COMMISSION DIRECTIVE 2001/58/EC

of 27 July 2001

amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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], and in particular Article 14 thereof,

Having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [2], as last amended by Commission Directive 2000/33/EC [3], and in particular Article 27 thereof,

Whereas:

(1) Article 14 of Directive 1999/45/EC provides that the person responsible for placing on the market certain specified preparations must provide a safety data sheet.

(2) Article 27 of Directive 67/548/EEC provides that the person responsible for placing dangerous substances on the market must also provide a safety data sheet.

(3) Safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work.

(4) Safety data sheets for dangerous substances and certain preparations, and their supply must comply with the provisions of Commission Directive 91/155/EEC [4], as amended by Directive 93/112/EC [5].

(5) Article 14(2.1)(b) of Directive 1999/45/EC introduces a new requirement for persons responsible for placing preparations on the market to provide on the request of professional users a safety data sheet containing proportionate information for preparations not classified as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, but which contain in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits.

(6) Directive 1999/45/EC also introduces a requirement for preparations to be classified and labelled for their effects on the environment.

(7) It is therefore necessary to amend Directive 91/155/EEC accordingly, as specified in Article 14(2.3) of Directive 1999/45/EC, before 30 July 2002.

(8) Article 4 of Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risk related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) [6] requires employers to determine whether any hazardous chemical agents are present at the workplace, and to assess any risk to the health and safety of workers arising from the presence of those chemical agents, taking into consideration the information provided by the supplier via safety data sheets; it is therefore opportune to amend the Annex to Directive 91/155/EEC accordingly.

(9) It is known from recent enforcement activities and studies in the Member States that many safety data sheets are of poor quality and do not provide adequate information for the user; one way of improving the quality of safety data sheets is to improve the guidance given to compilers of safety data sheets set out in the Annex to Directive 91/155/EEC; it is therefore opportune to amend the Annex to Directive 91/155/EEC accordingly; the Commission and the Member States will consider other means by which the quality of safety data sheets can be improved further in future.

(10) The measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives on the removal of technical barriers to trade in dangerous substances and preparations established under Article 20 of Directive 1999/45/EC,

[1] OJ L 200, 30.7.1999, p. 1.
[2] OJ 196, 16.8.1967, p. 1.
[3] OJ L 136, 8.6.2000, p. 90.
[4] OJ L 76, 22.3.1991, p. 35.
[5] OJ L 314, 16.12.1993, p. 38.
[6] OJ L 131, 5.5.1998, p. 11.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/155/EEC is amended as follows:

1. Article 1(1) is replaced by the following:

'1. (a) The person who is responsible for placing a chemical substance or preparation on the market, whether the manufacturer, importer or distributor, shall supply the recipient, who is a professional user of the substance or preparation, with a safety data sheet containing the information set out in Article 3 and the Annex to this Directive, if the substance or preparation is classified as dangerous according to Directive 67/548/EEC or European Parliament and Council Directive 1999/45/EC (*).

(b) Any person who is responsible for placing a preparation on the market, whether the manufacturer, importer or distributor, shall supply, on request of a professional user, a safety data sheet providing proportionate information as set out in Article 3 and the Annex to this Directive, if the preparation is not classified as dangerous according to Articles 5, 6 and 7 of Directive 1999/45/EC, but the preparation contains in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits.

(*) OJ L 200, 30.7.1999, p. 1.'

2. The Annex referred to in Article 3 is replaced by the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 July 2002 at the latest. They shall forthwith inform the Commission thereof.

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

(a) to preparations not within the scope of Council Directive 91/414/EEC [1] on the placing of plant protection products on the market, or Council Directive 98/8/EC [2] on the placing of biocidal products on the market as from 30 July 2002;

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

3. When Member States adopt 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.

Article 3

This Directive shall enter into force on the 20th 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, 27 July 2001.

For the Commission

Erkki LIIKANEN

Member of the Commission

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

ANNEX

'ANNEX

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

The purpose of this Annex is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 3, so that the resulting safety data sheets will enable professional users to take the necessary measures relating to protection of health and safety at the workplace, and protection of the environment.

The information provided by safety data sheets should meet the requirements set out in Council Directive 98/24/EC [1] on the protection of the health and safety of workers from the risks related to chemical agents at work. In particular, the safety data sheet should enable the employer to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use.

The information must be written in a clear and concise manner. The safety data sheet should be prepared by a competent person who should take into account the specific needs of the user audience, as far as it is known. Persons placing substances and preparations on the market should ensure that competent persons have received appropriate training, including refresher training.

For preparations not classified as dangerous, but for which a safety data sheet is required according to Article 14(2.1)(b) of Directive 1999/45/EC, proportionate information should be provided under each heading.

Additional information may be necessary in some cases in view of the wide range of properties of the substances and preparations. If in other cases it emerges that information on certain properties is of no significance or that it is technically impossible to provide, the reasons for this must be clearly stated under each heading. Information must be provided for each hazardous property. If it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

Give the date of issue of the safety data sheet on the first page.

When a safety data sheet has been revised, the changes should be brought to the attention of the recipient.

Note

Safety data sheets are also required for certain special substances and preparations (e.g. metals in massive form, alloys, compressed gases etc.) listed in chapters 8 and 9 of Annex VI to Directive 67/548/EEC, for which there are labelling derogations.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. **Identification of the substance or preparation**

The term used for identification must be identical to that provided on the label as set out in, Annex VI to Directive 67/548/EEC.

Other means of identification available may also be indicated.

1.2. **Use of the substance/preparation**

Indicate the intended or recommended uses of the substance or preparation as far as they are known. Where there are many possible uses, only the most important or common uses need be listed. This should include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.

1.3. **Company/undertaking identification**

Identify the person responsible for placing the substance or preparation on the market within the Community, whether it be the manufacturer, importer or distributor. Give the full address and telephone number of this person.

In addition, where this person is not located in the Member State where the substance or preparation is placed on the market, give a full address and telephone number for the person responsible in that Member State, if possible.

[1] OJ L 131, 5.5.1998, p. 11.

1.4. **Emergency telephone**

In addition to the abovementioned information, supply the emergency telephone number of the company and/or relevant official advisory body (this may be the body responsible for receiving information relating to health, which is referred to in Article 17 of Directive 1999/45/EC).

2. COMPOSITION/INFORMATION ON INGREDIENTS

The information given should enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself should be given under heading 3.

2.1. It is not necessary to give the full composition (nature of the ingredients and their concentration), although a general description of the components and their concentrations can be helpful.

2.2. For a preparation classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range:

(i) substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC, if they are present in concentrations equal to or greater than those laid down in the table set out in Article 3(3) of Directive 1999/45/EC (unless lower limits are given in Annex I to Directive 67/548/EEC or in Annexes II, III or V to Directive 1999/45/EC);

(ii) and substances for which there are Community workplace exposure limits, which are not already included under (i).

2.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations:

— substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC ([1]);

— and substances for which there are Community workplace exposure limits.

2.4. The classification (deriving either from Articles 4 and 6 or from Annex I to Directive 67/548/EEC) of the above substances shall be given, including the symbol letters and R phrases which are assigned in accordance with their physicochemical, health and environmental hazards. The R phrases do not need to be written out in full here: reference should be made to heading 16, where the full text of each relevant R phrase shall be listed.

2.5. The name and the Einecs or Elincs number of the above substances should be given in accordance with Directive 67/548/EEC. The CAS number and IUPAC name (if available) may also be helpful. For substances listed by a generic name, according to Article 15 of Directive 1999/45/EC or the footnote to point 2.3 of this Annex, a precise chemical identifier is not necessary.

2.6. If, in accordance with the provisions of Article 15 of Directive 1999/45/EC or the footnote to point 2.3 of this Annex, the identity of certain substances is to be kept confidential, their chemical nature shall be described in order to ensure safe handling. The name used must be the same as that which derives from the above procedures.

3. HAZARDS IDENTIFICATION

Give here the classification of the substance or preparation which arises from application of the classification rules in Directives 67/548/EEC or 1999/45/EC. Indicate clearly and briefly the hazards the substance or preparation presents to man and the environment.

Distinguish clearly between preparations which are classified as dangerous and preparations which are not classified as dangerous according to Directive 1999/45/EC.

Describe the most important adverse physicochemical, human health and environmental effects and symptoms relating to the uses and possible misuses of the substance or preparation that can reasonably be foreseen.

It may be necessary to mention other hazards, such as dustiness, suffocation, freezing or environmental effects such as hazards to soil-dwelling organisms, etc., which do not result in classification but which may contribute to the overall hazards of the material.

The information shown on the label should be given under heading 15.

([1]) Where the person responsible for placing the preparation on the market can demonstrate that the disclosure in the safety data sheet of the chemical identity of a substance which is exclusively classified as:
— irritant with the exception of those assigned R41 or irritant in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/45/EC,
— or harmful in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/45/EC presenting acute lethal effects alone,
will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Part B of Annex VI to Directive 1999/45/EC, refer to that substance either by means of a name that identifies the most important functional chemical groups, or by means of an alternative name.

4. FIRST AID MEASURES

Describe the first-aid measures.

Specify first whether immediate medical attention is required.

The information on first aid must be brief and easy to understand by the victim, bystanders and first-aiders. The symptoms and effects should be briefly summarised. The instructions should indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure.

Subdivide the information according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion, under different subheadings.

Indicate whether professional assistance by a doctor is needed or advisable.

For some substances or preparations it may be important to emphasise that special means to provide specific and immediate treatment must be available at the workplace.

5. FIRE-FIGHTING MEASURES

Refer to requirements for fighting a fire caused by the substance or preparation, or arising in its vicinity by indicating:

— suitable extinguishing media,

— extinguishing media which must not be used for safety reasons,

— special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases,

— special protective equipment for fire-fighters.

6. ACCIDENTAL RELEASE MEASURES

Depending on the substance or preparation involved, information may be needed on:

— *personal precautions such as:*

removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact,

— *environmental precautions such as:*

keeping away from drains, surface- and ground-water and soil, possible need to alert the neighbourhood,

— *methods for cleaning up such as:*

use of absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution.

Also consider the need for indications such as: "never use, neutralise with …".

Note

If appropriate refer to headings 8 and 13.

7. HANDLING AND STORAGE

Note

Information in this section should relate to the protection of health, safety and the environment. It should assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC.

7.1. **Handling**

Specify precautions for safe handling including advice on technical measures such as: containment, local and general ventilation, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g. use of filters or scrubbers on exhaust ventilation, use in a bunded area, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or preparation (e.g. procedures or equipment which are prohibited or recommended) and if possible give a brief description.