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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2001/59/EC

of 6 August 2001

adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]), as last amended by Commission Directive 2000/33/EC ([2]), and in particular Article 28 thereof,

Whereas:

(1) Annex I to Directive 67/548/EEC contains a list of dangerous substances, together with particulars of the classification and labelling of each substance. Present scientific and technical knowledge has shown that the list of dangerous substances in that Annex should be adapted to technical progress. Specifically, Tables A and B in the Foreword to Annex I require inclusion of the Finnish and Swedish nomenclature. Certain language versions of the Directive require technical corrections in specific sections of the Foreword to Annex I. It is useful to publish an updated and recast version of the Foreword to Annex I. Furthermore, the list itself should be updated to include notified new substances and further existing substances; the identity, nomenclature, classification, labelling and/or concentration limits for certain substances should be amended to reflect increased technical knowledge; the entries for three substances should be deleted from the list, since they are covered by other entries.

(2) Annex II to Directive 67/548/EEC contains a list of symbols and indications of danger for dangerous substances and preparations. Annex III to Directive 67/548/EEC contains a list of phrases indicating the nature of special risks attributed to dangerous substances and preparations. Annex IV to Directive 67/548/EEC contains a list of the phrases indicating the safety advice concerning dangerous substances and preparations. Annexes II, III and IV require inclusion of the Finnish and Swedish wordings. Certain language versions of the Directive require technical corrections in specific sections of Annexes II, III and IV. It is useful to publish updated and recast versions of Annexes II, III and IV.

(3) Article 1 of European Parliament and Council Directive 1999/33/EC ([3]) permitted Sweden from 1 January 1999 until 31 December 2000 to require the use of the additional R-phrase R340, not listed in Annex III, for substances classified as carcinogenic, category 3, instead of R-phrase R40. Member State experts have agreed to revise the text of R-phrase R40 to refer to carcinogenic, category 3 substances. A new R-phrase R-68 should be added to Annex III, containing the original text of R-phrase R40 for classification and labelling of mutagenic category 3 and harmful substances listed in Annex I. The classification and labelling and concentration limit references in Annex I that include R40 should therefore be revised for such mutagenic category 3 and harmful substances.

(4) Annex V to Directive 67/548/EEC lays down the methods for the determination of the physicochemical properties, toxicity and ecotoxicity of substances and preparations. It is necessary to adapt that Annex to technical progress. It is appropriate to reduce to a minimum the number of animals used for experimental purposes, in accordance with Council Directive 86/609/EEC ([4]). Chapter B.1 should therefore be deleted, since alternative methods, using fewer animals, are available. Due regard should be given to methods recognised and recommended by competent international organisations. The methods for subchronic oral toxicity in Chapters B.26 and B.27 should be revised accordingly and Chapters C.14 to C.20, on

([1]) OJ 196, 16.8.1967, p. 1.
([2]) OJ L 136, 8.6.2000, p. 90.
([3]) OJ L 199, 30.7.1999, p. 57.
([4]) OJ L 358, 18.12.1986, p. 1.

environmental toxicity should be added to Annex V. Certain language versions require technical corrections to specific sections of Annex V.

(5) Annex VI to Directive 67/548/EEC contains a guide to the classification and labelling of dangerous substances and preparations. It is necessary to adapt that Annex to technical progress. Certain language versions of the Directive require technical corrections in specific sections of Annex VI. Specific sections require publication in Finnish and Swedish. It is useful to publish an updated and recast version of Annex VI, particularly including reference to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ([1]).

(6) In accordance with the provisions of Directive 67/548/EEC, any new substance placed on the market should be notified to the competent authorities of the Member States by means of a notification containing certain information including a technical dossier. For new substances supplied and then consumed in a chemical reaction which are strictly controlled (intermediates with limited exposure), it is technically justifiable and appropriate to define a reduced test package (RTP). Current technical progress can guarantee minimum exposure for man and the environment through rigorous containment of the process.

(7) The technical dossier should contain a test package for intermediates with limited exposure which would supply the information necessary to evaluate their foreseeable risk for man and the environment. Annex VII should specify the content of this technical dossier and Annex VIII should detail additional tests and studies that may be required for intermediates with limited exposure marketed in higher volumes.

(8) The criteria for the notification of intermediates with limited exposure may need to be revised in the light of technical progress and experience gained with such notifications made in accordance with the new specific requirements laid down in this Directive.

(9) The measures provided for in this Directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives for the Elimination of Technical Barriers to Trade in Dangerous Substances and Preparations,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 67/548/EEC is hereby amended as follows:

1. Annex I is amended as follows:

   (a) Tables A and B in the foreword to Annex I shall include the Finnish and Swedish nomenclature. Certain language versions of the Directive shall include technical corrections in specific sections of the Foreword and Tables A and B. The Foreword including Tables A and B is replaced by Annex 1A to this Directive.

   (b) The corresponding entries are replaced by the entries in Annex 1B to this Directive.

   (c) The entries in Annex 1C to this Directive are inserted.

   (d) The entries in Annex 1D to this Directive are deleted.

   (e) The entries shown in Annex 1E to this Directive are amended by replacing classification references to 'Muta. Cat. 3; R40' by 'Muta. Cat. 3; R68' and by replacing labelling references to R40 by R68.

   (f) The entries shown in Annex 1F to this Directive are amended by replacing classification references to 'Xn; R40' by 'Xn; R68' and by replacing labelling references to R40 by R68.

   (g) The entry shown in Annex 1G to this Directive is amended by replacing concentration limit references to 'Xn; R40/20/21/22' by 'Xn; R68/20/21/22'.

   (h) The entry shown in Annex 1H to this Directive is amended by replacing concentration limit references to 'Xn; R20/21/22-40/20/21/22' by 'Xn; R20/21/22-68/20/21/22'.

   (i) The entries shown in Annex 1I to this Directive are amended by replacing classification references to 'Muta. Cat. 3; R40' by 'Muta. Cat. 3; R68'.

   (j) The entries shown in Annex 1J to this Directive are amended by replacing classification references to 'Muta. Cat. 3; R40' by 'Muta. Cat. 3; R68' and by adding R68 to the label.

2. Annex II shall include the Swedish and Finnish versions and technical corrections to certain language versions. Annex II is therefore replaced by Annex 2 to this Directive.

3. Annex III shall include the Swedish and Finnish versions and technical corrections to certain language versions. Annex III is therefore replaced by Annex 3 to this Directive.

4. Annex IV shall include the Swedish and Finnish versions and technical corrections to certain language versions. Annex IV is therefore replaced by Annex 4 to this Directive.

([1]) OJ L 200, 30.7.1999, p. 1.

5. Annex V is amended as follows:

(a) Chapter B.1 is deleted.

(b) The title of the English version of Chapter B13/14 is replaced by the text in Annex 5A.

(c) The last sentence of the French version of paragraph 1.4.2.2 of Chapter B.39 is replaced by the text in Annex 5B.

(d) The equation in the last sentence of section 1.7.1.6 of the English version of Chapter B.41 is replaced by the text in Annex 5C.

(e) The test method for subchronic oral toxicity tests in rodents is amended in accordance with Annex 5D to this Directive, which replaces Chapter B.26.

(f) The test method for subchronic oral toxicity tests in non-rodents is amended in accordance with Annex 5E to this Directive, which replaces Chapter B.27.

(g) The seven new test methods for environmental toxicity in Annex 5F to this Directive are included in Part C.

6. Annex VI shall include the Swedish and Finnish versions, technical corrections to certain language versions and further detailed technical updates. Annex VI is therefore replaced by Annex 6 to this Directive.

7. Annex VII.A shall include a technical dossier containing a test package for intermediates with limited exposure, supplying the information necessary to evaluate their foreseeable risk for man and the environment. Annex VII.A is therefore amended as follows:

(a) the text in Annex 7A to this Directive is inserted before section 0 of Annex VII.A;

(b) the text in Annex 7B to this Directive is inserted at the end of Annex VII.A.

8. Annex VIII shall include additional tests and studies that may be required for intermediates with limited exposure marketed in higher volumes. Annex VIII is therefore amended as follows:

(a) the text in Annex 8A to this Directive is inserted between 'Level 1' and 'Physicochemical studies' of Annex VIII;

(b) the text in Annex 8B to this Directive is inserted between 'Level 2' and 'Toxicological studies' of Annex VIII.

Article 2

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

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

(a) as from 30 July 2002 or an earlier date for dangerous substances;

(b) as from 30 July 2002 for preparations not within the scope of Council Directive 91/414/EEC [1] or European Parliament and Council Directive 98/8/EC [2];

(c) as from 30 July 2004 for preparations within the scope of Directive 91/414/EEC or Directive 98/8/EC.

They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the main provisions of national law which they adopt in the field covered by this Directive and a correlation table between this Directive and the national provisions adopted.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 August 2001.

For the Commission

Margot WALLSTRÖM

Member of the Commission

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 123, 24.4.1998, p. 1.

ANNEX 1A

FOREWORD TO ANNEX I

Introduction

Annex I is an index of dangerous substances for which harmonised classification and labelling have been agreed at Community level in accordance with the procedure laid down in Article 4(3) of this Directive.

Numbering of entries

Entries in Annex I are listed according to the atomic number of the element most characteristic of the substance's properties. A list of the chemical elements, arranged according to atomic number is shown in Table A. Organic substances, because of their variety, have been placed in the usual classes, as shown in Table B.

The index number for each substance is in the form of a digit sequence of the type ABC-RST-VW-Y, where:

— ABC is either the atomic number of the most characteristic chemical element (preceded by one or two zeros to make up the sequence) or the usual class number for organic substances,

— RST is the consecutive number of the substance in the series ABC,

— VW denotes the form in which the substance is produced or placed on the market,

— Y is the check-digit calculated in accordance with the ISBN (International Standard Book Number) method.

As an example, the index number for sodium chlorate is 017-005-00-9.

For dangerous substances in the European Inventory of Existing Commercial Chemical Substance (Einecs) (OJ C 146A, 15.6.1990), the Einecs number is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8.

For dangerous substances notified under the provisions of this Directive, the number of the substance in the European List of Notified Substance (Elincs) is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 400-010-9.

For dangerous substances in the list of 'No-longer polymers' (Document, Office for Official Publications of the European Communities, 1997. ISBN 92-827-8995-0) the 'No-longer polymer' number is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 500-001-0.

The Chemical Abstracts Service (CAS) number is also included to assist identification of the entry. It should be noted that the Einecs number includes both anhydrous and hydrated forms of a substance, and there are frequently different CAS numbers for anhydrous and hydrated forms. The CAS number included is for the anhydrous form only, and therefore the CAS number shown does not always describe the entry as accurately as the Einecs number.

Einecs, Elincs, 'No-longer polymer' or CAS numbers are not usually included for entries which comprise more than four individual substances.

Nomenclature

Wherever possible, dangerous substances are designated by their Einecs, Elincs or 'No-longer polymer' names. Other substances not listed in Einecs, Elincs or the list of 'No-longer polymers' are designated using an internationally recognised chemical name (e.g. ISO, IUPAC). An additional common name is included in some cases.

Impurities, additives and minor components are normally not mentioned unless they contribute significantly to the classification of the substance.

Some substances are described as a mixture of A and B. These entries refer to one specific mixture. In some cases where it is necessary to characterise the substance put on the market, the proportions of the main substances in the mixture are specified.

Some substances are described with a specific percentage purity. Substances containing a higher content of active material (e.g. an organic peroxide) are not included in the Annex I entry and may have other hazardous properties (e.g. explosive). Where specific concentration limits are shown, these apply to the substance or substances shown in the entry. In particular, in the case of entries which are mixtures of substances or substances described with a specific percentage purity, the limits apply to the substance as described in Annex I and not the pure substance.

Article 23(2)(a) requires that for substances appearing in Annex I, the name of the substance to be used on the label should be one of the designations given in the Annex. For certain substances, additional information has been added in square brackets in order to help identify the substance. This additional information need not be included on the label.

Certain entries contain a reference to impurities. An example is index No 607-190-00-X: methyl acrylamidomethoxyacetate (containing ≥ 0,1 % acrylamide). In these cases the reference in brackets forms part of the name, and must be included on the label.

Certain entries refer to groups of substances. An example is index No 006-007-00-5: 'hydrogen cyanide (salts of …) with exception of complex cyanides such as ferrocyanides, ferricyanides and mercuric oxycyanide'. For individual substances covered by these entries, the Einecs name or another internationally recognised name must be used.

Format of entries

The following information is given for each substance in Annex I:

(a) *the classification:*

(i) the process of classification consists of placing a substance in one or more categories of danger (as defined in Article 2(2) of Council Directive 92/32/EEC (OJ L 154, 5.6.1992, p. 1)) and assigning the qualifying risk phrase or phrases. The classification has consequences not only for labelling but also for other legislation and regulatory measures on dangerous substances;

(ii) the classification for each category of danger is normally presented in the form of an abbreviation representing the category of danger together with the appropriate risk phrase or phrases. However, in some cases (i.e. substances classified as flammable, sensitising and some substances classified as dangerous for the environment) the risk phrase alone is used;

(iii) the abbreviation for each of the categories of danger is shown below:

— explosive: E

— oxidising: O

— extremely Flammable: F+

— highly Flammable: F

— flammable: R10

— very toxic: T+

— toxic: T

— harmful: Xn

— corrosive: C

— irritant: Xi

— sensitising: R42 and/or R43

— carcinogenic: Carc. Cat. ([1])

— mutagenic: Muta. Cat. ([1])

— toxic for reproduction: Repr. Cat. ([1])

— dangerous for the environment: N or/and R52, R53, R59;

(iv) additional risk phrases which have been assigned to describe other properties (see sections 2.2.6 and 3.2.8 of the labelling guide) are shown although they are not formally part of the classification;

([1]) The category of carcinogen, mutagen or toxic for reproduction (i.e. 1, 2 or 3) is shown as appropriate.