygen in air, listed under point 5.2 in the ISO Standard ISO 10156, edition 15/12/1990 (new: 1996 edition) relating to "Gases and gas mixtures – Determination of fire potential and oxidising ability for the selection of cylinder valve outlets", are as follows.

O_2	1
N_2O	0.6

When no value for the Ci coefficient exists for a gas in the cited standard, a value of 40 is attributed to the coefficient.

9.1.3 Labelling

For mobile gas containers the requirements concerning labelling are deemed satisfied when they comply with Regulation 13.

However, by way of derogation for gas containers with a water capacity of less than or equal to 150 litres, the format and dimensions of the label can follow the prescriptions of the ISO Standard 7225 (1994 edition) relating to "Gas cylinders – Precautionary labels". In this case, the label can bear the generic name or industrial/commercial name of the preparation provided that the dangerous component substances of the preparation are shown on the body of the gas cylinder in a clear and indelible way.

The information to be included may be provided on a durable information disc or label held captive on the containers.

9.2 **Gas containers intended for preparations containing stenched propane, butane or liquefied petroleum gas (LPG)**

Propane, butane and liquefied petroleum gas are classified in Annex I. Although preparations containing these substances must be classified in accordance with the Directive of 1999, they do not present a danger to human health when they are placed on the market in closed refillable cylinders or in non-refillable cartridges within the scope on EN417 as fuel gases that are only released for combustion (EN 417, September 1992 edition, relating to "Non-refillable metallic gas cartridges for liquefied petroleum gases, with or without a valve, for use with portable appliances: construction, inspection, testing and marking".

Such cylinders and cartridges must be labelled with the appropriate symbol and the R- and S-phrases relating flammability. No information concerning effects on human health is required on the label. However, information concerning effects on human health that need not be included on the label, must be transmitted to professional users by the person responsible for placing the substance on the market in the format specified in Regulation 15 (Safety Data Sheet). For the consumer, sufficient information shall be transmitted to enable them to take all the necessary measures for health and safety as foreseen in paragraph 3 of Article 1 of Directive 91/155/EEC [37].

9.3 **Alloys, preparations containing polymers, preparations containing elastomers**

These preparations shall be classified according to the requirements of Regulations 8, 9 and 10 and labelled according to the requirements of Regulation 13.

However some of these preparations although satisfying the criteria for classification do not present a danger to human health by inhalation, ingestion or contact with the skin or to the aquatic environment in the form in which they are placed on the market. Such preparations do not require a label in accordance with Regulation 13. However, all the information that would otherwise have appeared on the label shall be transmitted to the professional user by means of an information system in a format specified in Regulation 15 (Safety data sheet).

9.4 **Preparations classified with R65**

Preparations classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R65 when placed on the market in aerosol containers or in containers with a sealed spray attachment.

9.5 **Organic peroxides**

Organic peroxides combine the properties of an oxidiser and a combustible substance in one molecule: when an organic peroxide decomposes, the oxidizing part of the molecule reacts exothermically with the combustible (oxidisable) part. In relation to oxidizing properties the existing methods included in Annex V cannot be applied to organic peroxides.

The following calculation method based on the presence of active oxygen must be used.

The available oxygen content (%) of an organic peroxide preparation is given by the formula:

$$16 \times \sum (ni \times ci/mi)$$

where: ni = number of peroxygen groups per molecule of organic peroxide i,
ci = concentration (mass %) of organic peroxide i,
mi = molecular mass of organic peroxide i.

9.6 **Additional labelling requirements for certain preparations**

For certain preparations, additional labelling requirements are specified in paragraph (1) of Regulation 13, in Annex XII and in Article 20 of the Directive of 1998.

SECOND SCHEDULE

Annex VII

ADDITIONAL SAFETY ADVICE

FS 1	Store / keep in original container, tightly closed, in a safe place / under lock and key / away from damp / sources of heat.
FS 2	Store / keep / apply / away from / install out of reach of pets / birds / bees / fish / (young) children and animals. or Keep / use / suspend only in positions inaccessible to children and pets / animals.
FS 3	Store unused sachets / mats / coils in a safe place. Do not store half-used sachets / mats / coils.
FS 4	Not to be used on food crops.
FS 5	For use only on (crop / foodstuff / surface / situation) for control of (process).
FS 6	To be used only by (professional) operators (instructed / or trained / in the use of chemical / product / type of product / and familiar with the precautionary measures to be observed).
FS 7	Do not spray / apply directly to livestock / poultry / pets /pets bedding / food / food crops / skin / children's clothing **.**
FS 8	Do not apply to clothing / fabric / bedding / hard / soft furnishings /hard porous / non-porous surfaces.
FS 9	Do not apply to those surfaces / on which food / feed is stored, prepared / or / eaten / which children are likely to touch.
FS 10	Do not prepare / use/ place bait / dust in / domestic kitchens / larders / food cupboards / where human or animal food or water could become contaminated.
FS 11	Do not use / spray in wet weather / strong winds / directly into breeze / wind.
FS 12	Avoid all contact by mouth / with skin / eyes.
FS 13	Avoid contact during pregnancy.

FS 14 Wear suitable respiratory equipment* / protective gloves / synthetic rubber gloves / PVC gloves / goggles / face shield / sou'wester / overalls / apron / impervious apron / mackintosh / boots / impervious boots / spray mask / dust mask / protective clothing (coveralls) / gauntlets and eye protection when handling / diluting / applying / spraying / dipping / using / removing / mixing the concentrate / liquid / dust / fumigant / bait / product / treated seed / freshly treated timber / trays / solution / growths from treated surfaces / and during maintenance of treatment equipment.

* a suitable type of respirator and canister should be specified.

or

Wear suitable protective clothing (coveralls) / suitable protective gloves / suitable respiratory protective equipment* when handling the concentrate / during application by hand-held equipment / during application by tractor drawn / mounted equipment

* dust mask

FS 15 Do not breathe dust / mist / smoke / fog / aerosol. (If necessary for personal comfort, wear a mask)

or

Avoid working in spray mist / smoke / fog.

FS 16 Wash off splashes immediately.

or

Wash splashes / dust / powder / concentrate / any contamination / paste / gel / from skin and eyes immediately.

FS 17 Wash hands and exposed skin / before eating, drinking or smoking and after work / before meals and after work / after use / handling

or

Wash hands before meals and after work.

FS 18 Extinguish all naked flames / including pilot lights / when applying the fumigant / dust / liquid / product.

FS 19 Do not apply /spray in the presence of / avoid / naked flames, hot surfaces / or / unprotected electrical equipment / any incandescent material.

FS 20 Do not work in confined spaces or enter spaces in which high concentrations of vapour are present. Where this precaution cannot be observed distance breathing or self-contained breathing apparatus must be worn, and the work should be done by trained operators.

FS 21 Ensure adequate ventilation when handling / applying (in confined spaces) / before and after treatment.

or

Wear (suitable) respiratory equipment during work in poorly ventilated areas / such as powered filtration or airline respiratory equipment with combined protective helmet and visor when spraying.

FS 22 Wash all protective clothing thoroughly after use, especially the insides of gloves.

or

Avoid excessive contamination of overalls / clothing and launder regularly.

FS 23 Do not handle seed unnecessarily.

FS 24 Not to be used as food or feed.

FS 25 Do not re-use sacks or containers that have been used for treated seed for food or feed.

or

Keep treated seed secure from people, domestic stock / pets and wildlife at all times during storage and use.

FS 26 Do not allow ... (product) ... to come into contact with food or cooking utensils.

or

Do not use on filter beds or sewage treatment works / internal timbers / suspended nests / uncovered food or grain, in grain storage or on food contact surfaces.

FS 27 Protect / cover food preparing equipment and eating utensils from contamination during application / before spraying.

or

Do not contaminate foodstuffs, eating utensils or food contact surfaces / other than storage boxes or containers / outdoor tables.

FS 28 Do not exceed use of one unit / strip per ... cu m (cu f).

FS 29 Do not apply more than ..... per (state amount).

FS 30 Do not apply more than ..... times per crop / season / time period.

FS 31 Keep children / pets / animals away from treated areas / baits for ..... hours / days / until dry.

FS 32 Remove / cover all / food / food processing equipment / eating utensils / foodstuffs / fish bowls / fish tanks / caged birds / pets / water storage tanks / before spraying / application / dusting / treatment.

FS 33 Protect exposed water / feed /milk machinery / milk containers from contamination.

or

Do not place bait / dust / gel in larders / food cupboards where human / or animal food / feed or water could become contaminated.

FS 34 Do not prepare / use / lay baits / dust / spray /operate dispenser where food / feed / water could become contaminated / in kitchens / or larders (when unwrapped food is stored) / in occupied hospital wards / in hospital operating theatres.

or

Do not use below level of damp proof course / in any buildings when livestock or other animals are kept or housed / as a broadcast treatment.

FS 35 Remove exposed milk / collect eggs before application.

or

Remove / all animals / pets / livestock / feed / exposed water / milk / collect eggs before application / spraying.

FS 36 Fumigate only under conditions that allow no leakage of gas to adjacent occupied premises.

or

Keep animals / birds out of premises where grain is under fumigation or being aired following fumigation.

FS 37 Do not harvest / crops for human / animal consumption / for at least (..... days/weeks) after last application.

or

Do not pick / gather / food / crops within ..... hours / days / weeks of treatment.

FS 38 For use on the following crops with stated minimum interval between last application and harvesting. Any table prepared should be based on cleared uses for the product in question. This safety information may be combined on the label with that on the efficient use of the product.

FS 39 Keep children / unprotected persons / livestock / pets / animals out of treated areas / for at least ..... (interval) / until walls / surfaces are dry / until / smoke has cleared / product / any product residue / the dust has been removed.

or

Ensure there is a physical barrier to prevent contact by unprotected persons and animals until treated surfaces are dry.

FS 40 Dangerous / Harmful to livestock. Keep all livestock / out of treated areas / away from treated water / for at least .... (interval). Bury or remove spillages.

or

Keep livestock out of treated areas for at least ..... (interval) / if poisonous weeds such as ragwort are present.

FS 41 Ventilate treated areas / rooms / confined spaces thoroughly / before occupying / after application when gas / smoke has cleared.

FS 42 Prevent access to baits by children, domesticated animals and pets, (particularly cats, dogs and pigs).

or

Keep / apply / suspend only in positions inaccessible to children and pets.

FS 43 Use bait containers clearly marked "Poison" at all / surface baiting points.

FS 44 Remove all remains of dust / bait / and bait containers / and dead rodents / after / at end of / treatment and burn / bury / destroy / dispose of safely.

or

Remove exposed dust thoroughly after use and bury / burn.

FS 45 Do not sow / plant / transplant .... (specify crops) ..... for at least ..... (interval).

FS 46 Do not use indoors / outdoors.

or

For indoor / outdoor use only.

FS 47 Do not use in occupied dwelling-houses / on internal timbers or residential property.

FS 48 Do not apply / treated seed from aircraft / the air / in and around drains.

FS 49 Dangerous / Harmful to game / wild / caged / birds / butterflies / animals / fish / bees / pets / bats. Bury spillages / Do not apply within reach of domestic animals / where animals may lick / come in contact with freshly treated surfaces.

or

High risk / Risk to non-target insects or other arthropods. Do not spray within 6m of the field boundary / See directions for use ./ For advice on use on Integrated Pest Management (IPM) see directions for use / general information.

FS 50 Dangerous / armful to bees. Do not apply / dust / spray / at flowering stage / crops in open flower / during bee activity. Keep down flowering weeds.

or

High risk to bees. Do not apply / spray / dust to crops / plants in flower or to those in which bees are actively foraging / except as directed on ….(crop) / Do not apply when flowering weeds are present.

FS 51 Extremely dangerous / Dangerous / Harmful to fish / and other aquatic life. Do not contaminate watercourses or ground / ponds, waterways / surface waters or ditches with the chemical or used container / The maximum concentration of active substance in treated water must not exceed (specify) ppm or such lower concentration as the appropriate water regulatory body may require.

or

Do not contaminate ponds, waterways or ditches with chemical or used container.

FS 52 Prevent any surface run off to / from entering storm / drains.

or

Avoid contamination of watercourses / ground.

FS 53 This material and its container must be disposed of in a safe way.

or

Dispose of used generator / contents of trap / baits / mats / coils and packaging safely.

FS 54 All washable containers should be labelled: Wash out container thoroughly / empty washings into spray tank / and dispose of safely / dispose of as follows: ..... (specify).

or

Rinse container thoroughly by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of safely/as follows ….. (specify).

FS 55 All non-washable containers should be labelled: Empty / and return used / container (completely) and dispose of safely / dispose of as follows: ..... (specify) / in a safe way.

or

Return empty container as instructed by supplier.

FS 56 Handle with care and mix only in closed container.

FS 57 Keep off skin / away from eyes.

FS 58 Avoid contaminating food

FS 59 Open containers outdoors / only as directed. (Protect from contact with moisture and keep away from burning or glowing material.

FS 60 Apply solutions from unbreakable containers carrying a pouring tube or similar device.

FS 61 Air / ventilate animal feed for at least ..... hours following fumigation.

FS 62 Keep animals / birds / out of premises where grain is under fumigation or being aired / ventilated following fumigation.

FS 63 Remove excess dust and air treated fabrics thoroughly before use.

FS 64 Search for and burn / bury all rodent bodies. Do not place in refuse bins or on rubbish tips.

FS 65 Spray only into the air / onto surfaces.

FS 66 Do not handle treated fabrics / nets until dry and air thoroughly before use.

FS 67 Avoid skin contact with / do not wear / freshly treated clothing.

FS 68 Do not use on beehives / beekeeping equipment.

FS 69 Avoid (direct) contact with plant life / leaves of growing plants (until solvent has evaporated).

FS 70 Dispose of surplus chemical / contaminated materials (including sawdust) and empty the container safely using a method approved by the Waste Disposal Authority.

FS 71 Sawdust from treated timber should be treated as contaminated waste and disposed of safely.

FS72 Treated wood / trays should not be used or dispatched / handled until surfaces are dry / at least 48 hours after treatment

or

Treated wood should be held under cover (with adequate ventilation)/up to 48 hours / or until dry, before dispatch (or erection)

FS 73 Do not allow direct spray from ground crop sprayers to fall within 5m / (specify) m / of the top of the bank of a static or flowing waterbody or within 1m / (specify) m / of the top of a ditch that is dry at the time of application. Direct spray away from water.

or

Do not allow direct spray from hand-held sprayers to fall within 1m of the top of the bank of a static or flowing waterbody. Direct spray away from water.

FS 74 Users must consult the appropriate local authority (County Council or Corporation) before using the product near water and must obtain their agreement before using this product to control aquatic weeds.

FS 75 Medical Advice.

Situations will arise where it is either desirable or necessary that medical advice additional to that provided in the context of safety phrases S 26, S 44, S 45, and S 46 be provided on labels. In such cases the following criteria apply:

Further Advice Poisons Information Centre, Beaumont Hospital, Dublin 9.
Telephone: 01-837 99 64 and 01-837 99 66

Organophosphorous plant protection products

Symptoms	These may include sweating, headache, weakness, faintness and giddiness, nausea, stomach pains, vomiting, small pupils, blurred vision, muscle twitching.
First Aid	If any of the above symptoms occur, particularly if there is known contamination; stop work; remove contaminated clothing; wash exposed skin and hair; prevent all exertion; and call doctor at once and show him the label.

Guide to Doctor

Specific treatment	1	Where signs and symptoms are present and as early as possible, inject treatment atropine sulphate 2 mg or pro rata for children and repeat (if necessary) until fully atropinised.
	2	If available administer pralidoxine 1g by intra-muscular injection. Repeat after 3-4 hours.
Other measures	1	Keep airway clear.
	2	Watch respiration - intubation with endotracheal tube, or tracheotomy may be necessary in conjunction with artificial ventilation.
	3	Put patient at complete rest in hospital for 24 hours at least.
Confirmation of Diagnosis	Estimate cholinesterase activity (5 ml blood unhaemolysed, collected in an anticoagulant).	

Carbamate plant protection products

Symptoms — These include excessive sweating, headache, weakness, faintness and giddiness, nausea, stomach pains, vomiting, small pupils, blurred vision, muscle twitching.

First Aid — If any of the above symptoms occur, particularly if there is known contamination; stop work; remove contaminated clothing; wash exposed skin and hair; prevent all exertion; call doctor at once and show him the label.

Guide to Doctor

Specific treatment
1. Where signs and symptoms are present and as early as possible inject atropine sulphate 3 mg or pro rata for children and repeat if necessary until fully atropinised.
2. Do not use pralidoxine.

Other measures
1. Keep airway clear.
2. Watch respiration - intubation with endotracheal tube or tracheotomy may be necessary in conjunction with artificial ventilation.
3. Put patient at complete rest in hospital for 24 hours at least.

Bipyridyl plant protection products

Symptoms — Following ingestion, nausea, vomiting, abdominal pain and diarrhoea (often bloody) may occur within a few hours and result in severe fluid and electrolyte disturbance. In severe cases, circulatory collapse and coma may occur. The concentrate may cause irritation to skin and eyes.

First Aid — Wash concentrate or spray from skin immediately; wash eye splashes with water for 10 to 15 minutes and seek medical attention; if swallowed, induce vomiting, if not already occurring and take patient to hospital immediately.

Guide to Doctor

Specific treatment
1. Give stomach washout and at the same time test urine and gastric aspirate for the presence of paraquat or diquat.
2. If the test is positive, purge the gastrointestinal tract immediately with up to one litre of a 15% suspension of Fuller's Earth and 200 ml of 20% mannitol in water.
3. Give a sodium or magnesium sulphate purgative separately.
4. Contact the Poisons Information Centre for further advice on treatment.

Test - quick qualitative — Paraquat and diquat can be detected by reduction to blue or green radical ion with sodium dithionite under alkaline conditions.

Quick test capsules can be prepared by mixing the following materials:

Sodium dithionite (hydrosulphite) 10 g

pH buffer powder	6 g
Sodium bicarbonate	25 g

The reagents, thoroughly mixed, and packed in 1 g amounts in gelatin capsules (gauge 0) can be stored at room temperature in a screw-capped container for at least six months.

The test is performed by breaking open the capsule and tipping the contents into 10ml of urine, and shaking gently until dissolved. A green or blue colour indicates the presence of paraquat or diquat.

THIRD SCHEDULE

Annex VIII

(Annex I to the Directive of 1999)

METHODS FOR THE EVALUATION OF PHYSICO-CHEMICAL PROPERTIES OF PREPARATIONS IN ACCORDANCE WITH REGULATION 8

PART A

Exemptions to test methods of Annex V - Part A to the Directive of 1967

See paragraph 2.2.5 of Annex VI.

PART B

Alternative calculation methods

B.1 Non-gaseous preparations

1 Method for the determination of oxidising properties of preparations containing organic peroxides.

See paragraph 2.2.2.1 of Annex VI.

B.2 *Gaseous preparations*

1 Method for the determination of oxidising properties

See paragraph 9.1.1.2 of Annex VI.

2 Method for the determination of flammability properties

See paragraph 9.1.1.1 of Annex VI.

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Annex IX

(Annex II to the Directive of 1999 as adapted by Commission Directive 2001/60/EC of 7 August 2001 [2])

METHODS FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS IN ACCORDANCE WITH REGULATION 9

Introduction

An assessment must be made for all the health effects corresponding to the health effects of substances contained in preparations. The conventional method described in Parts A and B of this Annex is a calculation method applicable to all preparations and takes into consideration all the health hazards of substances contained in preparations. For that purpose, dangerous health effects have been subdivided into:

1 acute lethal effects;

2 non-lethal irreversible effects after a single exposure;

3 severe effects after repeated or prolonged exposure;

4 corrosive effects, irritant effects;

5 sensitising effects, and

6 carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The health effects of individual preparations shall be assessed in accordance with Regulation 9 (1) (a), using the conventional method described in Parts A and B of this Annex using individual concentration limits:

(a) where the dangerous substances listed in Annex I are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Annex, those concentration limits must be used;

(b) where the dangerous substances do not appear in Annex I or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Annex, the concentration limits must be assigned in accordance with the specifications provided in Part B of this Annex.

The procedure for classification of preparations is set out in Part A of this Annex.

The classification of substances and the resulting classification of preparations are expressed:

- either by a symbol and one or more risk phrases, or
- by categories (category 1, category 2 or category 3) and risk phrases when substances and preparations are shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks that are assigned to each substance under consideration.

PART A

Procedure for evaluation of health hazards

The evaluation should be carried out in a stepwise manner, as follows:

1 *The following preparations shall be classified as very toxic:*

1.1 on the basis of their acute lethal effects and assigned the symbol "T", the indication of danger "very toxic" and the risk phrases R26, R27 or R28;

1.1.1 preparations containing one or more substances classified as very toxic that produces such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 1 of Part B of this Annex (Tables I and IA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

1.1.2 preparations containing more than one substance classified as very toxic, that are present in lower individual concentrations than the limits specified in points 1.1.1 (a) or (b) if

$$\sum \left[\frac{P_{T+}}{L_{T+}} \right] \geq 1$$

where: P_{T+} = the percentage by weight or by volume of each very toxic substance in the preparation,

L_{T+} = the very toxic limit specified for each very toxic substance, expressed as a percentage by weight or by volume;

1.2 on the basis of their non-lethal irreversible effects after a single exposure and assigned the symbol "T+", the indication of danger "very toxic" and the risk phrase R39/route of exposure;

preparations containing at least one dangerous substance that produces such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 2 of Part B of this Annex (Tables II and IIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

2 *The following preparations shall be classified as toxic*:

2.1. on the basis of their acute lethal effects and assigned the symbol "T", the indication of danger "toxic" and the risk phrases R23, R24 or R,25;

2.1.1 preparations containing one or more substances classified as very toxic or toxic that produces such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 1 of Part B of this Annex (Tables I and IA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

2.1.2 preparations containing more than one substance classified as very toxic or toxic, that are present in lower individual concentrations than the limits specified in points 2.1.1 (a) or (b) if

$$\sum \left[\frac{P_{T+}}{L_T} + \frac{P_T}{L_T} \right] \geq 1$$

where: P_{T+} = the percentage by weight or by volume of each very toxic substance in the preparation,

P_T = the percentage by weight or by volume of each toxic substance in the preparation,

L_T = the respective toxic limit specified for each very toxic or toxic substance, expressed as a percentage by weight or by volume;

2.2 on the basis of their non-lethal irreversible effects after a single exposure and assigned the symbol "T", the indication of danger "toxic" and the risk phrase R39/route of exposure;

preparations containing at least one dangerous substance classified as very toxic or toxic that produces such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 2 of Part B of this Annex (Tables II and IIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

2.3 on the basis of their long-term effects and assigned the symbol "T", the indication of danger "toxic" and the risk phrase R48/route of exposure;

preparations containing at least one dangerous substance that produces such effects, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 3 of Part B of this Annex (Tables III and IIIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

3 *The following preparations shall be classified as harmful*:

3.1 on the basis of their acute lethal effects and assigned the symbol "Xn", the indication of danger "harmful" and the risk phrases R20, R21 or R22:

3.1.1 preparations containing one or more substances classified as very toxic, toxic or harmful that produces such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 1 of Part B of this Annex (Tables I and IA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

3.1.2 preparations containing more than one substance classified as very toxic, toxic or harmful, that are present in lower individual concentrations than the limits specified in points 3.1.1 (a) or (b) if

$$\sum \left[\frac{P_{T+}}{L_{Xn}} + \frac{P_T}{L_{Xn}} + \frac{P_{Xn}}{L_{Xn}} \right] \geq 1$$

where: P_{T+} = the percentage by weight or by volume of each very toxic substance in the preparation,

P_T = the percentage by weight or by volume of each toxic substance in the preparation,

P_{Xn} = the percentage by weight or by volume of each harmful substance in the preparation,

L_{Xn} = the respective harmful limit specified for each very toxic, toxic or harmful substance, expressed as a percentage by weight or by volume;

3.2 on the basis of their acute effects on the lungs if swallowed and assigned the symbol "X", the indication of danger "harmful" and the risk phrase R65;

preparations classified as harmful in accordance with the criteria specified in paragraph 3.2.3 of Annex VI. In applying the conventional method specified at point 3.1 of this Annex, no account shall be taken of the classification of a substance as R65;

3.3 on the basis of their non-lethal irreversible effects following a single exposure and assigned the symbol "Xn", the indication of danger "harmful" and the risk phrase R68/route of exposure.

preparations containing at least one dangerous substance classified as very toxic, toxic or harmful that produce such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 2 of Part B of this Annex (Tables II and IIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

3.4 on the basis of their long-term effects and assigned the symbol "Xn", the indication of danger "harmful" and the risk phrase R48/route of exposure;

preparations containing at least one dangerous substance classified as toxic or harmful that produces such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex 1 for the substance or substances under consideration, or

(b) the concentration specified at point 3 of Part B of this Annex (Tables III and IIIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

4 *The following preparations shall be classified as corrosive*

4.1 and assigned the symbol "C" the indication of danger "corrosive" and the risk phrase R35;

4.1.1 preparations containing one or more substances classified as corrosive and assigned the phrase R35, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 of Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

4.1.2 preparations containing more than one substance classified as corrosive and assigned phrase R35, that are present in lower individual concentrations than the limits specified in points 4.1.1 (a) or (b) if

$$\sum \left[\frac{P_{C,\,R35}}{L_{C,\,R35}} \right] \geq 1$$

where: $P_{C,\,R35}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R35 in the preparation,

$L_{C,\,R35}$ = the corrosive limit R35 specified for each corrosive substance assigned the phrase R35, expressed as a percentage by weight or by volume;

4.2 and assigned the symbol "C", the indication of danger "corrosive" and the risk phrase R34;

4.2.1 preparations containing one or more substances classified as corrosive and assigned the phrase R35 or R34, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 of Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

4.2.2 preparations containing, more than one substance classified as corrosive and assigned the phrase R35 or R34, that are present in lower individual concentrations than the limits specified in points 4.2.1 (a) or (b) if

$$\sum \left[\frac{P_{C,\,R35}}{L_{C,\,R34}} + \frac{P_{C,\,R34}}{L_{C,\,R34}} \right] \geq 1$$

where: $P_{C,\,R35}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R35 in the preparation,

$P_{C,\,R34}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R34 in the preparation,

L_T = the respective corrosive limit R34 specified for corrosive substance assigned the phrase R35 or R34, expressed as a percentage by weight or by volume.

5 *The following preparations shall be classified as irritants*

5.1 liable to cause serious eye damage and assigned the symbol "Xi", the indication of danger "irritant" and the risk phrase R41;

5.1.1 preparations containing one or more substances classified as irritant and assigned phrase R41, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in point 4 of Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.1.2 preparations containing more than one substance classified as irritant and assigned the phrase R41, or classified corrosive and to which is assigned the phrase R35 or R34, that are present in lower individual concentrations than the limits specified in points 5.1.1 (a) or (b) if

$$\sum \left[\frac{P_{C,\,R35}}{L_{Xi,\,R41}} + \frac{P_{C,\,R34}}{L_{Xi,\,R41}} + \frac{P_{Xi,\,R41}}{L_{Xi,\,R41}} \right] \geq 1$$

where: $P_{C,\,R35}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R35 in the preparation,

$P_{C,\,R34}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R34 in the preparation,

$P_{Xi,\,R41}$ = the percentage by weight or by volume of each irritant substance assigned the phrase R41 in the preparation,

$L_{Xi,\,R41}$ = the respective irritant limit R41 specified for each corrosive substance assigned the phrase R35 or R34, or irritant substance assigned the phrase R41, expressed as a percentage by weight or by volume;

5.2 irritant to eyes and assigned the symbol "Xi", the indication of danger "irritant" and the risk phrase R36;

5.2.1 preparations containing one or more substances classified as corrosive and assigned phrase R35 or R34, or irritant and assigned phrase R41 or R36, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 of Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.2.2 preparations containing more than one substance classified as irritant and assigned the phrase R41 or R36, or as corrosive and assigned the phrase R35 or R34, that are present in lower individual concentrations than the limits specified in points 5.2.1 (a) or (b) if

$$\sum \left[\frac{P_{C,\,R35}}{L_{Xi,\,R36}} + \frac{P_{C,\,R34}}{L_{Xi,\,R36}} + \frac{P_{Xi,\,R41}}{L_{Xi,\,R36}} + \frac{P_{Xi,\,R36}}{L_{Xi,\,R36}} \right] \geq 1$$

where: $P_{C,\,R35}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R35 in the preparation,

$P_{C,\,R34}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R34 in the preparation,

$P_{Xi,\,R41}$ = the percentage by weight or by volume of each irritant substance assigned the phrase R41 in the preparation,

$P_{Xi,\,R36}$ = the percentage by weight or by volume of each irritant substance assigned the phrase R36 in the preparation,

$L_{Xi,\,R36}$ = the respective irritant limit R36 specified for each corrosive substance assigned the phrase R35 or R34, or irritant substance assigned the phrase R41 or R36, expressed as a percentage by weight or by volume;

5.3 irritant to skin and assigned the symbol "Xi", the indication of danger "irritant" and the risk phrase R38;

5.3.1 preparations containing one or more substances classified as irritant and assigned the phrase R38 or as corrosive and assigned the phrase R35 or R34, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 of Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex 1 or appear in it without concentration limits;

5.3.2 preparations containing more than one substance classified as irritant and assigned the phrase R38, or as corrosive and assigned the phrase R35 or R34, that are present in lower individual concentrations than the limits specified in points 5.3.1 (a) or (b) if

$$\sum \left[\frac{P_{C,\,R35}}{L_{Xi,\,R38}} + \frac{P_{C,\,R34}}{L_{Xi,\,R38}} + \frac{P_{Xi,\,R38}}{L_{Xi,\,R38}} \right] \geq 1$$

where: $P_{C,\,R35}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R35 in the preparation,

$P_{C,\,R34}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R34 in the preparation,

$P_{Xi,\,R38}$ = the percentage by weight or by volume of each irritant substance assigned the phrase R38 in the preparation,

$L_{Xi,\,R38}$ = the respective irritant limit R38 specified for each corrosive substance assigned the phrase R35 or R34, or irritant substance assigned the phrase R38, expressed as a percentage by weight or by volume;

5.4 irritant to the respiratory system and assigned the symbol "Xi", the indication of danger "irritant" and the risk phrase R37;

5.4.1 preparations containing one or more substances classified as irritant and assigned the phrase R37, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 of Part B of this Annex (Tables IV and IVA) where the substance or the substances do not appear in Annex 1 or appear in it without concentration limits;

5.4.2 preparations containing more than one substance classified as irritant and assigned phrase R37, that are present in lower individual concentrations than the limits specified in points 5.4.1 (a) or (b) if

$$\sum \left[\frac{P_{Xi,\,R37}}{L_{Xi,\,R37}} \right] \geq 1$$

where: $P_{Xi, R37}$ = the percentage by weight or by volume of each irritant substance assigned the phrase R37 in the preparation,

$L_{Xi, R37}$ = the irritant limit R37 specified for each irritant substance assigned the phrase R37, expressed as a percentage by weight or by volume;

5.4.3 gaseous preparations containing more than one substances classified as irritant and assigned the phrase R37 or as corrosive and assigned the phrase R35 or R34, that are present in lower individual concentrations than the limits specified in points 5.4.1 (a) or (b) if

$$\sum \left[\frac{P_{C, R35}}{L_{Xi, R37}} + \frac{P_{C, R34}}{L_{Xi, R37}} + \frac{P_{Xi, R37}}{L_{Xi, R37}} \right] \geq 1$$

where: $P_{C, R35}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R35 in the preparation,

$P_{C, R34}$ = the percentage by weight or by volume of each corrosive substance assigned the phrase R34 in the preparation,

$P_{Xi, R37}$ = the percentage by weight or by volume of each irritant substance assigned the phrase R37 in the preparation,

$L_{Xi, R37}$ = the respective irritant limit R37 specified for each gaseous corrosive substance assigned the phrase R35 or R34, or gaseous irritant substance assigned the phrase R37, expressed as a percentage by weight or by volume;

6 *The following preparations shall be classified as sensitising*:

6.1 by skin contact and assigned the symbol "Xi", the indication of danger "irritant" and the risk phrase R43;

preparations containing at least one substance classified as sensitising and assigned the phrase R43, that produce such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 5 of Part B of this Annex (Table V and VA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

6.2 by inhalation and assigned the symbol "Xn", the indication of danger "harmful" and the risk phrase R42;

preparations containing at least one substance classified as sensitising and assigned the phrase P42, that produce such effects and is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 5 of Part B of this Annex (Tables V and VA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

7 *The following preparations shall be classified as carcinogenic*:

7.1 those of category 1 or 2 that are assigned the symbol "T" and the phrase R45 or R49,

preparations containing at least one substance producing such effects, classified as carcinogenic and assigned the phrase R45 or R49, denoting carcinogenic substances in category 1 and category 2, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

7.2 those of category 3 that are assigned the symbol "Xn" and the phrase R40;

preparations containing at least one substance producing such effects, classified as carcinogenic and assigned the phrase R40 denoting carcinogenic substances in category 3, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

8 *The following preparations shall to be classified as mutagenic*:

8.1 those of category 1 or 2 that are assigned the symbol "T" and the phrase R46;

preparations containing at least one substance producing such effects, classified as mutagenic and assigned phrase R46 denoting mutagenic substances in category 1 and category 2, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, on

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

8.2 those of category 3 that are assigned the symbol "Xn" and the phrase R68;

preparations containing at least one substance producing such effects, classified as mutagenic and assigned the phrase R68 denoting mutagenic substances in category 3, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

9 *The following preparations shall be classified as toxic for reproduction*:

9.1 those of category 1 or 2 that are assigned the symbol "T" and the phrase R60 (fertility):

preparations containing at least one substance producing such effects, classified as toxic for reproduction and assigned the phrase R60 denoting substances toxic for reproduction of category 1 and category 2, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

9.2 those of category 3 that are assigned the symbol "Xn" and the phrase R62 (fertility):

preparations containing at least one substance producing such effects, classified as toxic for reproduction and assigned the phrase R62, denoting substances toxic for reproduction of category 3, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

9.3 those of category 1 or 2 that are assigned the symbol "T" and the phrase R61 (development):

preparations containing at least one substance producing such effects, classified as toxic for reproduction and assigned the phrase R61, denoting substances toxic for reproduction of category 1 and category 2, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B o this Annex (Tables VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

9.4 those of category 3 that are assigned the symbol "Xn" and the phrase R63 (development);

preparations containing at least one substance producing such effects, classified as toxic for reproduction and assigned the phrase R63, denoting substances toxic for reproduction of category 3, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 of Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

PART B

Concentration limits to be used in the evaluation of health hazards

For each health effect, the first table (Tables I to VI) sets out the concentration limits (expressed as a weight/weight percentage) to be used for non-gaseous preparations and the second table (Tables IA to VIA) sets out the concentration limits (expressed as a volume/volume percentage) to be used for gaseous preparations. These concentration limits are intended for use in the absence of specific concentration limits in Annex 1 for substances under consideration.

1 *Acute lethal effects*

1.1 Non-gaseous preparations

The concentration limits fixed in Table I, expressed as a weight/weight percentage, shall serve for the determination of the classification of preparations in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table I

Classification of the substance	Classification of the preparation		
	T+	T	Xn
T+ with R26, R27, R28	concentration ≥ 7 %	1 % ≤ concentration < 7 %	0.1 % ≤ concentration < 1 %
T with R23, R24, R25		concentration ≥ 25 %	3 % ≤ concentration ≤ 25 %
Xn with R20, R21, R22			concentration ≥ 25%

The R phrases denoting risk are to be assigned to the preparation in accordance with the following criteria:

- the label shall include one or more of the above mentioned R phrases in accordance with the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

1.2 Gaseous preparations

The concentration limits expressed as a volume/volume percentage in Table IA below, shall serve for the determination of the classification of gaseous preparations in relation to the individual concentration of the gas(es) present whose classification is also shown.

Table IA

Classification of the substance (gas)	Classification of the gaseous preparation		
	T+	T	Xn
T+ with R26, R27, R28	concentration ≥ 1 %	0.2 % ≤ concentration < 1 %	0.02 % ≤ concentration < 0.2%
T with R23, R24, R25		concentration ≥ 5 %	0.5 % ≤ concentration ≤ 5 %
Xn with R20, R21, R22			concentration ≥ 5 %

The R phrases denoting risk are to be assigned to the preparation in accordance with the following criteria:

- the label shall include one or more of the above mentioned R phrases in accordance with the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

2 *Non-lethal irreversible effects after a single exposure*

2.1 Non-gaseous preparations

For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table II, expressed as a weight/weight percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table II

Classification of the substance	Classification of the preparation		
	T+	T	Xn
T+ with R39/route of exposure	concentration ≥ 10% R39 (*) obligatory	1 % ≤ concentration < 10 % R39 (*) obligatory	0.1 % ≤ concentration < 1 % R68 (*) obligatory
T with R39/route of exposure		concentration ≥ 10% R39 (*) obligatory	1 % ≤ concentration ≤ 10 % R68 (*) obligatory
Xn with R68/route of exposure			concentration ≥ 10% R68 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI) are to be used.

2.2 Gaseous preparations

For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table IIA, expressed as a volume/volume percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table IIA

Classification of the substance (gas)	Classification of the gaseous preparation		
	T+	T	Xn
T+ with R39/route of exposure	concentration ≥ 1 % R39 (*) obligatory	0.2 % ≤ concentration < 1 % R39 (*) obligatory	0.02 % ≤ concentration < 0.2% R68 (*) obligatory
T with R39/route of exposure		concentration ≥ 5% R39 (*) obligatory	0.5 % ≤ concentration ≤ 5 % R68 (*) obligatory
Xn with R68/route of exposure			concentration ≥ 5 % R68 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI) are to be used.

3 *Severe effects after repeated or prolonged exposure*

3.1 Non-gaseous preparations

For substances that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table III, expressed as a weight/weight percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table III

Classification of the substance	Classification of the preparation	
	T	Xn
T with R48/route of exposure	concentration ≥ 10% R48 (*) obligatory	1 % ≤ concentration < 10 % R48 (*) obligatory
Xn with R48/route of exposure		concentration ≥ 10% R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI) are to be used.

3.2 Gaseous preparations

For gases that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table IIIA below expressed as a

volume/volume percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table IIIA

Classification of the substance (gas)	Classification of the gaseous preparation	
	T	Xn
T with R48/route of exposure	concentration ≥ 5 % R48 (*) obligatory	0.5 % ≤ concentration < 5 % R48 (*) obligatory
Xn with R48/route of exposure		concentration ≥ 5 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI) are to be used.

4 *Corrosive and irritant effect including serious damage to the eye*

4.1 Non-gaseous preparations

For substance that produce corrosive effects (R34, R35) or irritant effects (R36, R37, R38, R41), the individual concentration limits specified in Table IV, expressed as a weight/weight percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38
C with R35	concentration ≥ 10 % R35 obligatory	5 % ≤ concentration < 10 % R34 obligatory	5 % (*)	1 % ≤ concentration < 5 % R36/38 obligatory
C with R34		concentration ≥ 10% R34 obligatory	10 % (*)	5 % ≤ concentration < 10 % R36/38 obligatory
Xi with R41			concentration ≥ 10% R41 obligatory	5 % ≤ concentration < 10 % R36 obligatory
Xi with R36, R37, R 38				concentration ≥ 20% R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38

(*) According to the labelling guide (Annex VI), consideration must be given to assigning R41 to corrosive substances assigned risk phrases R35 or R34. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for classification of the preparation as corrosive, such substances ran contribute to a classification of the preparation as irritant with R41 or irritant with R36.

NB Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (*e.g.* pH of the preparation) are not taken into account. Therefore, in classifying preparations for corrosivity, the advice provided in paragraph 3.2.5 of Annex VI and the requirements specified in the second and third indents of paragraph (5) of Regulation 9 must be taken into account.

4.2 Gaseous preparations

For gases that produce such effects (R34, R35 or R36, R37, R38, R41), the individual concentration limits specified in Table IVA below, expressed as a volume/volume percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table IVA

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38
C with R35	concentration ≥ 1 % R35 obligatory	0.2 % ≤ concentration < 1 % R34 obligatory	0.2 % (*)	0.02 % ≤ concentration < 0.2% R36/37/38 obligatory
C with R34		concentration ≥ 5 % R34 obligatory	5 % (*)	0.5 % ≤ concentration < 5 % R36/37/38 obligatory

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38
Xi with R41			concentration ≥ 5 % R41 obligatory	0.5 % ≤ concentration < 5 % R36 obligatory

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38
Xi with R36, R37, R 38				concentration ≥ 5 % R36, R37, R38 are obligatory as appropriate

(*) According to the labelling guide (Annex VI), consideration must be given to assigning R41 to corrosive substances assigned risk phrases R35 or R34. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for classification of the preparation as corrosive, such substances ran contribute to a classification of the preparation as irritant with R41 or irritant with R36.

NB Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (*e.g.* pH of the preparation) are not taken into account. Therefore, in classifying preparations for corrosivity, the advice provided in paragraph 3.2.5 of Annex VI and the requirements specified in the second and third indents of paragraph (5) of Regulation 9 must be taken into account.

5 *Sensitising effects*

5.1 Non-gaseous preparations

Preparations that produce such effects shall be classified as sensitising and assigned:

- the symbol Xn and the phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and the phrase R43 it this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V, expressed as a weight/weight percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table V

Classification of the substance	Classification of the preparation	
	Sensitising with R42	Sensitising with R 43
Sensitising with R42	concentration ≥ 1 % R42 obligatory	
Sensitising with R 43		concentration ≥ 1 % R43 (*) obligatory

5.2 Gaseous preparations

Gaseous preparations that produce such effects shall be classified as sensitising and assigned:

- the symbol Xn and the phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and the phrase R43 it this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V A, expressed as a volume/volume percentage, shall serve for the determination, where appropriate, of the classification of preparations.

Table VA

Classification of the substance (gas)	Classification of the gaseous preparation	
	Sensitising with R42	Sensitising with R 43
Sensitising with R42	concentration ≥ 0.2 % R42 obligatory	
Sensitising with R 43		concentration ≥ 0.2 % R43 (*) obligatory

6 *Carcinogenic/mutagenic/toxic effects for reproduction*

6.1 Non-gaseous preparations

For substances that produce such effects, the concentration limits laid down in Table VI, expressed as a weight/weight percentage, shall serve for the determination, where appropriate, of the classification of preparations. The following symbol and risk phrases shall be assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61

Toxic for reproduction fertility category 3: Xn; R62

Toxic for reproduction development category 3: Xn; R63

Table VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	concentration ≥ 0.1 % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		concentration ≥ 1 % carcinogenic R40 obligatory
Mutagenic substances of category 1 or 2 with R46	concentration ≥ 0.1 % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		concentration ≥ 1 % mutagenic R68 obligatory
Substances toxic for reproduction of category 1 or 2 with R60 (fertility)	concentration ≥ 0.5 % toxic for reproduction (fertility) R60 obligatory	
Substances toxic for reproduction of category 3 with R62 (fertility)		concentration ≥ 5 % toxic for reproduction (fertility) R62 obligatory
Substances toxic for reproduction of category 1 or 2 with R61 (development)	concentration ≥ 0.5 % toxic for reproduction (development) R61 obligatory	
Substances toxic for reproduction of category 3 with R63 (development)		concentration ≥ 5 % toxic for reproduction (development) R63 obligatory

6.2 Gaseous preparations

For gases that produce such effects, the concentration limits laid down in Table VIA, expressed as a volume/volume percentage, shall serve for the determination, where appropriate, of the classification of preparations. The following symbol and risk phrases shall be assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn; R62
Toxic for reproduction development category 3:	Xn; R63

Table VIA

Classification of the substance (gas)	Classification of the gaseous preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	concentration ≥ 0.1 % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		concentration ≥ 1 % carcinogenic R40 obligatory
Mutagenic substances of category 1 or 2 with R46	concentration ≥ 0.1 % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		concentration ≥ 1 % mutagenic R68 obligatory
Substances toxic for reproduction of category 1 or 2 with R60 (fertility)	concentration ≥ 0.2 % toxic for reproduction (fertility) R60 obligatory	
Substances toxic for reproduction of category 3 with R62 (fertility)		concentration ≥ 1 % toxic for reproduction (fertility) R62 obligatory

Classification of the substance (gas)	Classification of the gaseous preparation	
	Categories 1 and 2	Category 3
Substances toxic for reproduction of category 1 or 2 with R61 (development)	concentration ≥ 0.2 % toxic for reproduction (development) R61 obligatory	
Substances toxic for reproduction of category 3 with R63 (development)		concentration ≥ 1 % toxic for reproduction (development) R63 obligatory

Annex X

(Annex III to the Directive of 1999)

METHODS FOR THE EVALUATION OF THE ENVIRONMENTAL HAZARDS OF PREPARATIONS IN ACCORDANCE WITH REGULATION 10

Introduction

The assessment of the dangerous properties for the environment of preparations shall be based upon the consideration of the dangerous properties of substances contained in it, and the concentration limits specified for those substances, expressed as a weight/weight percentage for non-gaseous preparations and expressed as a volume/ volume percentage for gaseous preparations, in conjunction with the classification of the substances concerned.

Part A contains details of the calculation procedure provided for in Regulation 10 (1) (a) and specifies the R phrases to be assigned to preparations.

Part B specifies the concentration limits to be used when applying the conventional method described in Part A in the case of substances for which concentration limits are not included in Annex I.

In accordance with Regulation 10 (1) (a) the environmental hazards of preparations shall be assessed using the conventional method described in Parts A and B using individual concentration limits:

(a) where the dangerous substances listed in Annex I are assigned concentration limits necessary for the application of the method of assessment described in Part A, those concentration limits must be used.

(b) where the dangerous substances do not appear in Annex I or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A, the concentration limits shall be assigned in accordance with the specifications provided in Part B.

Part C specifies the test methods to be used to permit evaluation of hazards for the aquatic environment.

PART A

Procedure for the evaluation of environmental hazards

(a) *Aquatic environment*

1 Conventional method for the evaluation of hazards to the aquatic environment

The conventional method for the evaluation of hazards to the aquatic environment is intended to take into account all the hazards that a substance may entail for this medium according to the following specifications.

The following preparations shall be classified as dangerous for the environment:

1 and be assigned the symbol "N", the indication of danger "dangerous for the environment" and the risk phrases R50 and R53 (R50-53):

1.1 preparations containing one or more substances classified as dangerous for the environment and assigned the phrases R50-53, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

1.2 preparations containing more than one substance classified as dangerous for the environment and assigned the phrases R50-53, that are present in lower individual concentrations than the limits specified in points 1.1.1 (a) or (b) if

$$\sum \left[\frac{P_{N,\,R50\text{-}53}}{L_{N,\,R50\text{-}53}} \right] \geq 1$$

where: $P_{N,\,R50\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R50-53, in the preparation,

$L_{N,\,R50\text{-}53}$ = the limit R50-53 for each substance dangerous for the environment assigned the phrases R50-53, expressed as a percentage by weight;

2 and be assigned the symbol "N", the indication of danger "dangerous for the environment" and the risk phrases R51 and R53 (R51-53), unless the preparation is already classified in accordance with point 1.1, above;

2.1 preparations containing one or more substance classified as dangerous for the environment and assigned the phrases R50-53 or R51-53, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

2.2 preparations containing more than one substance classified as dangerous for the environment and assigned the phrases R50-53 or R51-53, that are present in lower individual concentrations than the limits specified in points 1.2 (a) or (b) if

$$\sum \left[\frac{P_{N,\,R50\text{-}53}}{L_{N,\,R51\text{-}53}} + \frac{P_{N,\,R51\text{-}53}}{L_{N,\,R51\text{-}53}} \right] \geq 1$$

where: $P_{N,\,R50\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R50-53, in the preparation,

$P_{N,\,R51\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R51-53, in the preparation,

$L_{N,\,51\text{-}53}$ = the respective limit R51-53 specified for each substance dangerous for the environment assigned the phrases R50-53 or R51-53, expressed as a percentage by weight;.

3 and be assigned the risk phrases R52 and R53 (R52-53) unless the preparation is already classified in accordance with points 1.1 or 1.2 above.;

3.1 preparations containing one or more substances classified as dangerous for the environment and assigned the phrases R50-53 or R51-53 or R52-53, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

3.2 preparations containing more than one substances classified as dangerous for the environment and assigned the phrases R51-53 or R50-53 or R52-53, that are present in lower individual concentrations than the limits specified in points 1.3.1 (a) or (b) if

$$\sum \left[\frac{P_{N,\,R50\text{-}53}}{L_{R52\text{-}53}} + \frac{P_{N,\,R51\text{-}53}}{L_{R52\text{-}53}} + \frac{P_{R52\text{-}53}}{L_{R52\text{-}53}} \right] \geq 1$$

where: $P_{N,\,R50\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R50-53, in the preparation,

$P_{N, R51-53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R51-53, in the preparation,

P_{R52-53} = the percentage by weight of each substance dangerous for the environment and assigned the phrases R52-53, in the preparation,

L_{R52-53} = the respective limit R52-53 specified for each substance dangerous for the environment assigned the phrases R50-53 or R51-53 or R52-53, expressed as a percentage by weight;

4 and be assigned the symbol "N", the indication of danger "dangerous for the environment" and the risk phrase R50 unless the preparation is already classified in accordance with point 1.1 above:

4.1 preparations containing one or more substance classified as dangerous for the environment and assigned the phrase R50, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 2) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

4.2 preparations containing more than one substance classified as dangerous for the environment and assigned the phrase R50, that are present in lower individual concentrations than the limits specified in points 1.4.1(a) or (b) if-

$$\sum \left[\frac{P_{N, R50}}{L_{N, R50}} \right] \geq 1$$

where: $P_{N, R50}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R50, in the preparation,

$L_{N, R50}$ = the limit R50 for each substance dangerous for the environment assigned the phrases R50, expressed as a percentage by weight;

4.3 preparations containing one or more substances classified as dangerous for the environment and assigned the phrase R50, that do not satisfy the criteria specified at point 1.4.1 or 1.4.2 and that contains one or more substances classified as dangerous for the environment and assigned phrases R50-53 if

$$\sum \left[\frac{P_{N, R50}}{L_{N, R50}} + \frac{P_{N, R50-53}}{L_{N, R50}} \right] \geq 1$$

where: $P_{N, R50}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrase R50, in the preparation,

$P_{N, R50-53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R50-53, in the preparation,

$L_{N, R50}$ = the respective limit R50 specified for each substance dangerous for the environment assigned the phrases R50 or R50-53, expressed as a percentage by weight;.

5 and be assigned the risk phrase R52 unless the preparation is already classified in accordance with points 1.1, 1.2, 1.3, or 1.4 above:

5.1 preparations containing one or more substances classified as dangerous for the environment and assigned the phrase R52, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 3) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.2 preparations containing more than one substance classified as dangerous for the environment and assigned the phrase R52, that are present in individual concentrations lower than the limits specified in points 1.5.1 (a) or (b) if

$$\sum \left[\frac{P_{R52}}{L_{R52}} \right] \geq 1$$

where: P_{R52} = the percentage by weight of each substance dangerous for the environment and assigned the phrases R52, in the preparation,

L_{R52} = the limit R52 for each substance dangerous for the environment assigned the phrase R52, expressed as a percentage by weight;

6 and be assigned the risk phrase R53 unless the preparation is already classified in accordance with points 1.1, 1.2, or 1.3 above:

6.1 preparations containing one or more substance classified as dangerous for the environment and assigned the phrase R53, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 4) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

6.2 preparations containing more than one substance classified as dangerous for the environment and assigned the phrase R53, that is present in an individual concentration lower than the limits specified in points 1.6.1 (a) or (b) if

$$\sum \left[\frac{P_{R53}}{L_{R53}} \right] \geq 1$$

where: P_{R53} = the percentage by weight of each substance dangerous for the environment and assigned the phrases R53, in the preparation,

L_{R53} = the limit R53 for each substance dangerous for the environment assigned the phrase R53, expressed as a percentage by weight;

6.3 preparations containing one or more substances classified as dangerous for the environment and assigned the phrase R53, that does not satisfy the criteria specified at point 1.6.2 and containing one or more substances classified as dangerous for the environment and assigned the phrases R50-53 or R51-53 or R52-53 if

$$\sum \left[\frac{P_{R53}}{L_{R53}} + \frac{P_{N,\,R50\text{-}53}}{L_{R53}} + \frac{P_{N,\,R51\text{-}53}}{L_{R53}} + \frac{P_{R51\text{-}53}}{L_{R53}} \right] \geq 1$$

where: P_{R53} = the percentage by weight of each substance dangerous for the environment and assigned the phrases R53, in the preparation,

$P_{N,\,R50\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R50-53, in the preparation,

$P_{N,\,R51\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R51-53, in the preparation,

$P_{R52\text{-}53}$ = the percentage by weight of each substance dangerous for the environment and assigned the phrases R52-53, in the preparation,

L_{R53} = the respective limit R53 specified for each substance dangerous for the environment assigned the phrases R53 or R50-53 or R51-53 or R52-53, expressed as a percentage by weight.

(b) *Non-aquatic environment*

(1) OZONE LAYER

1 Conventional method for the evaluation of hazards presented by preparations to the ozone layer

The following preparations shall be classified as dangerous for the environment

1 and be assigned the symbol "N", the indication of danger "dangerous for the environment" and the risk phrase R59:

1.1 preparations containing one or more substances classified as dangerous for the environment and assigned the symbol "N" and the risk phrase R59, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

2 and be assigned the risk phrase R59:

2.1 preparations containing one or more substances classified as dangerous for the environment and assigned the risk phrase R59, that is present in an individual concentration equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

(2) TERRESTRIAL ENVIRONMENT

1 Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow from the detailed criteria for use of the phrases to be incorporated in Annex VI.

R54 Toxic to flora

R55 Toxic to fauna

R56 Toxic to soil organisms

R57 Toxic to bees

R58 May cause long-term adverse effects in the environment.

PART B

Concentration limits to be used in the evaluation of environmental hazards

I *For the aquatic environment*

The concentration limits specified in the following tables are expressed as a weight/weight percentage. Those concentration limits are intended for use in the absence of specific concentration limits in Annex 1 for substances under consideration and present in a preparation to be classified.

Table I

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
N, R50-53	concentration ≥ 25 %	2.5 % ≤ concentration < 25%	0.25 % ≤ concentration < 2.5%
N, R51-53		concentration ≥ 25%	2.5 % ≤ concentration < 25%
R52-53			concentration ≥ 25%

Table 2

Acute aquatic toxicity

Classification of the substance	Classification of the preparation N, R50
N, R50	concentration ≥ 25 %
N, R50-53	concentration ≥ 25 %

Table 3

Aquatic toxicity

Classification of the substance	Classification of the preparation R52
R52	concentration ≥ 25 %

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation R53
R53	concentration ≥ 25 %
N, R50-53	concentration ≥ 25 %
N, R51-53	concentration ≥ 25 %
R52-53	concentration ≥ 25 %

II *For the non-aquatic environment*

The concentration limits specified in the following tables are expressed as a weight/weight percentage for non-gaseous preparations and as a volume/volume percentage for gaseous preparation. Those concentration limits are intended for use in the absence of specific concentration limits in Annex 1 for substances under consideration and present in a preparation to be classified.

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	concentration ≥ 0.1 %

Classification of the substance	Classification of the preparation R59
R59	concentration ≥ 0.1 %

PART C

Test methods for the evaluation of hazards for the aquatic environment

Normally, the classification of a preparation is made on the basis of the conventional method. However, for the determination of acute aquatic toxicity, cases will arise for which it is appropriate to carry out tests on the preparation.

The result of such tests may only be used to modify a classification in relation to acute aquatic toxicity that was derived by application of the conventional method.

Where such tests are used, the tests must be conducted in compliance with the quality criteria of the test methods specified in Part C of Annex V.

Furthermore, tests must be carried out on all three species specified in accordance with the criteria of Annex VI (algae, daphnia and fish), unless the highest hazard classification in relation to acute aquatic toxicity is assigned to the preparation after testing on just one species, or unless a test result was already available prior to 30 July 1999.

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Annex XI

SPECIAL PROVISIONS FOR CONTAINERS CONTAINING PREPARATIONS OFFERED OR SOLD TO THE GENERAL PUBLIC

(Annex IV of the Directive of 1999, supplemented by the technical specifications listed in Annex IX of the Directive of 1967 as amended by the Directive of 1992 and adapted by Commission Directives 91/410/EEC and 2000/32/EC)

PART A

Containers to be fitted with child-resistant fastenings

1. Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Regulation 13, under the conditions laid down in Regulation 9, are to fitted with child-resistant fastenings.

2. Containers of whatever capacity containing preparations presenting an aspiration hazard (Xn, R65) and classified and labelled according to paragraph 3.2.3 of Annex VI, with the exception of preparations placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment.

3. Containers of whatever capacity, having at least one of the substances listed in the following table, present in a concentration equal to or greater than the maximum individual concentration specified,

No	Identification of the substance			Concentration limit
	CAS-Reg No	Name	Einecs No	
1	67-56-1	Methanol	2006596	χ 3 %
2	75-09-2	Dichloromethane	2008389	χ 1 %

which are offered or sold to the general public are to be fitted with child-resistant fastenings.

Reclosable packages Child-proof fastenings used on reclosable packages shall comply with ISO Standard 8317 (1 July 1989 edition) relating to “Child-resistant packages - Requirements and methods of testing for reclosable packages” adopted by the International Standard Organisation (ISO).

Non-reclosable packages Child-proof fastenings used on non-reclosable packages shall comply with CEN standard EN 862 (March 1997 edition) relating to "Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products" adopted by the European Committee for Standardisation (CEN).

Notes

1 Evidence of conformity with the above standard may be certified only by laboratories which conform to European Standards Series EN 45 000.

2 Specific cases

If it seems obvious that packaging is sufficiently safe for children because they cannot get access to the contents without the help of a tool, the test doesn't need to be performed.

In all other cases and when there are sufficient grounds for doubting the security of the closure for a child, the national authority may ask the person responsible for putting the product on the market to give it a certificate from a laboratory which conforms with European Standards Series EN 45 000, stating that either:

- the type of closure is such that it is not necessary to test to the ISO and CEN standards referred to above, or
- the closure has been tested and has been found to conform to the standards referred to above.

PART B

Provisions relating to tactile warnings

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with Regulation 13 and under the conditions laid down in Regulations 8 and 9, are to carry a tactile warning of danger.

This provision does not apply to aerosols classified and labelled only as extremely flammable or highly flammable.

The technical specifications for tactile warnings devices shall conform with EN ISO standard 11683 (1997 edition) relating to “Packaging - Tactile warning of danger – Requirements”

Annex XII

SPECIAL PROVISIONS FOR LABELLING CERTAIN PREPARATIONS

(Annex V of the Directive of 1999 as adapted by Commission Directive 2001/60/EC of 7 August 2001 [2])

A For preparations classified as dangerous in accordance with Regulations 8, 9 and 10

1 *Preparations sold to the general public*

1.1 The labels on packages containing such preparations, in addition to the specific safety advice, must bear relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI.

1.2 When such preparations are classified as very toxic (T+), toxic (T) or corrosive (C) and where it is physically impossible to give such information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

2 *Preparations intended for use by spraying*

The package label containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned in accordance with the criteria laid down in Annex VI.

3 *Preparations containing a substance assigned phrase R33: Danger of cumulative effects*

When a preparation contains at least one substance assigned the phrase R33, the label of the preparation must carry the phrase R33, when the concentration of the substance in the preparation is equal to or higher than 1 %, unless different values are set in Annex I.

4 *Preparations containing a substance assigned phrase R64: May cause harm to breastfed babies*

When a preparation contains at least one substance assigned phrase R64, the label of the preparation must carry the phrase R64, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I.

B **For preparations irrespective of their classification in accordance with Regulations 8, 9 and 10**

1 *Preparations containing lead*

1.1 Paint and varnishes

Labels of packages of paints and varnishes containing lead in quantities exceeding 0.15% (expressed as weight of metal) of the total weight of the preparation, determined in accordance with 1S0 standard 6503/1984, must show the following particulars:

"Contains lead. Should not be used on surfaces liable to be chewed or sucked by children".

In the case of packages the contents of which are less than 125 ml, the particulars may be as follows:

"Warning! Contains lead.".

2 *Preparations containing cyanoacrylates*

2.1 Adhesives

The immediate packaging of adhesives based on cyanoacrylate must bear the following inscriptions:

"Cyanoacrylate

Danger

Bonds skin and eyes in seconds

Keep out of the reach of children".

Appropriate advice on safety must accompany the package.

3 *Preparations containing isocyanates*

The package labels of preparations containing isocyanates (as monomers, oligomers, prepolymers, *etc*., or as mixtures thereof) must bear the following inscriptions:

"Contains isocyanates

See information supplied by the manufacturer".

4 *Preparations containing epoxy constituents with an average molecular weight ≤ 700*

The package labels of preparations containing epoxy constituents with an average molecular weight ≤ 700 must bear the following inscriptions:

"Contains epoxy constituents

See information supplied by the manufacturer".

5 *Preparations sold to the general public, which contain active chlorine*

The packaging of preparations containing more than 1 % of active chlorine must bear the following particular inscriptions:

"Warning! Do not use together with other products. May release dangerous gases (chlorine)".

6 *Preparations containing cadmium (alloys) and intended to be used for brazing or soldering*

The packaging of the above mentioned preparations must bear the following inscription printed in clearly legible and indelible characters:

"Warning! Contains cadmium

Dangerous fumes are formed during use

See information supplied by the manufacturer

Comply with the safety instructions".

7 *Preparations available as aerosols*

Without prejudice to the provisions of theses Regulations, preparations available as aerosols are also subject to the labelling provisions specified in accordance with points 2.2 and 2.3 of the Annex to Directive 75/324/EEC [33].

8 *Preparations containing substances not yet tested completely*

Where a preparation contains at least one substance that, in accordance with Article 13.3 of the Directive of 1967, bears the inscription "Warning - substance not yet tested completely", the label of the preparation must bear the inscription "Warning - this preparation contains a substance not yet tested completely" if the substance is present in a concentration ≥ 1 %.

9 *Preparations not classified as sensitising but containing at least one sensitising substance*

The packaging of preparations containing at least one substance classified as sensitising and present in a concentration equal to or greater than 0.1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I, must bear the inscription:

"Contains (name of sensitising substance). May produce an allergic reaction".

10 *Liquid preparations containing halogenated hydrocarbons*

For liquid preparations that show no flashpoint or a flashpoint higher than 55 °C and contain a halogenated hydrocarbon and more than 5 % flammable or highly flammable substances, the packaging must bear the following inscription as appropriate:

"Can become highly flammable in use" or "'Can become flammable in use".

11 *Preparations containing a substance assigned the phrase R67: vapours may cause drowsiness and dizziness*

The packaging of preparations containing one or more substances assigned the phrase R47, must bear the wording of the phrase as set out in Annex III, when the total concentration of these substances in the preparation is equal to or higher than 15 %, unless:

- the preparation is already assigned the phrases R20, R23, R26, R68/20, R39/23 or R39/26, or
- the preparation is in a package not exceeding 125 millilitres.

12 *Cements and cement preparations*

The packaging of cements and cement preparations containing more than 0.0002 % soluble chromium (VI) on a dry weight basis must bear the inscription:

"Contains chromium (VI). May produce an allergic reaction"

unless the preparation is already classified as a sensitiser and assigned the phrase R43.

C **For preparations not classified in accordance with the provisions of Regulations 8, 9 and 10 but containing at least one dangerous substance**

1 *Preparations not intended for the general public*

The label on the packaging of the preparations referred to in Regulation 13 must bear the following inscription:

"Safety data sheet available for professional user on request".

Annex XIII

CONFIDENTIALITY FOR THE CHEMICAL IDENTITY OF A SUBSTANCE

(Annex VI of the Directive of 1999)

PART A

Information to be communicated in support of a request for confidentiality

Introductory notes

A Regulation 16 specifies the procedures to be followed where the person responsible for placing a preparation on the market wishes to avail of the provisions concerning confidentiality.

B To avoid the need for multiple requests for confidentiality relating to the same substance used in different preparations, a single request for confidentiality may suffice where a number of preparations have:

- the same dangerous constituents present in the same concentration range,
- the same classification and labelling, and
- the same expected uses.

A single alternative denomination must be used to mask the chemical identity of the same substance in the preparations concerned. Furthermore, the request for confidentiality must contain all information indicated in the request, including the name or the trade name of each preparation.

C The alternative designation used on the label must be the same as that given under heading 2 "Composition / information on ingredients" of the Annex to Directive 91/155/EEC [37] concerning safety data sheets.

This implies that the alternative designation used will contain enough information about the substance to ensure risk-free handling.

D In making a request to use an alternative designation, the person responsible for placing the preparation on the market must take into account the need to provide sufficient information concerning health and safety precautions necessary in the workplace to ensure that risks associated with handling the preparation can be minimised.

Request for confidentiality

In accordance with Regulation 16 the request for confidentiality must contain the following information:

1 Name and full address (including telephone number) of the person established in the Community who is responsible for placing the preparation on the market (manufacturer, importer or distributor).

2 Precise identification of the substance(s) for which confidentiality is requested and the alternative designation.

CAS No	Einecs No	Chemical name according to international nomenclature and classification (Annex I or provisional classification)	Alternative designation
(a)			
(b)			
(c)			

NB: where substances are classified provisionally, accompanying information (bibliographical references) should be provided as evidence that the provisional classification takes account of all existing pertinent information available on the properties of the substance

3 Justification for confidentiality (probability – plausibility).

4 Designation(s) or commercial name(s) of the preparation(s).

5 Is the designation or commercial name the same for all the Community?

Yes ☐ No ☐

If no, specify the designation(s) or commercial name(s) used in the different Member States-

Austria:

Belgium:

Denmark:

Germany:

Greece:

Finland:

France:

Spain:

Sweden:

Ireland:

Italy:

Luxembourg:

Netherlands:

Portugal:

United Kingdom.

6 Composition of the preparation(s) as defined in point 2 of the Annex to Directive 91/155/EEC [37] concerning safety data sheets.

7 Classification of the preparation(s) in accordance with Regulation 9.

8 Labelling of the preparation(s) in accordance with Regulation 13.

9 Intended uses for the preparation(s).

10 Safety data sheet(s) in accordance with the requirements of Directive 91/155/EEC [37] concerning safety data sheets.

PART B

Lexicon guide for establishing alternative designations (generic names)

1 **Introductory note**

This lexicon guide is based on the procedure used for the classification of dangerous substances (division of substances into families) which appears in Annex I.

Alternative designations to those based on this guide may be used. However, in all cases the names chosen must provide sufficient information to ensure that the preparation can be handled without risk and that necessary health and safety precautions can be taken in the workplace.

The families are defined in the following manner

- inorganic or organic substances whose properties derive from a common chemical element that provides their chief characteristic. The family name is derived from the name of the chemical element. These families are identified as in Annex I by the atomic number of the chemical element (001 to 103),
- organic substances whose properties are identified by having a common functional group that provides their chief characteristics. The family name is derived from the functional group name.

These families are identified by the conventional number found in Annex I (601-650). Sub-families bringing together substances with a common specific character have been added in certain cases.

2 **Establishing the generic name**

General principles

For the purposes of establishing the generic name, the following general approach, involving two successive stages, is adopted:

(i) identification of the functional groups and chemical elements present in the molecule;

(ii) determination of the extent to which account should be taken of the most important functional groups and chemical elements.

The identified functional groups and elements taken into account are the names of the families and sub-families set out in point 3 in the form of a non-restrictive list.

3 **Division of substances into families and sub-families**

Family No Annex I	Families Sub-families
001	Hydrogen compounds Hydrides
002	Helium compounds

Family No Annex I	Families Sub-families
003	Lithium compounds
004	Beryllium compounds
005	Boron compounds Boranes Borates
006	Carbon compounds Carbamates Inorganic carbon compounds Salts of hydrogen cyanide Urea and derivatives
007	Nitrogen compounds Quaternary ammonium compounds Acid nitrogen compounds Nitrates Nitrites
008	Oxygen compounds
009	Fluorine compounds Inorganic fluorides
010	Neon compounds
011	Sodium compounds
012	Magnesium compounds organometallic magnesium derivatives
013	Aluminium compounds organometallic aluminium derivatives
014	Silicon compounds Silicones Silicates
015	Phosphorus compounds Acid phosphorus compounds Phosphonium compounds Phosphoric esters Phosphates Phosphites Phosphoramides and derivatives
016	Sulphur compounds Acid sulphur compounds Mercaptans Sulphates Sulphites
017	Chlorine compounds Chlorates

Family No Annex I	Families Sub-families
	Perchlorates
018	Argon compounds
019	Potassium compounds
020	Calcium compounds
021	Scandium compounds
022	Titanium compounds
023	Vanadium compounds
024	Chromium compounds Chromium VI compounds
025	Manganese compounds
026	Iron compounds
027	Cobalt compounds
028	Nickel compounds
029	Copper compounds
030	Zinc compounds Organometallic zinc derivatives
031	Gallium compounds
032	Germanium compounds
033	Arsenic compounds
034	Selenium compounds
035	Bromine compounds
036	Krypton compounds
037	Rubidium compounds
038	Strontium compounds
039	Yttrium compounds
040	Zirconium compounds
041	Niobium compounds
042	Molybdenum compounds
043	Technetium compounds
044	Ruthenium compounds
045	Rhodium compounds
046	Palladium compounds
047	Silver compounds
048	Cadmium compounds

Family No Annex I	Families Sub-families
049	Indium compounds
050	Tin compounds Organometallic tin derivatives
051	Antimony compounds
052	Tellurium compounds
053	Iodine compounds
054	Xenon compounds
055	Caesium compounds
056	Barium compounds
057	Lanthanum compounds
058	Cerium compounds
059	Praseodymium compounds
060	Neodymium compounds
061	Promethium compounds
062	Samarium compounds
063	Europium compounds
064	Gandolinium compounds
065	Terbium compounds
066	Dysprosium compounds
067	Holmium compounds
068	Erbium compounds
069	Thulium compounds
070	Ytterbium compounds
071	Lutetium compounds
072	Hafnium compounds
073	Tantalum compounds
074	Tungsten compounds
075	Rhenium compounds
076	Osmium compounds
077	Iridium compounds
078	Platinum compounds
079	Gold compounds
080	Mercury compounds Organometallic mercury derivatives

Family No Annex I	Families Sub-families
081	Thallium compounds
082	Lead compounds organometallic lead derivatives
083	Bismuth compounds
084	Polonium compounds
085	Astate compounds
086	Radon compounds
087	Francium compounds
088	Radium compounds
089	Actinium compounds
090	Thorium compounds
091	Protactinium compounds
092	Uranium compounds
093	Neptunium compounds
094	Plutonium compounds
095	Americium compounds
096	Curiurn compounds
097	Berkelium compounds
098	Californium compounds
099	Einsteinium compounds
100	Fermium compounds
101	Mendelevium compounds
102	Nobelium compounds
103	Lawrencium compounds
601	Hydrocarbons Aliphatic hydrocarbons Aromatic hydrocarbons Alicyclic hydrocarbons Polycyclic aromatic hydrocarbons (PAH)
602	Halogenated hydrocarbons Halogenated aliphatic hydrocarbons Halogenated aromatic hydrocarbons Halogenated alicyclic hydrocarbons (*) (*) Specify according to the family corresponding to halogen
603	Alcohols and derivatives Aliphatic alcohols Aromatic alcohols

Family No Annex I	Families Sub-families
	Alicyclic alcohols Alcanolamines Epoxy derivatives Ethers Glycoethers Glycols and polyols
604	Phenols and derivatives Halogenated phenol derivatives (*) (*) Specify according to the family corresponding to halogen
605	Aldehydes and derivatives Aliphatic aldehydes Aromatic aldehydes Alicyclic aldehydes Aliphatic acetals Aromatic acetals Alicyclic acetals
606	Ketones and derivatives Aliphatic ketones Aromatic ketones (*) Alicyclic ketones (*) Quinones included
607	Organic acids and derivatives Aliphatic acids Halogenated aliphatic acids (*) Aromatic acids Halogenated aromatic acids (*) Alicyclic acids Halogenated alicyclic acids (*) Aliphatic acid anhydrides Halogenated aliphatic acid anhydrides (*) Aromatic acid anhydrides Halogenated aromatic acid anhydrides (*) Alicyclic acid anhydrides Halogenated alicyclic acid anhydrides (*) Salts of aliphatic acids Salts of halogenated aliphatic acids (*) Salts of aromatic acids Salts of halogenated aromatic acids (*) Salts of alicyclic acids Salts of halogenated alicyclic acids (*) Esters of aliphatic acids Esters of halogenated aliphatic acid (*) Esters of aromatic acids Esters of halogenated aromatic acids (*) Esters of alicyclic acid Esters of halogenated alicyclic acids (*) Esters of glycol ether

Family No Annex I	Families Sub-families
	Acrylates Methacrylates Lactones Acyl halogenides (*) Specify according to the family corresponding to halogen
608	Nitriles and derivatives
609	Nitro compounds
610	Chloronitrated compounds
611	Azoxy and azo compounds
612	Amine compounds Aliphatic amines and derivatives Alicyclic amines and derivatives Aromatic amines and derivatives Aniline and derivatives Benzidine and derivatives
613	Heterocyclic bases and derivatives Benzimidazole and derivatives Imidazol and derivatives Pyrethrinoids Quinoline and derivatives Triazine and derivatives Triazole and derivatives
614	Glycosides and alkaloids Alkaloid and derivatives Glycosides and derivatives
615	Cyanates and isocyanates Cyanates Isocyanates
616	Amides and derivatives Acetamide and derivatives Anilides
617	Organic peroxides
647	Enzymes
643	Complex coal derivatives Acid extract Alkaline extract Anthracene oil Anthracene oil extract residue Anthracene oil fraction Carbolic oil Carbolic oil extract residue Coal liquids, liquid solvent extraction Coal liquids, liquid solvent extraction solvents

Family No Annex I	Families Sub-families
	Coal oil Coal tar Coal tar extract Coal tar solids residue Coke (coal tar) low temperature, high temperature pitch Coke (coal tar), high temperature pitch Coke (coal tar), mixed coal high temperature pitch Crude benzole Crude phenols Crude tar bases Distillate bases Distillate phenols Distillates Distillates (coal), liquid solvent extraction, primary Distillates (coal), solvent extraction, hydrocracked Distillates (coal), solvent extraction, hydrocracked hydrogenated middle Distillates (coal), solvent extraction, hydrocracked middle Extract residues (coal), low temperature coal tar alkaline Fresh oil Fuels, diesel, coal solvent extraction, hydrocracked, hydrogenated Fuels, jet aircraft, coal solvent extraction, hydrocracked, hydrogenated Gasoline, coal solvent extraction, hydrocracked naphtha Heat treatment products Heavy anthracene oil Heavy anthracene oil redistillate Light oil Light oil extract residues, high boiling Light oil extract residues, intermediate boiling Light oil extract residues, low boiling Light oil redistillate, high boiling Light oil redistillate, intermediate boiling Light oil redistillate, low boiling Methylnaphthalene oil Methylnaphthalene oil extract residue Naphtha (coal), solvent extraction, hydrocracked Naphthalene oil Naphthalene oil extract residue Naphthalene oil redistillate Pitch Pitch redistillate Pitch residue Pitch residue, heat treated Pitch residue, oxidised Pyrolysis products Redistillates Residues (coal), liquid solvent extractions Tar brown coal Tar brown coal, low temperature Tar oil, high boiling Tar oil, intermediate boiling Wash oil

Family No Annex I	Families Sub-families
	Wash oil extract residue Wash oil redistillate
649	Complex oil derivatives Crude oil Petroleum gas Low boiling point naphtha Low boiling point modified naphtha Low boiling point cat-cracked naphtha Low boiling point cat-reformed naphtha. Low boiling point thermally cracked naphtha Low boiling point hydrogen treated naphtha Low boiling point naphtha – unspecified Straight-run kerosine Kerosine – unspecified Cracked gas oil Gas oil – unspecified Heavy fuel oil Grease Unrefined or mildly refined base oil Base oil - unspecified Distillate aromatic extract Distillate aromatic extract (treated) Foots oil Slack wax Petrolatum
650	Various substances Do not use this family. Instead, use the families or subfamilies mentioned above

4 **Practical application**

After conducting a search to see if the substance belongs to one or more families or subfamilies on the list, the generic name can be established in the following manner:

4.1 if the name of a family or sub-family is sufficient to characterise the chemical elements or important functional groups, that name should be chosen as the generic name -

Examples:

- 1,4 dihydroxybenzen
  family 604: phenols and derivatives
  generic name: phenol derivatives

- butanol
  family 603: alcohols and derivatives
  sub-family: aliphatic alcohols
  generic name: aliphatic alcohol

- 2-Isopropoxyethanol
  family 603: alcohols and derivatives
  sub-family: glycolethers
  generic name: glycolether

- methacrylate
  family 607: organic acids and derivatives
  sub-family: acrylates
  generic name: acrylate

4.2 if the name of a family or sub-family is not sufficient to characterise the chemical elements of important functional groups, the generic name chosen should be a combination of the corresponding different family or sub-family names:

Examples:

- chlorobenzene
  family 602: halogenated hydrocarbons
  sub-family: halogenated aromatic hydrocarbons
  family 017: chlorine compounds
  generic name: chlorinated aromatic hydrocarbon

- 2,3,6-trichlorophenylacctic acid
  family 607: organic acids
  sub-family: halogenated aromatic acids
  family 017: chlorine compounds
  generic name: chlorinated aromatic acid

- 1-chloro-1-nitropropane
  family 610: chloronitrated derivatives
  family 601: hydrocarbons
  sub-family: aliphatic hydrocarbons
  generic name: chlorinated aliphatic hydrocarbon

- tetrapropyl dithiopyrophosphate

family 015: phosphorus compounds
sub-family: phosphoric esters
family 016: sulphur compounds
generic name: thiophosphoric ester

NB: in the case of certain elements, notably metals, the name of the family or sub-family may be indicated by the words 'organic' or 'inorganic'.

Examples:

- dimercury chloride
  family 080: mercury compounds
  generic name: inorganic mercury compound

- barium acetate
  family 056: barium compounds
  generic name: organic barium compound

- ethyl nitrite
  family 007: nitrogen compounds
  sub-family: nitrites
  generic name: organic nitrite

- sodium hydrosulphite
  family 016: sulphur compounds
  generic name: inorganic sulphur compound

(The examples cited are substances taken from Annex I in respect of which requests for confidentiality may be submitted).

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FOURTH SCHEDULE

Annex XIV

PREPARATION (FORMULATION) TYPES AND CODES*

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of active substance(s) in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.

Code	Description	Definition
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of active substance(s) in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 □.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 □.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.

Code	Description	Definition
MG	Microgranule	A granule in the particle size range from 100 to 600 □.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a plant protection product	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate (= flowable concentrate)	A stable suspension of active substance(s) in a fluid intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance(s) after solution in water but which may contain insoluble inert ingredients.

Code	Description	Definition
SS	Water soluble powder for water before application seed treatment	A powder to be dissolved in to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

* based upon the "Catalogue of Pesticide Formulation types and International Coding System", GCPF (GIFAP) Technical Monograph No 2, 4th Edition, 1999.

FIFTH SCHEDULE

Information and documentation to support a notification for a biocide product in accordance with subparagraph (3) (b) of Regulation 5 or paragraph (3) of Regulation 11

List of information/documentation required		explanation of requirement
1	Notifier	name of company, address, contact person, telephone, facsimile numbers and e-mail address
2	Product name (trade name)	
3	Biocide product type	select from categories listed hereunder
4	Brief description of intended use(s)	*e.g.* disinfectant for use on surfaces and equipment in the meat industry
5	User Type	professional or amateur user
6	Formulation type	use GCPF code *e.g*. EC, wax bloc, paint *etc.* (see Annex XIV)
7	Packaging	packaging type (material, type of closure), size(s)
8	Wholesale distributor(s)	
9	Detailed specification of the preparation	minimum content of each technical active substance(s) in g/kg; minimum content of each pure active substance(s) in g/kg; content of other formulants in g/kg
10	Material Safety Data Sheet for the preparation	
11	Current label (in compliance with these Regulations) for the preparation	
12	Manufacturer of the preparation	name of company, name and address of plant , contact person, telephone, facsimile numbers and e-mail address
13	Manufacturer of each active substance in the preparation	name of company, name and address of plant , contact person, telephone, facsimile numbers and e-mail address
14	Detailed specification of each active substance in the preparation	minimum content in g/kg of pure active substance; maximum content in g/kg of inactive isomers; the ratio of the content of isomers / diastereo-isomers; maximum content in g/kg of each further component, including by-products and impurities; content in g/kg of additives,
15	Details of the manufacturing process (synthesis pathway) for each active substance,	identity of the starting materials, the chemical pathways involved, the identity of by-products and impurities present in the final product
16	Material Safety Data Sheet for each active substance	
17	Material Safety Data Sheet for each formulant	

Biocide Products by Type

(Each biocide product notified should be identified as being of one or more of the following product types - see item 3 in the preceding tabular presentation of notification requirements)

Type 1	**Human hygiene biocidal products**	biocidal products used for human hygiene purposes
Type 2	**Private area and public health area disinfectants**	products for disinfection of air, surfaces materials, equipment and furniture (excluding uses involving direct contact with food or feed), in private, public, and industrial areas including hospitals and algaecides (*e.g.* use in swimming pools, aquaria, bathing and other waters, air conditioning systems, walls and floors, chemical toilets, waste water, hospital waste, soil or other substrates
Type 3	**Veterinary hygiene biocidal products**	biocide products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported
Type 4	**Food and Feed area disinfectants**	products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals
Type 5	**Drinking water disinfectants**	products for disinfection of drinking water for humans and animals
Type 6	**In-can preservatives**	products for preservation of manufactured products other than foodstuffs or feedingstuffs, in containers, *via* control of microbial deterioration - to ensure shelf life
Type 7	**Film preservatives**	products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works
Type 8	**Wood preservatives**	products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms (preventative and curative products)
Type 9	**Fibre, leather, rubber and polymerised materials preservatives**	products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration
Type 10	**Masonry preservatives**	products used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack
Type 11	**Preservatives for liquid -cooling and processing systems**	products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels - does not include products used for the preservation of drinking water
Type 12	**Slimicides**	products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes *e.g.* on wood and paper pulp, porous sand strata in oil extraction

Type 13	**Metalworking-fluid preservatives**	products used for the preservation of metalworking fluids by the control of microbial deterioration
Type 14	**Rodenticides**	products used for the control of mice, rats or other rodents
Type 15	**Avicides**	products used for the control of birds
Type 16	**Molluscicides**	products used for the control of molluscs
Type 17	**Piscicides**	products used for the control of fish; these products exclude products for the treatment of fish diseases
Type 18	**Insecticides, acaricides and products to control other arthropods**	products used for the control of arthropods (*e.g.* insects, arachnids and crustaceans)
Type 19	**Repellents and attractants**	products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly
Type 20	**Preservatives for food or feedstocks**	products used for the preservation of food or feedstocks by the control of harmful organisms
Type 21	**Antifouling products**	products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water
Type 22	**Embalming and taxidermist fluids**	products used for the disinfection and preservation of human or animal corpses, or parts thereof
Type 23	**Control of other vertebrates**	products used for the control of vermin

A form for use by notifiers of biocide products is provided hereunder

Notification Form for Biocide Products

Product (brand name): .....

Biocide product type: (select from list of categories attached - enter type numbers) .....

Formulation Type (GCPF Code): (*e.g.* EC, SC, wax block, paint *etc*.) .....

Brief description of intended use(s): .....

.....

Name and address of the formulator (manufacturer) of the biocide product: .....

.....

.....

Notifier: .....

.....

Primary wholesale distributor (s): .....

.....

.....

Pack sizes	Packaging type (materials and construction)

For Amateur Use: Yes ☐ No ☐ For Professional Use: Yes ☐ No ☐

Material Safety Data Sheet (MSDS) for the biocide product enclosed: Yes ☐ No ☐

Current/proposed product label (in compliance with the Regulations) enclosed: Yes ☐ No ☐

For Official Use

PCS No: .....

Category: .....

Reference product: .....

Associated products: .....

Initials: .....

Detailed Specification of the preparation:

	Identity of each substance in the preparation *	CAS number	Manufacturer of the active substance	minimum content of technical material (g/kg)	minimum content of pure technical material (g/kg)	MSDS enclosed (indicate yes or no)	Letter of access enclosed (if required - yes or no)
1							
2							
3							
4							
5							
6							
7							

	Identity of each formulant (other than active substance) in the preparation *	Trade name (if applicable	Manufacturer of the formulant	function of the formulant	minimum content of formulant (g/kg)	MSDS enclosed (indicate yes or no)	Letter of access enclosed (if required - yes or no)
1							
2							
3							
4							
5							
6							
8							
9							
10							

Fifth schedule **Information and documentation to support a notification for a biocide in accordance with subparagraph (3) (b) of Regulation 5 or paragraph (3) of Regulation 11**

Detailed specification of each active substance in the product (to be completed for each such active substance)

Active substance: (specify *)	**minimum content of pure material:**	**g/kg**
Identity of each by-product or impurity *		maximum content in g/kg
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
Identity of each inactive isomer *		maximum content in g/kg
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
Ratio of the content of isomers/diastereoisomers: (specify)		
Identity of each additive *		maximum content in g/kg
1		
2		
3		
4		
5		

Details of the manufacturing process (synthesis pathway) for each active substance in the biocide product (to be completed for each such active substance):

Fifth schedule **Information and documentation to support a notification for a biocide in accordance with subparagraph (3) (b) of Regulation 5 or paragraph (3) of Regulation 11**

Active substance: (specify *)	
Identity of each starting material *	
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Brief description of the chemicals pathways involved	
Identity of by-products and impurities present in the final product *	
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

* ISO common names, where available should be used, in other cases the chemical name of each constituent (EINECS or ELINCS), and the CAS and EC numbers should be provided

SIXTH SCHEDULE

CERTIFICATE OF RESULT OF ANALYSIS CARRIED OUT BY A DESIGNATED ANALYST

Laboratory Reference Number .....

Sample of .....

received by the designated analyst on .....

from .....

Methods of analysis used .....

.....

.....

This is to certify that the above mentioned sample, which was duly fastened and sealed, has been analyzed under the provisions of the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001 and that the results of the analysis are as follows:-

.....

.....

.....

.....

.....

.....

This certificate is issued under the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001

Date ..... Signed .....
Designated Analyst

.....
Designated Analyst

.....

Designated Analyst

SEVENTH SCHEDULE

CERTIFICATE OF RESULT OF ANALYSIS CARRIED OUT BY THE STATE CHEMIST

Laboratory Reference Number .....

Sample of .....

taken at the premises of ..... on .....

temperature and place of storage .....

Date ..... Signed .....
Authorized Officer

received by the State Chemist on .....

from
.....

Methods of analysis used .....

.....
.

.....
.

This is to certify that the above mentioned sample, which was duly fastened and sealed, has been analyzed under the provisions of the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001 and that the results of the analysis are as follows:-

.....
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.....
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.....
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.....
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This certificate is issued under the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001

Date ..... Signed .....…….....
State Chemist.

EIGHTH SCHEDULE

APPLICATION AND ANNUAL FEES FOR CLEARANCE AND NOTIFICATION OF PLANT PROTECTION PRODUCTS AND BIOCIDE PRODUCTS

PART I

A Each active substance contained in the plant protection product or biocide product

Column (1)	Column (2) Type of clearance and fee payable			
Category	Trial	Limited	Provisional	Restricted or Commercial
	€	€	€	€
I	190	2,540	5,080	5,715

B Each preparation

Column (1)	Column (2) Type of clearance and fee payable			
Category	Trial	Limited	Provisional	Restricted or Commercial
	€	€	€	€
I	127	508	1,270	1,905
II	95	254	508	762

In this Schedule -

"Category I" means a plant protection product or biocide product containing one or more active substances of particular specification not previously cleared;

or

means a plant protection product or biocide product for which clearance, for a major new area of use or for a major formulation change, is sought;

"Category II" means a plant protection product or biocide product for which clearance, for a minor extension in use or for a minor formulation changes, is sought;

"Commercial clearance" means clearance for commercial sale and use of a plant protection product or biocide product;

"Limited clearance"	means clearance for commercial sale and use of a plant protection product or biocide product, in limited quantities or for a limited period or both, subject to specified restrictions or conditions;
"Provisional clearance"	means clearance for commercial sale and use of a plant protection product or biocide product, sometimes for a limited period, subject to specified restrictions or conditions;
"Restricted clearance"	means clearance for commercial sale and use of a plant protection product or biocide product subject to restriction(s) imposed by other statutory provisions or subject to special restrictions;
"Trial clearance"	means clearance for experimental use of a plant protection product or biocide product subject to specified restrictions or conditions.

C Reduced fees payable for plant protection products or biocide products for specialised use or uses, already on the market for 3 calendar years

Column (1) Wholesale sales in each of three calendar years immediately prior to the year in which the fee is payable	Column (2) Percentage of the fee payable
	%
less than €6,350	10
€6,350 to €12,699	25
€12,700 to €25,395	50

Eighth schedule **Application and annual fees for clearance and notification of plant protection products and biocide productss**

D Reduced fees payable for plant protection products or biocide products for specialised use or uses, on the market for less than 3 calendar years

Column (1) Estimated potential annual wholesale sales	Column (2) Percentage of the fee payable
	%
less than €12,700	10
€12,700 to €25,394	25
€25,395 to €50,790	50

PART 2

Type of Clearance	Amount
Annual Fee for a Limited, Provisional, Commercial, or Restricted Clearance, and for Notified plant protection products and biocide products	€254
Trial Clearance	€65

PART 3

Type of Clearance	Amount
Late Annual Fee for a Limited, Provisional, Commercial, or Restricted Clearance, and for Notified plant protection products and biocide products	€380

Given under my Official Seal this 18th day of December 2001

L.S.

Joe Walsh
Minister for Agriculture, Food and Rural Development

Explanatory Note

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations specify the methods to be used for identification of hazards associated with handling and use of plant protection products and biocide products in accordance with Directive 1999/45/EC of the European Parliament and of the Council. They prescribe the classification, packaging and labelling conditions that must be complied with in relation to their being placed on the market, in accordance with that Directive.

In addition the Regulations define the conditions under which existing plant protection products and biocide products can continue to be placed on the market. Provision is made for the detailed review of the studies conducted and information used to identify the hazards arising and to establish the nature and extent of the foreseeable risks which the handling or use of plant protection products and biocide products entail.

The Regulations specify the fees, including the annual fees to be paid in relation to plant protection products and biocide products.

These Regulations provide a mechanism to permit a register of biocide products on the market to be compiled. They also introduce basic transitional arrangements for biocide products pending their regulation pursuant to 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

These Regulations replace the European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1994 to 2001 (S.I. No. 138 of 1994; S.I. No. 463 of 1999; and S.I. No. 140 of 2001), which are revoked.

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