

# Official Journal

## of the European Communities

ISSN 0378 - 6978

L 187

Volume 31

16 July 1988

English edition

## Legislation

### Contents

#### I *Acts whose publication is obligatory*

.....

#### II *Acts whose publication is not obligatory*

##### Council

88/378/EEC:

- ★ Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys ..... 1

88/379/EEC:

- ★ Council Directive of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ..... 14

88/380/EEC:

- ★ Council Directive of 13 June 1988 amending Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species ..... 31

## II

*(Acts whose publication is not obligatory)*

## COUNCIL

## COUNCIL DIRECTIVE

of 3 May 1988

on the approximation of the laws of the Member States concerning the safety of toys

(88/378/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

In cooperation with the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas the laws, regulations and administrative provisions in force in the various Member States relating to the safety characteristics of toys differ in scope and content; whereas such disparities are liable to create barriers to trade and unequal conditions of competition within the internal market without necessarily affording consumers in the common market, especially children, effective protection against the hazards arising from the products in question;

Whereas these obstacles to the attainment of an internal market in which only sufficiently safe products would be sold should be removed; whereas, for this purpose, the marketing and free movement of toys should be made subject to uniform rules based on the objectives regarding protection of consumer health and safety as set out in the Council resolution of 23 June 1986 concerning the future orientation

of the policy of the European Economic Community for the protection and promotion of consumer interests <sup>(4)</sup>;

Whereas, to facilitate proof of conformity with the essential requirements, it is necessary to have harmonized standards at European level which concern, in particular, the design and composition of toys so that products complying with them may be assumed to conform to the essential requirements; whereas these standards harmonized at European level are drawn up by private bodies and must remain non-mandatory texts; whereas for that purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by one or both of those bodies upon a remit from the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations <sup>(5)</sup>, as last amended by the Act of Accession of Spain and Portugal, and on the basis of the general guidelines;

Whereas, in accordance with the Council resolution of 7 May 1985 on a new approach to technical harmonization and standards <sup>(6)</sup>, the harmonization to be achieved should consist in establishing the essential safety requirements to be satisfied by all toys if they are to be placed on the market;

<sup>(1)</sup> OJ No C 282, 8. 11. 1986, p. 4.

<sup>(2)</sup> OJ No C 246, 14. 9. 1987, p. 91 and Decision of 9 March 1988 (not yet published in the Official Journal).

<sup>(3)</sup> OJ No C 232, 31. 8. 1987, p. 22.

<sup>(4)</sup> OJ No C 167, 5. 7. 1986, p. 1.

<sup>(5)</sup> OJ No L 109, 26. 4. 1983, p. 8.

<sup>(6)</sup> OJ No C 136, 4. 6. 1985, p. 1.

Whereas, in view of the size and mobility of the toy market and the diversity of the products concerned, the scope of this Directive should be determined on the basis of a sufficiently broad definition of 'toys'; whereas, nevertheless, it should be made clear that some products are not to be regarded as toys for the purposes of this Directive either because they are not in fact intended for children or because they call for supervision or special conditions of use;

Whereas toys placed on the market should not jeopardize the safety and/or health either of users or of third parties; whereas the standard of safety of toys should be determined in relation to the criterion of the use of the product as intended, but allowance should also be made for any foreseeable use, bearing in mind the normal behaviour of children who do not generally show the same degree of care as the average adult user;

Whereas the standard of safety of the toy must be considered when it is marketed, bearing in mind the need to ensure that this standard is maintained throughout the foreseeable and normal period of use of the toy;

Whereas compliance with the essential requirements is likely to guarantee consumer health and safety; whereas all toys placed on the market must comply with these requirements and, if they do, no obstacle must be put in the way of their free movement;

Whereas toys may be presumed to comply with these essential requirements where they are in conformity with the harmonized standards, reference numbers of which have been published in the *Official Journal of the European Communities*;

Whereas toys that conform to a model approved by an approved body may also be regarded as complying with the essential requirements; whereas such conformity must be certified by the affixing of a European mark;

Whereas certification procedures must be established to define the way in which national approved bodies have to approve models of toys not in conformity with standards and issue type-examination certificates for them and for toys in conformity with standards, a model of which is submitted to them for approval;

Whereas adequate information for the Member States, the Commission and all the approved bodies must be provided for at the various stages of the certification and inspection procedures;

Whereas Member States must appoint bodies, called 'approved bodies', for the purposes of applying the system introduced for toys; whereas adequate information on these bodies must be provided and they must all comply with minimum criteria for their approval;

Whereas cases might arise where a toy does not satisfy the essential safety requirements; whereas, in such cases, the Member State which ascertains this fact must take all appropriate measures to withdraw the products from the market or to prohibit their being placed on the market; whereas a reason must be given for this decision and, where the reason is a shortcoming in the harmonized standards, these, or a part thereof, must be withdrawn from the list published by the Commission;

Whereas the Commission is to ensure that the harmonized European standards in all the areas covered by the essential requirements listed in Annex II are drawn up in sufficient time to enable Member States to adopt and publish the necessary provisions by 1 July 1989; whereas the national provisions adopted on the basis of this Directive should consequently become effective on 1 January 1990;

Whereas provision must be made for suitable action to be taken against anyone wrongfully affixing a mark of conformity;

Whereas checks on the safety of toys already on the market must be carried out by the competent authorities of the Member States;

Whereas, for some categories of toys that are particularly dangerous or intended for very young children, warnings or details of precautions to be taken must also be given;

Whereas the Commission must receive regular information on activities carried out under this Directive by the approved bodies;

Whereas those to whom any decision taken under this Directive is addressed must know the reason for that decision and the remedies open to them;

Whereas the opinion of the Scientific Advisory Committee for the evaluation of the toxicity and ecotoxicity of chemical compounds has been taken into account with respect to the health-based limits of bioavailability of metallic compounds in toys to children,

#### HAS ADOPTED THIS DIRECTIVE:

##### *Article 1*

1. This Directive shall apply to toys. A 'toy' shall mean any product or material designed or clearly intended for use in play by children of less than 14 years of age.
2. The products listed in Annex I shall not be regarded as toys for the purposes of this Directive.

*Article 2*

1. Toys may be placed on the market only if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.

2. In the condition in which it is placed on the market, taking account of the period of foreseeable and normal use, a toy must meet the safety and health conditions laid down in this Directive.

3. For the purposes of this Directive, the expression 'placed on the market' shall cover both sale and distribution free of charge.

*Article 3*

Member States shall take all steps necessary to ensure that toys cannot be placed on the market unless they meet the essential safety requirements set out in Annex II.

*Article 4*

Member States shall not impede the placing on the market on their territory of toys which satisfy the provisions of this Directive.

*Article 5*

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of toys bearing the EC mark provided for in Article 11, hereinafter referred to as 'EC mark', denoting conformity with the relevant national standards which transpose the harmonized standards the reference numbers of which have been published in the *Official Journal of the European Communities*. Member States shall publish the reference numbers of such national standards.

2. Member States shall presume that toys in respect of which the manufacturer has not applied the standards referred to in paragraph 1, or has applied them only in part, or for which no such standards exist, satisfy the essential requirements referred to in Article 3 where, after receipt of an EEC type-examination certificate, their conformity with the approved model has been certified by the affixation of the EC mark.

*Article 6*

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (1) do not entirely satisfy the essential requirements referred to in Article 3, the Commission or the Member State shall refer the matter to the Standing Committee set up under Directive

83/189/EEC, hereinafter referred to as 'the committee', setting out its reasons. The committee shall issue an opinion as a matter of urgency.

After receiving the committee's opinion, the Commission shall notify the Member States whether or not the standards concerned or a part thereof have to be withdrawn from the publications referred to in Article 5 (1).

2. The Commission shall inform the European standardization body concerned and, if necessary, issue a new standardization brief.

*Article 7*

1. Where a Member State ascertains that toys bearing the EC mark which are used as intended or in accordance with Article 2 are likely to jeopardize the safety and/or health of consumers and/or third parties, it shall take all appropriate measures to withdraw the products from the market, or to prohibit or restrict their placing on the market. The Member State shall inform the Commission immediately of this measure and indicate the reasons for its decision, stating in particular whether the non-compliance results from:

- (a) failure to meet the essential requirements referred to in Article 3, if the toy does not meet the standards referred to in Article 5 (1);
- (b) incorrect application of the standards referred to in Article 5 (1);
- (c) shortcomings in the standards referred to in Article 5 (1).

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified, it shall forthwith so inform the Member State that took the action and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them and shall initiate the procedures referred to in Article 6.

3. Where the toy which does not comply with the requirements bears the EC mark, the competent Member State shall take appropriate measures and inform the Commission, which shall inform the other Member States.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

*Article 8*

- 1. (a) Before being placed on the market, toys manufactured in accordance with the harmonized

standards referred to in Article 5 (1) must have affixed to them the EC mark by which the manufacturer or his authorized representative established within the Community confirms that the toys comply with those standards;

(b) The manufacturer or his authorized representative established within the Community shall keep the following information available for inspection:

- a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity of production with the standards referred to in Article 5 (1) and, as appropriate: an EC type-certificate drawn up by an approved body; copies of the documents the manufacturer has submitted to the approved body; a description of the means whereby the manufacturer ensures conformity with the approved model,
- the addresses of the places of manufacture and storage,
- detailed information concerning the design and manufacture.

Where neither the manufacturer nor his authorized representative are established within the Community, the above obligation to keep a dossier available shall be the responsibility of the person who places the toy on the Community market.

2. (a) Toys which do not conform in whole or in part to the standards referred to in Article 5 (1) must have affixed to them, before being placed on the market, the EC mark by which the manufacturer or his authorized representative established within the Community confirms that the toy concerned conforms to the model examined in accordance with the procedures laid down in Article 10 which an approved body has stated complies with the essential requirements referred to in Article 3;

(b) the manufacturer or his authorized representative established within the Community shall keep the following information available for inspection:

- a detailed description of manufacture,
- a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity with the approved model,
- the addresses of the places of manufacture and storage,
- copies of the documents the manufacturer has submitted to an approved body in accordance with Article 10 (2),
- the test certificate for the sample or a certified copy thereof.

Where neither the manufacturer nor his authorized representative is established within the Community,

the above obligation to keep a dossier available shall be the responsibility of the person who places the toy on the market in the Community.

3. In the event of non-observance of the obligations laid down in paragraphs 1 (b) and 2 (b), the competent Member State shall take appropriate measures to ensure that those obligations are observed.

Where non-observance of the obligations is obvious, it may in particular require the manufacturer or his authorized representative established within the Community to have a test performed at his own expense within a specified period by an approved body in order to verify compliance with the harmonized standards and essential safety requirements.

#### Article 9

1. The minimum criteria which Member States must meet in order to appoint the approved bodies referred to in this Directive are contained in Annex III.

2. Each Member State shall notify the Commission of the approved bodies responsible for carrying out the EC type-examination referred to in Articles 8 (2) and 10. The Commission shall publish a list of these bodies, with the distinguishing numbers it has given them, in the *Official Journal of the European Communities* for information and shall be responsible for updating it.

3. A Member State which has approved a body shall withdraw approval if it finds that the body no longer meets the criteria listed in Annex III. It shall forthwith inform the Commission thereof.

#### Article 10

1. EC type-examination is the procedure by which an approved body ascertains and certifies that a model of a toy satisfies the essential requirements referred to in Article 3.

2. The application for EC type-examination shall be lodged with an approved body by the manufacturer or by his authorized representative established within the Community.

The application shall include:

- a description of the toy,
- the name and address of the manufacturer or of his authorized representative or representatives, and the place of manufacture of the toy,
- comprehensive manufacturing and design data; and shall be accompanied by a model of the toy to be manufactured.

3. The approved body shall carry out the EC type-examination in the manner described below:

- it shall examine the documents supplied by the applicant and establish whether they are in order,
- it shall check that the toy would not jeopardize safety and/or health, as provided for in Article 2,
- it shall carry out the appropriate examinations and tests
  - using as far as possible the harmonized standards referred to in Article 5 (1) — in order to check whether the model meets the essential requirements referred to in Article 3,
- it may ask for further examples of the model.

4. If the model complies with the essential requirements referred to in Article 3, the approved body shall draw up an EC type-examination certificate which shall be notified to the applicant. This certificate shall state the conclusions of the examination, indicate any conditions attaching to it and be accompanied by the descriptions and drawings of the approved toy.

The Commission, the other approved bodies and the other Member States may obtain on request a copy of the certificate and, on reasoned request, a copy of the design and manufacturing schedule and the reports on the examinations and tests carried out.

5. An approved body which refuses to issue an EC type-examination certificate shall so inform the Member State which approved it and the Commission, giving the reasons for refusal.

#### Article 11

1. The EC mark referred to in Articles 5, 7 and 8 and the name and/or trade name and/or mark and address of the manufacturer or his authorized representative or the importer into the Community shall as a rule be affixed either to the toy or on the packaging in a visible, easily legible and indelible form. In the case of small toys and toys consisting of small parts these particulars may be affixed in the same way to the packaging, to a label or to a leaflet. Where the said particulars are not affixed to the toy, the consumer's attention must be drawn to the advisability of keeping them.

2. The EC mark shall consist of the symbol 'CE'.

3. The affixing to toys of marks or inscriptions that are likely to be confused with the EC mark shall be prohibited.

4. The particulars referred to in paragraph 1 may be abbreviated provided that the abbreviation enables the manufacturer, his authorized representative or the importer into the Community to be identified.

5. Annex IV sets out the warnings and indications of precautions to be taken during use that have to be given for certain toys. Member States may require that these warnings and precautions, or some of them, together with the information specified in paragraph 4, be given in their own national language or languages when the toys are placed on the market.

#### Article 12

1. Member States shall take the necessary measures to ensure that sample checks are carried out on toys which are on their market, so as to verify their conformity with this Directive.

The authority responsible for inspection:

- shall obtain access, on request, to the place of manufacture or storage and to the information referred to in Article 8 (1) (b) and (2) (b),
- may ask the manufacturer, his authorized representative or the person responsible for marketing the toy established within the Community to supply the information as provided for in Article 8 (1) (b) and (2) (b) within a period specified by the Member State,
- may select a sample and take it away for examination and testing.

2. Every three years, Member States shall send the Commission a report on the application of this Directive.

3. The Member States and the Commission shall take the necessary measures to guarantee confidentiality with regard to the forwarding of the copies relating to the EC type-examination referred to in Article 10 (4).

#### Article 13

Member States shall regularly inform the Commission of the activities carried out in pursuance of this Directive by the bodies they have approved so that the Commission may ensure that the inspection procedures are implemented correctly and without discrimination.

#### Article 14

Any decision taken pursuant to this Directive and involving restrictions on the placing of the toy on the market shall state the exact grounds on which it is based. It shall be notified at the earliest opportunity to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits applying to such remedies.

*Article 15*

1. Member States shall adopt and publish by 30 June 1989 the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply these provisions from 1 January 1990.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

*Article 16*

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1988.

*For the Council*  
*The President*  
M. BANGEMANN

## ANNEX I

## PRODUCTS NOT REGARDED AS TOYS FOR THE PURPOSE OF THIS DIRECTIVE

## (Article 1 (1))

1. Christmas decorations
2. Detailed scale models for adult collectors
3. Equipment intended to be used collectively in playgrounds
4. Sports equipment
5. Aquatic equipment intended to be used in deep water
6. Folk dolls and decorative dolls and other similar articles for adult collectors
7. 'Professional' toys installed in public places (shopping centres, stations, etc.)
8. Puzzles with more than 500 pieces or without picture, intended for specialists
9. Air guns and air pistols
10. Fireworks, including percussion caps <sup>(1)</sup>
11. Slings and catapults
12. Sets of darts with metallic points
13. Electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts
14. Products containing heating elements intended for use under the supervision of an adult in a teaching context
15. Vehicles with combustion engines
16. Toy steam engines
17. Bicycles designed for sport or for travel on the public highway
18. Video toys that can be connected to a video screen, operated at a nominal voltage exceeding 24 volts
19. Babies' dummies
20. Faithful reproductions of real fire arms
21. Fashion jewellery for children

---

<sup>(1)</sup> With the exception of percussion caps specifically designed for use in toys without prejudice to more stringent provisions already existing in certain Member States.

## ANNEX II

## ESSENTIAL SAFETY REQUIREMENTS FOR TOYS

## I. GENERAL PRINCIPLES

1. In compliance with the requirements of Article 2 of the Directive, the users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children. Such risks are those:
  - (a) which are connected with the design, construction or composition of the toy;
  - (b) which are inherent in the use of the toy and cannot be completely eliminated by modifying the toy's construction and composition without altering its function or depriving it of its essential properties.
2.
  - (a) The degree of risk present in the use of a toy must be commensurate with the ability of the users, and where appropriate their supervisors, to cope with it. This applies in particular to toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.
  - (b) To observe this principle, a minimum age for users of toys and/or the need to ensure that they are used only under adult supervision must be specified where appropriate.
3. Labels on toys and/or their packaging and the instructions for use which accompany them must draw the attention of users or their supervisors fully and effectively to the risks involved in using them and to the ways of avoiding such risks.

## II. PARTICULAR RISKS

## 1. Physical and mechanical properties

- (a) Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.
- (b) Accessible edges, protrusions, cords, cables and fastenings on toys must be so designed and constructed that the risks of physical injury from contact with them are reduced as far as possible.
- (c) Toys must be so designed and constructed as to minimize the risk of physical injury which could be caused by the movement of their parts.
- (d) Toys, and their component parts, and any detachable parts of toys which are clearly intended for use of toys which are clearly intended for use by children under 36 months must be of such dimensions as to prevent their being swallowed and/or inhaled.
- (e) Toys, and their parts and the packaging in which they are contained for retail sale must not present risk of strangulation or suffocation.
- (f) Toys intended for use in shallow water which are capable of carrying or supporting a child on the water must be designed and constructed so as to reduce as far as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.
- (g) Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the latter can open easily from the inside.
- (h) Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy developed by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.
- (i) The form and composition of projectiles and the kinetic energy they may develop when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no unreasonable risk of physical injury to the user or to third parties.

- (j) Toys containing heating elements must be so constructed as to ensure that:
- the maximum temperature of any accessible surfaces does not cause burns when touched,
  - liquids and gases contained within toys do not reach temperatures or pressures which are such that their escape from a toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.

## 2. Flammability

- (a) Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which:
1. do not burn if directly exposed to a flame or spark or other potential seat of fire; or
  2. are not readily flammable (the flame goes out as soon as the fire cause disappears); or
  3. if they do ignite, burn slowly and present a low rate of spread of the flame; or
  4. irrespective of the toy's chemical composition, are treated so as to delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

- (b) Toys which, for reasons essential to their functioning, contain dangerous substances or preparations as defined in Council Directive 67/548/EEC <sup>(1)</sup>, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or preparations which may become flammable due to the loss of non-flammable volatile components.
- (c) Toys must not be explosive or contain elements or substances likely to explode when used as specified in Article 2 (1) of the Directive. This provision does not apply to toy percussion caps, for which reference should be made to point 10 of Annex I and the related footnote.
- (d) Toys and, in particular, chemical games and toys, must not contain as such substances or preparations:
- which, when mixed, may explode:
    - through chemical reaction, or through heating,
    - when mixed with oxidizing substances,
  - which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

## 3. Chemical properties

1. Toys must be so designed and constructed that, when used as specified in Article 2 (1) of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes.

They must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations.

2. In particular, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day:
- 0,2 µg for antimony,
  - 0,1 µg for arsenic,
  - 25,0 µg for barium,
  - 0,6 µg for cadmium,
  - 0,3 µg for chromium,
  - 0,7 µg for lead,
  - 0,5 µg for mercury,
  - 5,0 µg for selenium,

<sup>(1)</sup> OJ No 196, 16. 8. 1967, p. 1/67.

or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence.

The bioavailability of these substances means the soluble extract having toxicological significance.

3. Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC <sup>(1)</sup> in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used.

However, where a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardization (CEN) according to the procedure of the committee set up by Directive 83/189/EEC, provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Annex IV.

#### 4. Electrical properties

- (a) Electric toys must not be powered by electricity of a nominal voltage exceeding 24 volts and no part of the toy may exceed 24 volts.
- (b) Parts of toys which are connected to, or liable to come into contact with a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.
- (c) Electric toys must be so designed and constructed as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

#### 5. Hygiene

Toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness in order to avoid any risk of infection, sickness and contamination.

#### 6. Radioactivity

Toys must not contain radioactive elements or substances in forms or proportions likely to be detrimental to a child's health. Council Directive 80/836/Euratom shall apply <sup>(2)</sup>.

---

<sup>(1)</sup> See page 14 of this Official Journal.

<sup>(2)</sup> OJ No L 246, 17. 9. 1980, p. 1.

*ANNEX III***CONDITIONS TO BE FULFILLED BY THE APPROVED BODIES****(Article 9 (1))**

The bodies designated by the Member States must fulfil the following minimum conditions:

1. availability of personnel and of the necessary means and equipment;
2. technical competence and professional integrity of personnel;
3. independence, in carrying out the tests, preparing the reports, issuing the certificates and performing the surveillance provided for in this Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with toys;
4. maintenance of professional secrecy by personnel;
5. subscription of a civil liability insurance unless that liability is covered by the state under national law.

Fulfilment of the conditions under 1 and 2 shall be verified at intervals by the competent authorities of the Member States.

---

## ANNEX IV

## WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING TOYS

(Article 11 (5))

Toys must be accompanied by appropriate clearly legible warnings in order to reduce inherent risks in their use as described in the essential requirements, and specifically:

**1. Toys not intended for children under 36 months**

Toys which might be dangerous for children under 36 months of age shall bear a warning, for example: 'Not suitable for children under 36 months' or 'Not suitable for children under three years' together with a brief indication, which may also appear in the instructions for use, of the specific risks calling for this restriction.

This provision does not apply to toys which, on account of their function, dimensions, characteristics, properties or other cogent grounds, are manifestly unsuitable for children under 36 months.

**2. Slides, suspended swings and rings, trapezes, ropes and similar toys attached to a crossbeam**

Such toys shall be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at intervals, and pointing out that, if these checks are not carried out, the toy may cause a fall or overturn.

Instructions must also be given as to correct assembly of the toy, indicating those parts which can present dangers if it is incorrectly assembled.

**3. Functional toys**

Functional toys or their packaging shall bear the marking 'Warning: to be used under the direct supervision of an adult'.

In addition, these toys shall be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions would expose the user to the hazards — to be specified — normally associated with the appliance or product of which the toy is a scale model or an imitation. It will also be indicated that the toy must be kept out of the reach of very young children.

'Functional toys' means toys which are used in the same way as, and are often scale models of, appliances or installations intended for adults.

**4. Toys containing inherently dangerous substances or preparations. Chemical toys**

(a) Without prejudice to the application of the provisions laid down in Community directives on the classification, packaging and labelling of dangerous substances or preparations, the instructions for use of toys containing inherently dangerous substances or preparations shall bear a warning of the dangerous nature of these substances or preparations and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toys must be kept out of reach of very young children.

(b) In addition to the instructions provided for in (a), chemical toys shall bear the following marking on their packaging:

'Warning: for children over <sup>(1)</sup> years of age only. For use under adult supervision'.

In particular, the following are regarded as chemical toys: chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys.

<sup>(1)</sup> Age to be decided by the manufacturer.

**5. Skates and skateboards for children**

If these products are offered for sale as toys they shall bear the marking:

'Warning: protective equipment should be worn'.

Moreover, the instructions for use shall contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user and third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

**6. Toys intended for use in water**

The toys intended for use in water defined in Section II.1 (f) of Annex II shall contain the warning in accordance with CEN's brief to adapt standard EN/71, parts 1 and 2:

'Warning! Only to be used in water in which the child is within its depth and under supervision'.

---

## COUNCIL DIRECTIVE

of 7 June 1988

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

(88/379/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

In cooperation with the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas rules on dangerous substances have already been laid down in 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 <sup>(4)</sup>, as last amended by Directive 79/831/EEC <sup>(5)</sup>;

Whereas rules on certain dangerous preparations having very specific uses have already been laid down:

- in Council Directive 73/173/EEC of 4 June 1973 on the approximation of Member States' laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations (solvents) <sup>(6)</sup>, as last amended by Directive 80/781/EEC <sup>(7)</sup>,
- in Council Directive 77/728/EEC of 7 November 1977 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of paints, varnishes, printing inks, adhesives and similar

products <sup>(8)</sup>, as last amended by Directive 83/265/EEC <sup>(9)</sup>,

Whereas, despite the abovementioned Community provisions, the rules, if any, applying to certain dangerous preparations in the Member States exhibit considerable differences as regards classification according to the degree of risk; whereas these differences constitute a not insignificant barrier to trade and directly affect the establishment and functioning of the common market;

Whereas it is therefore necessary to remove this barrier by approximating the relevant legislation existing in the Member States and incorporating in it the '*acquis communautaires*';

Whereas this Directive must, at the same time, ensure protection for the general public and, in particular, of persons who come into contact with dangerous preparations in the course of their work or in the pursuit of a hobby, of consumers, especially children and the visually handicapped, and also for the environment;

Whereas provisions on the classification, packaging and labelling of the preparations must be laid down at Community level; whereas the provisions concerning the information appearing on the label, the dimensions of the label and the assignment of the various danger symbols, standard phrases concerning risks and safety advice have also to be brought into line with Directive 67/548/EEC;

Whereas some preparations, although they contain constituents which are dangerous to health, are not necessarily dangerous in the form in which they are placed on the market; whereas there are exceptions, however, and whereas the latter must be the subject of special labelling, as appropriate, in accordance with the provisions of Directive 67/548/EEC as amended by Directive 79/831/EEC, or of Annex II to this Directive;

Whereas the assessment of the health hazards of a preparation may, under Article 3, be carried out by a calculation method, by determining the toxicological properties according to well-defined test methods or by a combination of the two; whereas Directive 86/609/EEC stipulates in Article 7 <sup>(2)</sup> that an experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the

<sup>(1)</sup> OJ No C 317, 10. 12. 1986, p. 10 and OJ No C 353, 30. 12. 1987, p. 1.

<sup>(2)</sup> OJ No C 318, 30. 11. 1987, p. 73 and Decision of 13 April 1988 (not yet published in the Official Journal).

<sup>(3)</sup> OJ No C 189, 28. 7. 1986, p. 1.

<sup>(4)</sup> OJ No 196, 16. 8. 1967, p. 1.

<sup>(5)</sup> OJ No L 259, 15. 10. 1979, p. 10.

<sup>(6)</sup> OJ No L 189, 11. 7. 1973, p. 7.

<sup>(7)</sup> OJ No L 229, 30. 8. 1980, p. 57.

<sup>(8)</sup> OJ No L 303, 28. 11. 1977, p. 23.

<sup>(9)</sup> OJ No L 147, 6. 6. 1983, p. 11.

<sup>(10)</sup> OJ No L 358, 18. 12. 1986, p. 1.

use of an animal, is reasonably and practically available; whereas this Directive makes use of the results of assessments of toxicological properties only when these are already known and entails no obligation to conduct further experiments on animals;

Whereas the label constitutes a basic tool for users of the preparations by giving them the initial essential concise information; whereas it nevertheless needs to be supplemented by a two-fold system of more detailed information, one intended for professional users, and the second for the bodies appointed by the Member States and whose responsibility it is to give information reserved solely for medical purposes, both curative and preventive;

Whereas dangerous preparations may, although conforming to the provisions of this Directive, nevertheless constitute a danger to health or the environment; whereas it is therefore advisable to provide a procedure to reduce this danger;

Whereas the Commission will, on the basis of information to be supplied by the Member States be obliged to submit a report, within two years of application of this Directive, concerning any inadequacies or loopholes, as compared with the present Directive, in Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) <sup>(1)</sup>, as last amended by Directive 84/291/EEC <sup>(2)</sup>; whereas on the basis of this report, the Commission will, if appropriate, submit the necessary proposals,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

1. The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States on the:

- classification,
- packaging, and
- labelling

of preparations dangerous to man and the environment when they are placed on the market in the Member States.

2. This Directive shall apply to preparations which are placed on the market in the Member States and which:

- contain at least one substance classified as dangerous, within the meaning of Article 2, and
- are regarded as dangerous within the meaning of Article 3.

<sup>(1)</sup> OJ No L 206, 29. 7. 1978, p. 13.

<sup>(2)</sup> OJ No L 144, 30. 5. 1984, p. 1.

This Directive shall also apply to the preparations listed in Annex II.

3. This Directive shall not apply to:

- (a) medicinal or veterinary products as defined by Directive 65/65/EEC <sup>(3)</sup>, as last amended by Directive 87/21/EEC <sup>(4)</sup>;
- (b) cosmetic products as defined by Directive 76/768/EEC <sup>(5)</sup>, as last amended by Directive 86/199/EEC <sup>(6)</sup>;
- (c) mixtures of substances which, in the form of waste, are covered by Directive 75/442/EEC <sup>(7)</sup> and Directive 78/319/EEC <sup>(8)</sup>, as last amended by the Act of Accession of Spain and Portugal;
- (d) pesticides covered by Directive 78/631/EEC, as last amended by Directive 83/291/EEC;
- (e) munitions and explosives placed on the market with a view to obtaining a practical effect by explosion or a pyrotechnic effect.

In addition, this Directive shall not apply to:

- (f) foodstuffs in a finished stage intended for the final consumer;
- (g) animal feedingstuffs in a finished stage intended for the final consumer;
- (h) the carriage of dangerous substances by rail, road, inland waterway, sea or air;
- (i) preparations in transit which are under customs supervision provided they do not undergo any treatment or processing.

#### Article 2

The definitions appearing in Article 2 of Directive 67/548/EEC, with the exception of the definition in paragraph 1 (d) thereof, shall apply to this Directive.

#### Article 3

1. The general principles of the classification and labelling of preparations shall be applied according to the criteria in Annex VI to Directive 67/548/EEC, save where the alternative criteria referred to below are applied.

2. The requisite physico-chemical properties for the classification of preparations shall be determined by the methods specified in Annex V (A) to Directive 67/548/EEC.

<sup>(3)</sup> OJ No 22, 9. 2. 1965, p. 369/65.

<sup>(4)</sup> OJ No L 15, 17. 1. 1987, p. 36.

<sup>(5)</sup> OJ No L 262, 27. 9. 1976, p. 169.

<sup>(6)</sup> OJ No L 149, 3. 6. 1986, p. 38.

<sup>(7)</sup> OJ No L 194, 25. 7. 1975, p. 39.

<sup>(8)</sup> OJ No L 84, 31. 3. 1978, p. 43.

Preparations shall be regarded as explosive, oxidizing, extremely flammable, highly flammable or flammable when the results of the tests carried out by the methods mentioned above comply with the definitions in Article 2 of Directive 67/548/EEC and the specific evaluation criteria detailed in those methods.

By way of derogation from the preceding:

- (a) the determination of the explosive, oxidizing, extremely flammable, highly flammable or flammable properties is not necessary provided, however, that none of the constituents possesses such properties and that on the basis of the information available to the manufacturer the preparation is unlikely to present dangers of this kind;
- (b) the preparations placed on the market in the form of aerosols are subject to the flammability criteria specified in paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC<sup>(1)</sup>, as last amended by the Act of Accession of Spain and Portugal.

3. The health hazards of a preparation shall be assessed by one or more of the following methods:

- (a) by the conventional method described below using concentration limits;
- (b) by determining by means of the methods specified in point B of Annex V to Directive 67/548/EEC, the toxicological properties of the preparation necessary for an appropriate classification and label in accordance with the criteria in Annex VI to that Directive.

Any one or more of the toxicological properties of the preparation which are not assessed by the method set out in (b) hereof shall be assessed in accordance with the conventional method.

Where a toxicological property has been established by both the methods above, the result of method (b) shall be used for classifying the preparation except in the case of carcinogenic, mutagenic and teratogenic effects.

Furthermore, where it can be demonstrated that:

- toxicological effects on man differ from those suggested by a toxicological determination or a conventional assessment, then the preparation shall be classified according to its effects on man,
- owing to effects such as potentiation a conventional assessment would underestimate the toxicological

hazard, these effects shall be taken into account in classifying the preparation,

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

4. For preparations of a known composition classified in accordance with method 3 (b) above a new health hazard assessment either by method 3 (a) or (b) shall be performed whenever:

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

| Initial concentration range of the constituent | Permitted variation in initial concentration of the constituent |
|------------------------------------------------|-----------------------------------------------------------------|
| $\leq 2,5 \%$                                  | $\pm 15 \%$                                                     |
| $> 2,5 \leq 10 \%$                             | $\pm 10 \%$                                                     |
| $> 10 \leq 25 \%$                              | $\pm 6 \%$                                                      |
| $> 25 \leq 50 \%$                              | $\pm 5 \%$                                                      |
| $> 50 \leq 100 \%$                             | $\pm 2,5 \%$                                                    |

- changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions of this Directive, are introduced by the manufacturer.

5. In accordance with Article 3 (3) (a), the health hazards shall be assessed by the conventional method described below, using individual concentration limits.

Where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described below, these concentration limits must be used.

Where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described below, the concentration limits shall be assigned in accordance with the specifications in Annex I to this Directive.

When a preparation contains at least one substance which, in accordance with Article 8 (2) of Directive 67/548/EEC, bears the warning 'Caution — substance not yet fully tested', the label of the preparation must bear the warning 'Caution — this preparation contains a substance not yet fully tested' if the substance is present in a concentration equal to or in excess of 1 %.

<sup>(1)</sup> OJ No L 147, 9. 6. 1975, p. 40.

However, this substance must be treated on the same basis as the other substances present in the preparation when applying the method of evaluation by calculation, if the labelling gave at least an indication of the health hazard.

In that case,

(a) The following preparations shall be regarded as very toxic:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 1 of Annex I (Table I) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(ii) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each very toxic substance in the preparation by the limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{T+}}{L_{T+}} \right) \geq 1$$

where:

$P_{T+}$  = is the percentage by weight of each very toxic substance in the preparation,

$L_{T+}$  = is the limit specified for each very toxic substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

(b) The following preparations shall be regarded as toxic:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or in individual concentrations exceeding:

— either the concentrations specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 1 of Annex I (Table I) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(ii) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic or toxic in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the toxic limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{T+}}{L_T} + \frac{P_T}{L_T} \right) \geq 1$$

where:

$P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,

$P_T$  is the percentage by weight of each toxic substance in the preparation,

$L_T$  is the limit specified for each very toxic or toxic substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (iv) owing to their long-term effects, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 3 of Annex I (Table III) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.
- (c) The following preparations shall be regarded as harmful:
- (i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or harmful in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 1 of Annex I (Table I) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (ii) owing to their acute lethal effects, preparations containing more than one of the substances classified or regarded as very toxic or toxic or harmful in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the harmful limit specified for that substance is 1 or more, i.e.
- $$\sum \left( \frac{P_{T+}}{L_{Xn}} + \frac{P_T}{L_{Xn}} + \frac{P_{Xn}}{L_{Xn}} \right) \geq 1$$
- where:
- $P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,
- $P_T$  is the percentage by weight of each toxic substance in the preparation,
- $P_{Xn}$  is the percentage by weight of each harmful substance in the preparation,
- $L_{Xn}$  is the limit specified for each very toxic, toxic or harmful substance expressed as a percentage;
- (iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (iv) owing to their long-term effects, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 3 of Annex I (Table III) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (v) owing to their sensitizing effects by inhalation, preparations containing at least one dangerous substance to which is assigned phrase R 42 that produces such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 5 of Annex I (Table V) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.
- (d) The following preparations shall be regarded as very corrosive <sup>(1)</sup>:
- (i) preparations containing one or more substances classified or regarded as corrosive to which is assigned phrase R 35 in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance
- <sup>(1)</sup> Within the meaning of this Directive 'very corrosive substance' means a substance to which is assigned the symbol C and the phrase denoting a risk R 35.

or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (ii) preparations containing more than one substance classified or regarded as corrosive to which is assigned phrase R 35 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each corrosive substance in the preparation by the corrosive limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{C,R35}}{L_{C,R35}} \right) \geq 1$$

where:

$P_{C,R35}$  is the percentage by weight of each corrosive substance in the preparation,

$L_{C,R35}$  is the corrosive limit specified for each corrosive substance to which is assigned phrase R 35 expressed as a percentage by weight.

- (e) The following preparations shall also be regarded as corrosive:

- (i) preparations containing one or more substances classified or regarded as corrosive to which is assigned phrase R 34 in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (ii) preparations containing more than one substance classified or regarded as corrosive to which is assigned phrase R 34 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each corrosive substance in the preparation by the corrosive limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{C,R35}}{L_{C,R34}} + \frac{P_{C,R34}}{L_{C,R34}} \right) \geq 1$$

where:

$P_{C,R35}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 35 in the preparation,

$P_{C,R34}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 34 in the preparation,

$L_{C,R34}$  is the corrosive limit specified for each corrosive substance to which is assigned phrase R 34 expressed as a percentage by weight.

- (f) The following preparations shall be regarded as liable to cause serious eye damage:

- (i) preparations containing one or more substances classified or regarded as irritant and to which is assigned phrase R 41 in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (ii) preparations containing more than one of the substances classified or regarded as corrosive or irritant to which is assigned phrase R 41 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{Xi,R41}}{L_{Xi,R41}} \right) \geq 1$$

where:

$P_{Xi,R41}$  is the percentage by weight of each irritant substance to which is assigned phrase R 41 in the preparation,

$L_{Xi,R41}$  is the irritant limit specified for each irritant substance to which is assigned phrase R 41 expressed as a percentage by weight.

- (g) The following preparations shall be regarded as skin irritants:

- (i) preparations containing one or more substances classified or regarded as corrosive or irritant to

which is assigned phrase R 38 in individual concentrations exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (ii) preparations containing more than one of the substances classified or regarded as corrosive or irritant to which is assigned phrase R 38 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{C,R35}}{L_{Xi,R38}} + \frac{P_{C,R34}}{L_{Xi,R38}} + \frac{P_{Xi,R38}}{L_{Xi,R38}} \right) \geq 1$$

where:

$P_{C,R35}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 35 in the preparation,

$P_{C,R34}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 34 in the preparation,

$P_{Xi,R38}$  is the percentage by weight of each irritant substance to which is assigned phrase R 38 in the preparation,

$L_{Xi,R38}$  is the irritant limit specified for each corrosive or irritant substance to which is assigned phrase R 38 expressed as a percentage by weight;

- (iii) owing to their sensitizing effects by skin contact, preparations containing at least one dangerous substance to which is assigned phrase R 43 that produces such effects in individual concentrations exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 5 of Annex I (Table V) to this Directive where the substance or

substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

- (h) The following preparations shall be regarded as eye irritants:

- (i) preparations containing one or more substances classified or regarded as irritant to which is assigned phrase R 41 or R 36 in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (ii) preparations containing more than one of the substances classified or regarded as irritant to which is assigned phrase R 41 or phrase R 36 in individual concentrations not exceeding the limits specified in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{Xi,R41}}{L_{Xi,R36}} + \frac{P_{Xi,R36}}{L_{Xi,R36}} \right) \geq 1$$

where:

$P_{Xi,R41}$  is the percentage by weight of each irritant substance which is assigned phrase R 41 in the preparation,

$P_{Xi,R36}$  is the percentage by weight of each irritant substance to which is assigned phrase R 36 in the preparation,

$L_{Xi,R36}$  is the irritant limit specified for each irritant substance to which is assigned phrase R 41 or phrase R 36 expressed as a percentage by weight.

- (i) The following preparations shall be regarded as irritants for the respiratory system:

- (i) preparations containing one or more substances classified or regarded as irritant to which is assigned phrase R 37 in individual concentrations exceeding:

— either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

- the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (ii) preparations containing more than one of the substances classified or regarded as irritant to which is assigned phrase R 37 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

$$\sum \left( \frac{P_{Xi,R37}}{L_{Xi,R37}} \right) \geq 1$$

where:

$P_{Xi,R37}$  is the percentage by weight of each irritant substance to which is assigned phrase R 37 in the preparation,

$P_{Xi,R37}$  is the irritant limit specified for each irritant substance to which is assigned phrase R 37 expressed as a percentage by weight.

- (j) Preparations shall be regarded as:

carcinogenic and assigned at least the symbol and indication of danger 'toxic', if they contain a substance producing such effects, to which is assigned the standard phrase R 45, which denotes carcinogenic substances in category 1 and category 2, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

- (k) Preparations shall be regarded as:

suspect for humans owing to their possible carcinogenic effects and assigned at least the symbol and indication of danger 'harmful', if they contain a substance producing such effects to which is assigned the standard phrase R 40, which denotes carcinogenic substances in category 3, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 in Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

- (l) Preparations shall be regarded as:

mutagenic and assigned at least the symbol and indication of danger 'toxic' if they contain a substance producing such effects, to which is assigned the standard phrase R 46 which denotes mutagenic substances in category 1, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

- (m) Preparations shall be regarded as having to be treated as mutagenic and assigned at least the symbol and indication of danger 'harmful' if they contain a substance producing such effects to which is assigned the standard phrase R 46, which denotes mutagenic substances in category 2, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

- (n) Preparations shall be regarded as:

suspect for humans because of their possible mutagenic effects and assigned at least the symbol and indication of danger 'harmful' if they contain a substance producing such effects to which is assigned the standard phrase R 40, which denotes mutagenic substances in category 3, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

## (o) Preparations shall be regarded as:

teratogenic and assigned at least the symbol and indication of danger 'toxic' if they contain a substance producing such effects, which is assigned the standard phrase R 47, which denotes teratogenic substances in category 1, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

## (p) Preparations shall be regarded as:

having to be treated as teratogenic and assigned at least the symbol and indication of danger 'harmful', if they contain a substance producing such effects to which is assigned the standard phrase R 47, which denotes teratogenic substances in category 2, in a concentration equal to or exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

## (q) Preparations shall be regarded as:

having specific effects on health not further defined and assigned at least the symbol and indication of danger 'harmful' if they contain a substance which does not yet appear in Annex I to Directive 67/548/EEC but to which is provisionally assigned the standard phrase R 40 denoting such substances in a concentration exceeding that specified at point 6 of Annex I (Table VI) to this Directive.

## 6. For preparations covered by this Directive:

- (a) No account shall be taken of substances whether or not listed in Annex I to Directive 67/548/EEC, whether existing as impurities or as additives, if their concentration by weight is less than:
- 0,1 % for substances classified as very toxic or toxic,
  - 1 % for substances classified as harmful, corrosive or irritant,

unless lower values have been specified in Annex I to Directive 67/548/EEC.

- (b) Dangerous substances not listed in Annex I to Directive 67/548/EEC but used as constituents of a preparation in a concentration by weight higher than that given at point (a) of this paragraph shall be given concentration limits characterizing the health hazards.

Some substances may have more than one property harmful to health, e.g. harmfulness/irritation, corrosiveness/harmfulness, corrosiveness/sensitization; each of these properties must therefore be characterized by its specific concentration limit.

These concentration limits shall be determined in accordance with Annex I to this Directive by the manufacturer or any other person who places such a preparation on the market.

*Article 4*

The classification of dangerous preparations according to the degree of hazard and the specific nature of the risks involved shall be based on the definitions laid down in Article 2. The preparations shall be classified according to the greatest degree of hazard in accordance with Article 7 (1) (d).

*Article 5*

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

2. If there is any doubt with regard to the compliance referred to in paragraph 1, Member States may request information on the composition of the preparation and any other pertinent information.

3. To this end, the manufacturer, or those responsible for placing the preparation on the market, shall hold the data used for the classification and labelling of the preparation at the disposal of the authorities of the Member States.

*Article 6*

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

- (a) dangerous preparations are not placed on the market unless their packaging meets the requirements of Article 15 (1) of Directive 67/548/EEC with respect to their strength, leak-tightness and fastening systems;
- (b) containers which contain dangerous preparations offered or sold to the general public do not have:
- either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers,

- or a presentation and/or a designation used for human and animal foodstuffs, medicinal or cosmetic products.

2. Member States shall take all the necessary measures to ensure that containers containing certain categories of dangerous preparations offered or sold to the general public and defined in accordance with the procedure referred to in paragraph 3:

- are fitted with child-resistant fastenings,
- carry a tactile warning of danger.

3. The categories of dangerous preparations the packaging of which have to be fitted with the devices referred to in paragraph 2 shall be defined by the procedure referred to in Article 21 of Directive 67/548/EEC.

The technical specifications relating to such devices are given in parts A and B of Annex IX to Directive 67/548/EEC.

#### Article 7

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

- (a) the trade name or designation of the preparation;
- (b) the name and full address including the telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;
- (c) the chemical name of the substance or substances present in the preparation in accordance with the following detailed rules:
  - (i) — in the case of preparations classified as T<sup>+</sup>, T or X<sub>n</sub> in accordance with Article 3, only T<sup>+</sup>, T and X<sub>n</sub> substances present in concentrations equal to or in excess of the lowest limit (X<sub>n</sub> limit) for each of them laid down in Annex I to this Directive or to Directive 67/548/EEC must be taken into consideration,
    - in the case of preparations classified as C in accordance with Article 3, only C substances present in concentrations equal to or in excess of the lowest limit (X<sub>i</sub> limit) laid down in Annex I to this Directive or to Directive 67/548/EEC must be taken into consideration,
    - in the case of preparations to which are assigned phrases R 42, R 43, or R 42/43 in accordance with Article 3, only substances to which those phrases are assigned and which are present in concentrations equal to or in excess of the limit laid down in Annex I to this Directive or to Directive 67/548/EEC must be taken into consideration;
  - (ii) as a general rule a maximum of four chemical names shall suffice to identify the substances

primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding phrases referring to the risk involved. In some cases, more than four chemical names may be necessary.

If the preparation is assigned in accordance with Article 3, one of the standard phrases R 39, R 40, R 42, R 43, R 42/43, R 45, R 46, R 47 and/or R 48, the name of the substance or substances must be mentioned.

The chemical name shall be one of the designations listed in Annex I to Directive 67/548/EEC or an internationally recognized designation if it is not yet listed therein.

Where a manufacturer can demonstrate that the disclosure of the chemical identity of a harmful substance not assigned one or more of the R phrases mentioned above on the label of a preparation will put at risk the confidential nature of his property, he shall be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative name.

Where this is the case, the manufacturer must inform the authorities of the Member State where the preparation is first placed on the market. These authorities shall inform the Commission and the other Member States.

Confidential information brought to the attention of the authorities of a Member State or of the Commission shall be treated in accordance with Article 11 (4) of Directive 67/548/EEC;

- (d) the symbols, where specified in this Directive, for and indications of the dangers involved in the use of the preparation, in accordance with Article 16 (2) (c) of Directive 67/548/EEC read in conjunction with Annex II thereto, and, in the case of aerosol preparations, in accordance with points 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC as far as flammability hazards are concerned.

Where more than one danger symbol has to be assigned to a preparation:

- the obligation to apply the symbol T shall make the symbols C and X optional,
  - the obligation to apply the symbol C shall make the symbol X optional,
  - the obligation to apply the symbol E shall make the symbols F and O optional;
- (e) standard phrases indicating the special risks arising from such dangers (R phrases).

The indications concerning special risks (R phrases) shall conform to the wording in Annex III to Directive 67/548/EEC and shall be provided by the manufacturer or any other person placing the preparation on the market, in accordance with Annex I to this Directive and Annex VI, point II (D) to Directive 67/548/EEC.

As a general rule a maximum of four R phrases shall suffice to describe the risks; for this purpose the combined phrases listed in the aforementioned Annex III shall be regarded as single phrases. If the preparation falls within more than one danger category, however, these standard phrases must cover all the principal hazards associated with the preparation.

Thus, if a preparation is classified as both harmful and irritant, it shall be labelled 'harmful' and attention shall be drawn to its twin harmful and irritant characteristics by the appropriate R phrases.

The standard phrases 'extremely flammable' or 'highly flammable' need not appear if they repeat an indication of danger used pursuant to paragraph (d);

- (f) one or more standard phrases indicating the safety advice relating to the use of the preparation (S phrases).

The indications giving safety advice (S phrases) shall conform to the wording in Annex IV to Directive 67/548/EEC and shall be provided by the manufacturer or any other person placing the preparation on the market, in accordance with Annex II to this Directive and Annex VI, point II (D) to Directive 67/548/EEC.

As a general rule, a maximum of four S phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in the aforementioned Annex IV shall be regarded as single phrases.

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

In the case of highly flammable and flammable oxidizing preparations, there is no need to give a reminder of the special risks or the safety advice if the contents of the package do not exceed 125 ml. The same shall apply in the case of irritant preparations except where they contain substances that might cause sensitization.

- (g) the nominal quantity (nominal mass or nominal volume) of the contents in the case of preparations sold to the general public.

2. The special provisions applicable to certain preparations are set out in Annex II.

3. Article 3 (6) (a) shall apply *mutatis mutandis* to labelling.

4. Information such as 'non toxic', 'not harmful' or any other statement indicating that the preparation is not dangerous may not appear on the packaging or labelling of the preparations referred to in this Directive.

#### Article 8

1. Where the particulars required by Article 7 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that the said particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

| Capacity of the package                                     | Dimensions (in millimetres)  |
|-------------------------------------------------------------|------------------------------|
| — not exceeding three litres:                               | if possible at least 52 × 74 |
| — greater than three litres<br>but not exceeding 50 litres: | at least 74 × 105            |
| — greater than 50 litres but<br>not exceeding 500 litres:   | at least 105 × 148           |
| — greater than 500 litres:                                  | at least 148 × 210           |

Each symbol shall cover at least one-tenth of the surface area of the label but shall not be less than 1 cm<sup>2</sup>. The entire surface of the label shall adhere to the package immediately containing the preparation.

These dimensions are intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety information.

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

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

4. Member States may make the placing of dangerous preparations on the market in their territory subject to the use of their official language or languages for the purposes of labelling.

5. For the purpose of this Directive, labelling requirements shall be deemed to be satisfied:

- (a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in

accordance with international rules on the transport of dangerous preparations and the inner package or packages are labelled in accordance with this Directive;

- (b) in the case of a single package, if such a package is labelled in accordance with international rules on the transport of dangerous preparations and with Article 7 (1) (a), (b), (c), (e) and (f), and (3).

For dangerous preparations that are not leaving the territory of a Member State, the labelling may be in accordance with national regulations instead of with the international rules on the transport of dangerous preparations.

#### *Article 9*

1. Member States may:

- (a) permit the labelling required by Article 7 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 8 (1) and (2);
- (b) by way of derogation from Articles 6 and 7, permit the packaging of dangerous preparations which are neither explosive, very toxic nor toxic to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no reason to fear any danger to persons handling such preparations or to other persons.

2. If a Member State makes use of the options provided for in paragraph 1, it shall forthwith inform the Commission thereof.

#### *Article 10*

Member States shall take the measures necessary to implement a system of specific information (in safety data-sheet form) relating to dangerous preparations.

The detailed arrangements for this system shall be laid down in accordance with the procedure provided for in Article 21 of Directive 67/548/EEC within a period of three years after the adoption of the Directive, taking into account the systems in force in the Member States.

This information is principally intended for use by industrial users and must enable them to take the necessary measures as regards the protection of health and safety at the place of work.

#### *Article 11*

This Directive shall not affect the right of Member States to specify, in due compliance with the Treaty, the requirements

they deem necessary to ensure that workers are protected when using the dangerous preparations in question, provided this does not mean that the classification, packaging, and labelling of dangerous preparations are modified in a way not provided for in this Directive.

#### *Article 12*

Member States shall appoint the body or bodies responsible for receiving information on dangerous preparations, including their chemical composition, placed on the market.

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

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

For preparations already on the market, Member States shall take measures to comply with this Directive within three years from the adoption thereof.

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

#### *Article 13*

Member States shall not prohibit, restrict or impede, on the grounds of classification, packaging or labelling as defined in this Directive, the placing on the market of dangerous preparations which satisfy this Directive and in particular Annex II thereto.

#### *Article 14*

1. Where a Member State has detailed evidence that a preparation, although satisfying the requirements of this Directive, constitutes a hazard by reason of its classification, packaging or labelling, it may provisionally prohibit the sale of that hazardous preparation or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. In the case referred to in paragraph 1, the Commission shall consult the Member States concerned as soon as possible and then deliver its opinion without delay and take the appropriate measures.

If the Commission considers that technical adaptations to this Directive are necessary, such adaptations shall be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC. In such a case, Member States which have adopted safeguard measures may maintain them until the adaptations enter into force.

#### *Article 15*

Amendments required to adapt the Annexes to technical progress shall be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC.

#### *Article 16*

1. Member States shall bring into force not later than 36 months after the adoption of this Directive the laws, regulations and administrative provisions necessary to comply therewith. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive not more than six months thereafter.

3. On the date this Directive enters into force, Directives 73/173/EEC and 77/728/EEC shall cease to apply. Nevertheless, preparations which are in conformity with the specifications of the abovementioned Directives may continue to be placed on the market until one year after the abovementioned date.

#### *Article 17*

This Directive is addressed to the Member States.

Done at Luxembourg, 7 June 1988.

*For the Council*

*The President*

M. BANGEMANN

## ANNEX I

## CONCENTRATION LIMITS TO BE USED IN APPLYING THE CONVENTIONAL METHOD OF ASSESSING HEALTH HAZARDS IN ACCORDANCE WITH ARTICLE 3 (5)

An assessment must be made of all the health hazards that the use of a substance might entail. For that purpose the dangerous health effects have been subdivided into:

- acute lethal effects,
- non-lethal irreversible effects after a single exposure,
- severe effects after repeated or prolonged exposure;
  
- corrosive effects,
- irritant effects,
- sensitizing effects;
  
- carcinogenic effects,
- mutagenic effects,
- teratogenic effects.

The systematic assessment of all the dangerous health effects is expressed by means of concentration limits in conjunction with the classification of the substance, i.e. the symbol and phrases denoting the risk. Therefore given the symbol priority rule, it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

## 1. Acute lethal effects

The concentration limits fixed in Table I determine the classification of the preparation 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 <sup>+</sup>                    | T                         | X <sub>n</sub>              |
| T <sup>+</sup> with R 26, R 27, R 28 | concentration ≥ 7 %               | 1 % ≤ concentration < 7 % | 0,1 % ≤ concentration < 1 % |
| T with R 23, R 24, R 25              |                                   | concentration ≥ 25 %      | 3 % ≤ concentration < 25 %  |
| X <sub>n</sub> with R 20, R 21, R 22 |                                   |                           | concentration ≥ 25 %        |

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria:

- the label shall include one or more of the abovementioned R phrases according to 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

For substances that produce non-lethal irreversible effects after a single exposure (R 39, R 40), the individual concentration limits specified in Table II determine, when appropriate, the classification of the preparation and shall determine which particular standard R phrase is to be assigned to it.

TABLE II

| Classification of the substance | Classification of the preparation           |                                                   |                                                    |
|---------------------------------|---------------------------------------------|---------------------------------------------------|----------------------------------------------------|
|                                 | T <sup>+</sup>                              | T                                                 | X <sub>n</sub>                                     |
| T <sup>+</sup> with R 39        | concentration ≥ 10 %<br>R 39 (*) obligatory | 1 % ≤ concentration < 10 %<br>R 39 (*) obligatory | 0,1 % ≤ concentration < 1 %<br>R 40 (*) obligatory |
| T with R 39                     |                                             | concentration ≥ 10 %<br>R 39 (*) obligatory       | 1 % ≤ concentration < 10 %<br>R 40 (*) obligatory  |
| X <sub>n</sub> with R 40        |                                             |                                                   | concentration ≥ 10 %<br>R 40 (*) obligatory        |

(\*) In accordance with the labelling guide of Annex VI, point II (D) of Directive 67/548/EEC and depending on the classification, the standard R phrases R 20 to R 28 are also to be assigned to indicate route of administration or means of exposure.

### 3. Severe effects after repeated or prolonged exposure

For substances that produce severe effects after repeated or prolonged exposure (R 48), the individual concentration limits specified in Table III determine, when appropriate, the classification of the preparation and shall determine which particular standard R phrase is to be assigned to it.

TABLE III

| Classification of the substance | Classification of the preparation           |                                                   |
|---------------------------------|---------------------------------------------|---------------------------------------------------|
|                                 | T                                           | X <sub>n</sub>                                    |
| T with R 48                     | concentration ≥ 10 %<br>R 48 (*) obligatory | 1 % ≤ concentration < 10 %<br>R 48 (*) obligatory |
| X <sub>n</sub> with R 48        |                                             | concentration ≥ 10 %<br>R 48 (*) obligatory       |

(\*) In accordance with the labelling guide of Annex VI, point II (D) of Directive 67/548/EEC and depending on the classification, the standard R phrases R 20 to R 28 are also to be assigned to indicate route of administration or means of exposure.

### 4. Corrosive and irritant effects

For substances that produce corrosive effects (R 34, R 35) or irritant effects (R 36, R 37, R 38, R 41) the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

TABLE IV

| Classification of the substance and/or relevant standard risk phrase | Classification of the preparation and standard risk phrase |                                                   |                                             |                                                                                                                                                             |
|----------------------------------------------------------------------|------------------------------------------------------------|---------------------------------------------------|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                      | at least C with R 35                                       | at least C with R 34                              | at least X <sub>i</sub> with R 41           | at least X <sub>i</sub> with R 36, R 37, R 38                                                                                                               |
| at least C with R 35                                                 | concentration ≥ 10 %<br>R 35;<br>obligatory                | 5 % ≤ concentration < 10 %<br>R 34;<br>obligatory |                                             | 1 % ≤ concentration < 5 %<br>R 36, R 38;<br>obligatory                                                                                                      |
| at least C with R 34                                                 |                                                            | concentration ≥ 10 %<br>R 34;<br>obligatory       |                                             | 5 % ≤ concentration < 10 %<br>R 36, R 38;<br>obligatory                                                                                                     |
| at least X <sub>i</sub> with R 41                                    |                                                            |                                                   | concentration ≥ 10 %<br>R 41;<br>obligatory | 5 % ≤ concentration < 10 %<br>R 36<br>obligatory                                                                                                            |
| at least X <sub>i</sub> with R 36, R 37, R 38                        |                                                            |                                                   |                                             | concentration ≥ 20 %<br>R 36, R 37 and R 38<br>are obligatory in the light of the concentration present if they apply to the substances under consideration |

## 5. Sensitizing effects

Substances that produce such effects are classified:

- at least as harmful ( $X_n$ ) and assigned R 42 if this effect can be produced by inhalation,
- at least as irritant ( $X_i$ ) and assigned R 43 if this effect can be produced through contact with the skin,
- at least as harmful ( $X_n$ ) and assigned R 42/43 if this effect can be produced in both these ways.

The individual concentration limits specified in Table V determine, when appropriate, the classification of the preparation, and shall determine which particular R phrase is to be assigned to it.

TABLE V

| Classification of the substance | Classification of the preparation and standard risk phrase |                                             |
|---------------------------------|------------------------------------------------------------|---------------------------------------------|
|                                 | At least $X_n$ and R 42                                    | At least $X_i$ and R 43                     |
| At least $X_n$ and R 42         | concentration $\geq 1\%$<br>R 42 obligatory                |                                             |
| At least $X_i$ and R 43         |                                                            | concentration $\geq 1\%$<br>R 43 obligatory |
| At least $X_n$ and R 42/43      | concentration $\geq 1\%$<br>R 42/43 obligatory             |                                             |

## 6. Carcinogenic/mutagenic/teratogenic effects

For substances which produce such effects and for which specific concentration limits do not yet appear in Annex I to Directive 67/548/EEC and for those which, in accordance with point 3.1.1 of Annex III to Directive 83/467/EEC, are provisionally assigned the phrase R 40, the concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparation and the compulsory R phrase to be assigned to it.

TABLE VI

| Substance                                                                                                 | Classification of the preparation and standard risk phrase |                                 |
|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------|
|                                                                                                           | At least T                                                 | At least $X_n$                  |
| At least T with R 45 for carcinogenic substances of category 1 or 2                                       | $\geq 0,1\%$<br>R 45 obligatory                            |                                 |
| At least $X_n$ with R 40 for carcinogenic substances of category 3                                        |                                                            | $\geq 1\%$<br>R 40 obligatory   |
| At least T with R 46 for mutagenic substances of category 1                                               | $\geq 0,1\%$<br>R 46 obligatory                            |                                 |
| At least $X_n$ with R 46 for mutagenic substances of category 2                                           |                                                            | $\geq 0,1\%$<br>R 46 obligatory |
| At least $X_n$ with R 40 for mutagenic substances of category 3                                           |                                                            | $\geq 1\%$<br>R 40 obligatory   |
| At least T with R 47 for teratogenic substances of category 1                                             | $\geq 0,5\%$<br>R 47 obligatory                            |                                 |
| At least $X_n$ with R 47 for teratogenic substances of category 2                                         |                                                            | $\geq 5\%$<br>R 47 obligatory   |
| At least $X_n$ and R 40 provisionally in accordance with point 3.1.1 of Annex III to Directive 83/467/EEC |                                                            | $\geq 1\%$<br>R 40 obligatory   |

## ANNEX II

## SPECIAL PROVISIONS ON THE LABELLING OF CERTAIN PREPARATIONS

## 1. PREPARATIONS CLASSIFIED AS VERY TOXIC, TOXIC OR CORROSIVE, SOLD TO THE GENERAL PUBLIC

- 1.1. The labels on packages containing such preparations must compulsorily bear the safety advice S<sub>1</sub>/S<sub>2</sub> and S<sub>46</sub> in addition to the specific safety advice.
- 1.2. 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 necessary, instructions for the destruction of the empty package.

## 2. PREPARATIONS CONTAINING LEAD

2.1. *Paints and varnishes*

Labels of packages of paints and varnishes containing lead in quantities exceeding 0,25 % expressed as weight of metal, of the total weight of the preparation, as determined in accordance with ISO 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 millilitres, the particulars may be as follows:

'Warning. Contains lead.'

## 3. PREPARATIONS CONTAINING CYANOACRYLATES

3.1. *Glues*

The immediate packaging of glues 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.

## 4. 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.'

5. PREPARATIONS CONTAINING EPOXY CONSTITUENTS WITH AN AVERAGE MOLECULAR WEIGHT  $\leq 700$ 

The package labels of preparations containing epoxy constituents with an average molecular weight  $\leq 700$  must bear the following inscriptions:

'Contains epoxy constituents.

See information supplied by the manufacturer.'

## 6. PREPARATIONS INTENDED FOR USE BY SPRAYING

The package label on preparations intended for use by spraying must bear the safety advice S 23 and S 38 or S 23 and S 51 depending on the application criteria specified in Directive 83/467/EEC.

## COUNCIL DIRECTIVE

of 13 June 1988

amending Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species

(88/380/EEC)

## THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Whereas, for the reasons given below, the following Directives on the marketing of seed and propagating material should be amended:

- Council Directive 66/400/EEC of 14 June 1966 on the marketing of beet seed <sup>(3)</sup>, as last amended by Directive 88/95/EEC <sup>(4)</sup>,
- Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed <sup>(5)</sup>, as last amended by Directive 87/480/EEC <sup>(6)</sup>,
- Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed <sup>(7)</sup>, as last amended by Directive 87/120/EEC <sup>(8)</sup>,
- Council Directive 66/403/EEC of 14 June 1966 on the marketing of seed potatoes <sup>(9)</sup>, as last amended by Directive 87/374/EEC <sup>(10)</sup>,
- Council Directive 69/208/EEC of 30 June 1969 on the marketing of seed of oil and fibre plants <sup>(11)</sup>, as last amended by Directive 87/480/EEC,
- Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species <sup>(12)</sup>, as last amended by Directive 86/155/EEC <sup>(13)</sup>,

— Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed <sup>(14)</sup>, as last amended by Directive 87/481/EEC <sup>(15)</sup>;

Whereas, owing to their increased importance in the Community, rescue grass, Alaska brome-grass, California bluebell, triticale, Chinese cabbage and industrial chicory should be included in the scope of the Directives; whereas, for the same reason, hybrid varieties of certain additional cereal species and sunflower should also be included in the scope of the Directives; whereas the conditions to be satisfied by the crop and by the seed of those species and variety types should be in conformity with the schemes for seed moving in international trade laid down by the Organization for Economic Cooperation and Development (OECD), except for cross-pollinating varieties of triticale and hybrid varieties of certain additional cereal species, where the OECD has not yet adopted such conditions;

Whereas it seems advisable, on the one hand, to revise certain provisions in order to facilitate the reproduction of seed in Member States other than that of origin and, on the other hand, to provide for Community measures to ensure the identity of that seed marketed as grown for processing;

Whereas it seems advisable that additional periods should be granted to Member States to allow seed of self-pollinating cereal species which has not been the subject of an official field inspection to be certified officially under certain conditions and to permit the marketing of specific varieties of rye not satisfying certain conditions laid down in Annex II to Directive 66/402/EEC, in order that the necessary experience for a more general and definitive solution may be acquired, in particular, with regard to rye, in the light of information to be supplied by the United Kingdom;

Whereas it seems advisable that, for the purpose of seeking improved alternative solutions to certain elements of the certification schemes adopted under the Directives, temporary experiments under specific conditions should be organized; whereas, therefore, a legal basis to that effect should be introduced;

Whereas the provisions on the information required for the official label in respect of species and variety names should be

<sup>(1)</sup> OJ No C 356, 31. 12. 1985, p. 37.

<sup>(2)</sup> OJ No C 68, 24. 3. 1986, p. 155.

<sup>(3)</sup> OJ No 125, 11. 7. 1966, p. 2290/66.

<sup>(4)</sup> OJ No L 56, 2. 3. 1988, p. 42.

<sup>(5)</sup> OJ No 125, 11. 7. 1966, p. 2298/66.

<sup>(6)</sup> OJ No L 273, 26. 9. 1987, p. 43.

<sup>(7)</sup> OJ No 125, 11. 7. 1966, p. 2309/66.

<sup>(8)</sup> OJ No L 49, 18. 2. 1987, p. 39.

<sup>(9)</sup> OJ No 125, 11. 7. 1966, p. 2320/66.

<sup>(10)</sup> OJ No L 197, 18. 7. 1987, p. 36.

<sup>(11)</sup> OJ No L 169, 10. 7. 1969, p. 3.

<sup>(12)</sup> OJ No L 225, 12. 10. 1970, p. 1.

<sup>(13)</sup> OJ No L 118, 7. 5. 1986, p. 23.

<sup>(14)</sup> OJ No L 225, 12. 10. 1970, p. 7.

<sup>(15)</sup> OJ No L 273, 26. 9. 1987, p. 45.

improved with the aim of providing better information for seed users and facilitating intra-Community trade;

Whereas it should be ensured that the suppliers' labels required under national provisions are drawn up in such a way that they cannot be confused with the official labels;

Whereas it is desirable to make it easier for Member States to exclude seed of cereal species or oil and fibre plant species of low economic importance from the scope of Directives 66/402/EEC and 69/208/EEC;

Whereas, in the case of Directive 70/458/EEC, certain provisions on varieties of vegetable species should be adapted in such a manner as to permit current developments to be taken into account in the process of renewal of the official acceptance of certain varieties;

Whereas, as a general rule, the conditions in respect of the value of a variety for cultivation or use should not be required for the acceptance of varieties (inbred lines, hybrids) which are intended solely as components for hybrid varieties;

Whereas it should be possible to require the suitability for specific purposes of varieties of grasses not intended for the production of fodder plants to be shown;

Whereas applications by the Hellenic Republic to be authorized to prohibit the marketing in all or part of its territory of seed or propagating material of certain varieties listed in the Common Catalogue of Varieties of Agricultural Plant Species or the Common Catalogue of Varieties of Vegetable Species should be taken into consideration in order to permit the Hellenic Republic to complete the adaptation of its seed and propagating material production and marketing to the Community requirements relating to the common catalogues;

Whereas it is useful to clarify certain provisions of the abovementioned Directives;

Whereas it is appropriate to postpone the date of implementation of the amendments already made to the abovementioned Directives by Council Directive 86/155/EEC and Commission Directive 86/320/EEC so as to bring the date into conformity with the main date of implementation of this Directive,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Directive 66/400/EEC is hereby amended as follows:

1. in Article 2 (1) (E), '(bb)' is replaced by '(aa) (a) and (bb)';
2. the following paragraph is inserted in Article 2:
 

'1a. The different types of varieties, including the components, eligible for certification under the provisions of this Directive, may be specified and defined in accordance with the procedure laid down in Article 21.'

3. former Article 12 becomes Article 12 (1);

4. the following paragraph is added in Article 12:

'2. The label referred to in paragraph 1 shall be drawn up in such a manner that it cannot be confused with the official label referred to in Article 11 (1).';

5. the following Article 13a is inserted:

#### 'Article 13a

For the purpose of seeking improved alternatives to certain elements of the certification scheme adopted under this Directive, it may be decided to organize temporary experiments under specified conditions at Community level in accordance with the provisions laid down in Article 21.

In the framework of such experiments, Member States may be released from certain obligations laid down in this Directive. The extent of that release shall be defined with reference to the provisions to which it applies. The duration of an experiment shall not exceed seven years.;

6. in Article 14 (2) (c), '(bb)' is replaced by '(aa) (a) and (bb)';

7. the fifth and sixth indents of Article 14 (3) (c) are replaced by the following:

— species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both; indication whether sugar beet or fodder beet,

— variety, indicated at least in roman characters,;

8. Article 15 is replaced by the following:

#### 'Article 15

1. Member States shall provide that beet seed
  - which has been produced directly from basic seed officially certified in one or more Member States or in a third country which has been granted equivalence under Article 16 (1) (b), and
  - which has been harvested in another Member State,

shall, on request and without prejudice to the provisions of Directive 70/457/EEC, be officially certified as certified seed in any Member State if that seed has undergone field inspection satisfying the conditions laid down in Annex I (A) for the relevant category and if official examination has shown that the conditions laid down in Annex I (B) for the same category are satisfied.

Where in such cases the seed has been produced directly from officially certified seed of generations

prior to basic seed, Member States may also authorize official certification as basic seed, if the conditions laid down for that category are satisfied.

2. Beet seed which has been harvested in another Member State, and which is intended for certification in accordance with the provisions laid down in paragraph 1, shall

- be packed and labelled with an official label satisfying the conditions laid down in Annex IV (A) and (B), in accordance with the provisions laid down in Article 10 (1), and
- be accompanied by an official document satisfying the conditions laid down in Annex IV (C).

3. The Member States shall also provide that beet seed

- which has been produced directly from basic seed officially certified in one or more Member States or in a third country which has been granted equivalence under Article 16 (1) (b), and

- which has been harvested in a third country,

shall, on request, be officially certified as certified seed in any of those Member States where the basic seed was either produced or officially certified, if the seed has undergone field inspection satisfying the conditions laid down in an equivalence decision made under Article 16 (1) (a) for the relevant category, and if official examination has shown that the conditions laid down in Annex I (B) for the same category are satisfied. Other Member States may also authorize official certification of such seed.;

9. Annex III (A) (I) (4) is replaced by the following:

- '4. Species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both; indication whether sugar beet or fodder beet';

10. the following is added to Annex III (A) (I) (5):

'indicated at least in roman characters.';

11. Annex III (B) (6) is replaced by the following:

- '6. Species, indicated at last in roman characters; indication whether sugar beet or fodder beet';

12. the following is added to Annex III (B) (7):

'indicated at least in roman characters,';

13. the following Annex is added:

#### 'ANNEX IV

#### Label and document provided in the case of seed not finally certified, harvested in another Member State

##### A. Information required for the label

- authority responsible for field inspection and Member State or their initials,
- species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both; indication whether sugar beet or fodder beet,
- variety, indicated at least in roman characters,
- category,
- field or lot reference number,
- declared net or gross weight,
- the words "seed not finally certified".

##### B. Colour of the label

The label shall be grey.

##### C. Information required for the document

- authority issuing the document,
- species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both; indication whether sugar beet or fodder beet,
- variety, indicated at least in roman characters,
- category,
- reference number of the seed used to sow the field and name of the country or countries which certified that seed,
- field or lot reference number,
- area cultivated for the production of the lot covered by the document,
- quantity of seed harvested and number of packages,
- attestation that the conditions to be satisfied by the crop from which the seed comes have been fulfilled,
- where appropriate, results of a preliminary seed analysis.'

#### Article 2

Directive 66/401/EEC is hereby amended as follows:

1. in Article 2 (1) (A) (a),

'*Bromus catharticus*  
Vahl

Rescue grass

'*Bromus sitchensis* Trin.

Alaska brome-grass'

is inserted after

'*Arrhenatherum elatius*  
(L.) P. Beau. ex J. S. and  
K. B. Presl.

Tall oatgrass'

and in Article 2 (1) (A) (c),

'*Phacelia tanacetifolia*  
Benth.

California bluebell'

is inserted after

'*Brassica oleracea* L.  
convar. *acephala* (DC)  
Alef. var. *medullosa*  
Thell + var. *viridis* L.

Fodder kale';

2. in Article 2 (1a) of the English version, 'descriptions' is replaced by 'names';

3. former Article 2 (1b) and (1c) become 2 (1c) and (1d) respectively;

4. the following paragraph is inserted in Article 2:

'1b. The different types of varieties, including the components, eligible for certification under this Directive may be specified and defined in accordance with the procedure laid down in Article 21.';

5. former Article 11 becomes Article 11 (1);

6. the following paragraph is added in Article 11:

'2. The label referred to in paragraph 1 shall be drawn up in such a manner that it cannot be confused with the official label referred to in Article 10 (1).';

7. the following Article 13a is inserted:

*'Article 13a*

For the purpose of seeking improved alternatives to certain elements of the certification scheme adopted under this Directive, it may be decided to organize temporary experiments under specified conditions at Community level in accordance with the procedure laid down in Article 21.

In the framework of such experiments, Member States may be released from certain obligations laid down in this Directive. The extent of that release shall be defined with reference to the provisions to which it applies. The duration of an experiment shall not exceed seven years.';

8. the fifth and sixth indents of Article 14 (3) (c) are replaced by the following:

— species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,

— variety, indicated at least in roman characters,';

9. the following sentence is added to Article 14 (3):

'In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.';

10. Article 15 is replaced by the following:

*'Article 15*

1. The Member States shall provide that fodder plant seed

— which has been produced directly from basic seed or certified seed officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 16 (1) (b), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and

— which has been harvested in another Member State,

shall, on request and without prejudice to the provisions of Directive 70/457/EEC, be officially certified as certified seed in any Member State if that seed has undergone field inspection satisfying the conditions laid down in Annex I for the relevant category and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied.

Where in such cases the seed has been produced directly from officially certified seed of generations prior to basic seed, Member States may also authorize official certification as basic seed, if the conditions laid down for that category are satisfied.

2. Fodder plant seed which has been harvested in another Member State, and which is intended for certification in accordance with the provisions laid down in paragraph 1, shall:

— be packed and labelled with an official label satisfying the conditions laid down in Annex V (A) and (B), in accordance with the provisions laid down in Article 9 (1), and

— be accompanied by an official document satisfying the conditions laid down in Annex V (C).

3. The Member States shall also provide that fodder plant seed

— which has been produced directly from basic seed or certified seed officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 16 (1) (b), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and

— which has been harvested in a third country,

shall, on request, be officially certified as certified seed in any of those Member States where the basic seed or certified seed referred to above was either produced or officially certified, if the seed has undergone field inspection satisfying the conditions laid down in an equivalence decision made under Article 16 (1) (a) for

the relevant category, and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied. Other Member States may also authorize official certification of such seed.';

11. in Annex I (2) in the first column of the table, '*Phacelia tanacetifolia*' is inserted each time after '*Brassica* spp.';

12. in the second sentence of the French version of Annex I (3) 'la variété' is replaced by 'l'espèce';

13. in the heading of column 4 of the French version of Annex II (I) (2) (A), 'animale' is replaced by 'minimale';

14. in Annex II (I) (2) (A) the following are inserted after '*Arrhenatherum elatius*' and '*Brassica oleracea* convar. *acephala*', respectively:

| 1                             | 2      | 3 | 4  | 5   | 6   | 7   | 8   | 9 | 10 | 11 | 12    | 13        | 14     | 15 |
|-------------------------------|--------|---|----|-----|-----|-----|-----|---|----|----|-------|-----------|--------|----|
| <i>Bromus catharticus</i>     | 75 (a) |   | 97 | 1,5 | 1,0 | 0,5 | 0,3 |   |    |    | 0 (g) | 0 (j) (k) | 10 (n) |    |
| <i>Bromus sitchensis</i>      | 75 (a) |   | 97 | 1,5 | 1,0 | 0,5 | 0,3 |   |    |    | 0 (g) | 0 (j) (k) | 10 (n) |    |
| and                           |        |   |    |     |     |     |     |   |    |    |       |           |        |    |
| <i>Phacelia tanacetifolia</i> | 80 (a) |   | 96 | 1,0 | 0,5 |     |     |   |    |    | 0     | 0 (j) (k) |        |    |

15. in Annex II (II) (2) (A) the following are inserted after '*Arrhenatherum elatius*' and '*Brassica oleracea* convar. *acephala*', respectively:

| 1                             | 2   | 3  | 4 | 5 | 6 | 7 | 8   |
|-------------------------------|-----|----|---|---|---|---|-----|
| <i>Bromus catharticus</i>     | 0,4 | 20 | 5 | 5 | 5 |   | (j) |
| <i>Bromus sitchensis</i>      | 0,4 | 20 | 5 | 5 | 5 |   | (j) |
| and                           |     |    |   |   |   |   |     |
| <i>Phacelia tanacetifolia</i> | 0,3 | 20 |   |   |   |   |     |

16. in Annex III the following are inserted after '*Arrhenatherum elatius*' and '*Brassica oleracea* convar. *acephala*', respectively:

| 1                             | 2  | 3   | 4   |
|-------------------------------|----|-----|-----|
| <i>Bromus catharticus</i>     | 10 | 200 | 200 |
| <i>Bromus sitchensis</i>      | 10 | 200 | 200 |
| and                           |    |     |     |
| <i>Phacelia tanacetifolia</i> | 10 | 300 | 40  |

17. the following is added to Annex IV (A) (I) (a) (4):

'indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,';

18. the following sentence shall be added to Annex IV (A) (I) (a):

'In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of

individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.';

19. the following is added to Annex IV (A) (I) (a) (5):

'indicated at least in roman characters,';

20. the following is added to Annex IV (A) (I) (b) (5):

'indicated at least under its botanical name, which may

be given in abridged form and without the authorities' names, in roman characters';

21. the following is added to Annex IV (A) (I) (b):

'In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.';

22. the following is added to Annex IV (A) (I) (c) (4) after 'shown by species and, where appropriate, by variety':

'both indicated at least in roman characters;

23. in the last sentence of the Italian version of Annex IV (A) (I) (c) (4), 'al fornitore' is replaced by 'all'acquirente';

24. the following is added to Annex IV (B) (a) (6):

'indicated at least in roman characters,';

25. the following is added to Annex IV (B) (a) (7):

'indicated at least in roman characters,';

26. the following is added to Annex IV (B) (b) (6):

'indicated at least in roman characters,';

27. the following is added to Annex IV (B) (c) (11) after 'shown by species and, where appropriate, by variety':

'both indicated at least in roman characters;

28. the following Annex is added:

**'ANNEX V**

**Label and document provided in the case of seed not finally certified, harvested in another Member State**

**A. Information required for the label**

- authority responsible for field inspection and Member States or their initials,
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,
- variety, indicated at least in roman characters,
- category,
- field or lot reference number,

- declared net or gross weight,
- the words "seed not finally certified".

In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.

**B. Colour of the label**

The label shall be grey.

**C. Information required for the document**

- authority issuing the document,
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities names, in roman characters,
- variety, indicated at least in roman characters,
- category,
- reference number of the seed used to sow the field and name of the country or countries which certified that seed,
- field or lot reference number,
- area cultivated for the production of the lot covered by the document,
- quantity of seed harvested and number of packages,
- number of generations after basic seed, in the case of certified seed,
- attestation that the conditions to be satisfied by the crop from which the seed comes have been fulfilled,
- where appropriate, results of a preliminary seed analysis.'

**Article 3**

Directive 66/402/EEC is hereby amended as follows:

1. in Article 2 (1) (A),

'X *Triticosecale* Wittm.                      Triticale'  
are inserted after

'*Sorghum sudanense* (Piper) Stapf      Sudan grass';

2. in Article 2 (1) (A) of the German version, in the line '*Phalaris canariensis* L', 'Kanariensaar' is replaced by 'Kanariengras':

3. in Article 2 (1) (C) the introductory words are replaced by:

- 'C. Basic seed (oats, barley, rice, canary grass, rye, triticale, wheat, durum wheat and spelt wheat, other than hybrids in each case): seed';
4. the following is added in Article 2 (1):
- 'Ca. Basic seed (hybrids of oats, barley, rice, wheat, durum wheat and spelt wheat):
- (a) which is intended for the production of hybrids;
  - (b) which, subject to the provisions of Article 4, satisfies the conditions laid down in Annexes I and II for basic seed; and
  - (c) which has been found by official examination to satisfy the abovementioned conditions.';
5. in Article 2 (1) (E) the introductory words are replaced by the following:
- 'E. Certified seed (canary grass and rye, other than hybrids in each case, sorghum, Sudan grass, maize and hybrids of oats, barley, rice, wheat, durum wheat and spelt wheat): seed';
6. in Article 2 (1) (F), the introductory words are replaced by the following:
- 'F. Certified seed of the first generation (oats, barley, rice, triticale, wheat, durum wheat and spelt wheat, other than hybrids in each case): seed';
7. in Article 2 (1) (G), the introductory words are replaced by the following:
- 'G. Certified seed of the second generation (oats, barley, rice, triticale, wheat, durum wheat and spelt wheat, other than hybrids in each case): seed';
8. in Article 2 (1a) of the English version, 'descriptions' is replaced by 'name';
9. former Article 2 (1b) and (1c) become Article 2 (1d) and (1e) respectively;
10. the following paragraphs are inserted in Article 2:
- 1b. Amendments to be made to paragraph 1 (C) (Ca), (E), (F) and (G) for the purpose of including hybrids of canary grass, rye and triticale in the scope of this Directive shall be adopted in accordance with the procedure laid down in Article 21.
  - 1c. The different types of varieties, including the components, eligible for certification under the provisions of this Directive, may be specified and defined in accordance with the procedure laid down in Article 21. In accordance with the same procedure the definitions in paragraph 1 (B) shall be adapted accordingly.';
11. in Article 2 (1) (c), '30 June 1982' is replaced by '30 June 1987' and the second indent is deleted;
12. in Article 2 (2) (d), '31 December 1982' is replaced by '30 June 1989';
13. the following paragraph is added to Article 4:
- '3. In the case of triticale seed intended for marketing in their own territory, Member States may reduce to 80 % the minimum germination required under Annex II. If, in such cases, triticale seed does not satisfy the conditions laid down in Annex II in respect of germination, this fact, and the fact that the seed is for marketing only in the territory of the Member State concerned, shall be stated on the label.';
14. former Article 11 becomes Article 11 (1);
15. the following paragraph is added to Article 11:
- '2. The label referred to in paragraph 1 shall be drawn up in such a manner that it cannot be confused with the official label referred to in Article 10 (1).';
16. the following Article 13a is inserted:
- 'Article 13a*
- For the purpose of seeking improved alternatives to certain elements of the certification scheme adopted under this Directive, it may be decided to organize temporary experiments under specified conditions at Community level in accordance with the procedure laid down in Article 21.
- In the framework of such experiments, Member States may be released from certain obligations laid down in this Directive. The extent of that release shall be defined with reference to the provisions to which it applies. The duration of an experiment shall not exceed seven years.';
17. in Article 14 (2) (a), ', triticale' is added after 'rice';
18. the fifth and sixth indents of Article 14 (3) (c) are replaced by the following:
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,
  - variety, indicated at least in roman characters,';
19. the following is added to Article 14 (3):
- 'In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of

individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.;

20. Article 15 is replaced by the following:

*'Article 15*

1. The Member States shall provide that cereal seed

— which has been produced directly from basic seed or certified seed of the first generation officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 16 (1) (b), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and

— which has been harvested in another Member State,

shall, on request and without prejudice to the provisions of Directive 70/457/EEC, be officially certified as certified seed in any Member State if that seed has undergone field inspection satisfying the conditions laid down in Annex I for the relevant category and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied.

Where in such cases the seed has been produced directly from officially certified seed of generations prior to basic seed, Member States may also authorize official certification as basic seed, if the conditions laid down for that category are satisfied.

2. Cereal seed which has been harvested in another Member State, and which is intended for certification in accordance with the provisions laid down in paragraph 1, shall

— be packed and labelled with an official label satisfying the conditions laid down in Annex V (A) and (B), in accordance with the provisions laid down in Article 9 (1), and

— be accompanied by an official document satisfying the conditions laid down in Annex V (C).

3. The Member States shall also provide that cereal seed

— which has been produced directly from basic seed or certified seed of the first generation officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 16 (1) (b), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and

— which has been harvested in a third country,

shall, on request, be officially certified as certified seed in any of those Member States where the basic seed was either produced or officially certified, if the

seed has undergone field inspection satisfying the conditions laid down in an equivalence decision made under Article 16 (1) (a) for the relevant category, and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied. Other Member States may also authorize official certification of such seed.;

21. The following Article 21b is inserted:

*'Article 21b*

Amendments to be made to the content of the Annexes in order to establish the conditions to be satisfied by the crop and the seed of hybrids of oats, barley, rice, wheat, durum wheat, spelt wheat and other species for which hybrids are included in the scope of this Directive pursuant to Article 2 (1b) and the conditions to be satisfied by the crop and the seed of cross-pollinating varieties of triticale shall be adopted according to the procedure laid down in Article 21.;

22. in Article 22, 'Annex II (2)' is replaced by 'Annex II (3)';

23. Article 23a is replaced by the following Article:

*'Article 23a*

Upon application by a Member State, which will be dealt with as provided in Article 21, that State may be wholly or partially released from the obligation to apply the provisions of this Directive, with the exception of Article 14 (1):

(a) in respect of the following species:

- canary grass,
- sorghum,
- Sudan grass;

(b) in respect of other species which are not normally reproduced or marketed in its territory.;

24. in the table in Annex I (2) the following is inserted before 'Zea mays':

*'Triticosecale, self-pollinating varieties*

- |                                        |        |
|----------------------------------------|--------|
| — for the production of basic seed     | 50 m   |
| — for the production of certified seed | 20 m'; |

25. in Annex I (5) (B) (a), 'Triticosecale' is inserted after 'Phalaris canariensis';

26. in the French version of Annex I (5) (B) (b), '3' is replaced by '1' and '1' by '3';

27. in Annex II (1) (A) 'other than hybrids in each case' is inserted after 'Triticum spelta';

28. the following is inserted after Annex II (1) (A):

'Aa Self-pollinating varieties of *Triticosecale*

| Category                          | Minimum varietal purity (%) |
|-----------------------------------|-----------------------------|
| Basic seed                        | 99,7                        |
| Certified seed, first generation  | 99,0                        |
| Certified seed, second generation | 98,0                        |

The minimum varietal purity shall be examined mainly in field inspections carried out in accordance with the conditions laid down in Annex I.;

29. in Annex II (2) (A), the following is inserted after '*Sorghum* spp.':

| 1                                             | 2  | 3  | 4  | 5 | 6     | 7 | 8     | 9  | 10 |
|-----------------------------------------------|----|----|----|---|-------|---|-------|----|----|
| <i>Triticosecale</i>                          |    |    |    |   |       |   |       |    |    |
| — basic seed                                  | 85 | 98 | 4  |   | 1 (b) | 3 | 0 (c) | 1  |    |
| — certified seed, first and second generation | 85 | 98 | 10 |   | 7     | 7 | 0 (c) | 3' |    |

30. In Annex III, '*Triticosecale*' is inserted after '*Secale cereale*';

31. the following is added to Annex IV (A) (a) (4):

,indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters';

32. the following sentence is added to Annex IV (A) (a):

'In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.';

33. Annex IV (A) (a) (5) is replaced by the following:

'Variety, indicated at least in roman characters';

34. Annex IV (A) (a) (9) is replaced by the following:

'9. In the case of varieties which are hybrids or inbred lines:

- for basic seed where the hybrid or inbred line to which the seed belongs has been officially accepted under Directive 70/457/EEC:

the name of this component, under which it has been officially accepted, with or without reference to the final variety, accompanied, in the case of hybrids or inbred lines which are intended solely as components for final varieties, by the word "component",

- for basic seed in other cases:

the name of the component to which the basic seed belongs, which may be given in code form, accompanied by a reference to the final variety, with or without reference to its function (male or female), and accompanied by the word "component",

- for certified seed:

the name of the variety to which the seed belongs, accompanied by the word "hybrid".;

35. in Annex IV (A) (b) (1), 'or varieties' is inserted after 'species';

36. the following is added to Annex IV (A) (b) (4):

‘; the names of the species and of the varieties shall be indicated at least in roman characters.’;

37. the following Annex is added:

#### ANNEX V

Label and document provided in the case of seed not finally certified, harvested in another Member State

##### A. Information required for the label

- authority responsible for field inspection and Member State or their initials,
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,

- variety, indicated at least in roman characters; in the case of varieties (inbred lines, hybrids), which are intended solely as components for hybrid varieties, the word "component" shall be added,
- category,
- in the case of hybrid varieties the word "hybrid",
- declared net or gross weight,
- the words "seed not finally certified".

In accordance with the procedure laid down in Article 21, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.'

#### B. *Colour of the label*

The label shall be grey.

#### C. *Information required for the document*

- authority issuing the document,
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,
- category,
- reference number of the seed used to sow the field and name of the country or countries which certified that seed,
- field or lot reference number,
- area cultivated for the production of the lot covered by the document,
- quantity of seed harvested and number of packages,
- number of generations after basic seed, in the case of certified seed,
- attestation that the conditions to be satisfied by the crop from which the seed comes have been fulfilled,
- where appropriate, results of a preliminary seed analysis.'

#### Article 4

Directive 66/403/EEC is hereby amended as follows:

1. former Article 11 becomes Article 11 (1);
2. the following paragraph is added to Article 11:
 

'2. The label referred to in paragraph 1 shall be drawn up in such a manner that it cannot be confused with the official label referred to in Article 10 (1).';

3. the fourth and fifth indents of Article 13 (4) (c) are replaced by the following:
  - species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both,
  - variety, indicated at least in roman characters,';

4. the following is added to Annex III (A) (4):

' , indicated at least in roman characters'.

#### Article 5

Directive 69/208/EEC is hereby amended as follows:

1. in Article 2 (1) (B), '(varieties other than hybrids of sunflower)' is inserted after 'Basic seed';

2. the following is inserted after Article 2 (1) (B):

"Ba. Basic seed (hybrids of sunflower):

1. Basic seed of inbred lines: seed

- (a) which, subject to the provisions of Article 4, satisfies the conditions laid down in Annexes I and II for basic seed; and
- (b) which has been found by official examination to satisfy the abovementioned conditions.

2. Basic seed of simple hybrids: seed

- (a) which is intended for the production of three-way-cross hybrids or double-cross hybrids;
- (b) which, subject to the provisions of Article 4, satisfies the conditions laid down in Annexes I and II for basic seed; and
- (c) which has been found by official examination to satisfy the abovementioned conditions.';

3. in Article 2 (1a) of the English version, 'descriptions' is replaced by 'names';

4. former Article 2 (1b) becomes 2 (1c);

5. the following paragraph is inserted in Article 2:

'1b. The different types of varieties, including the components, eligible for certification under the provisions of this Directive may be specified and defined in accordance with the procedure laid down in Article 20.';

6. in Article 2 (2) (b) of the English version, 'or linseed' is inserted after 'flax';

7. former Article 11 becomes Article 11 (1);

8. the following paragraph is added to Article 11:

'2. The label referred to in paragraph 1 shall be drawn up in such a manner that it cannot be confused with the official label referred to in Article 10 (1).';

9. the following Article 12a is inserted:

*'Article 12a*

For the purpose of seeking improved alternatives to certain elements of the certification scheme adopted under this Directive, it may be decided to organize temporary experiments under specified conditions at Community level in accordance with the procedure laid down in Article 21.

In the framework of such experiments, Member States may be released from certain obligations laid down in this Directive. The extent of that release shall be defined with reference to the provisions to which it applies. The duration of an experiment shall not exceed seven years.';

10. the fifth and sixth indents of Article 13 (3) (c) are replaced by the following:

- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,
- variety, indicated at least in roman characters,';

11. the following sentence is added to Article 13 (3):

'In accordance with the procedure laid down in Article 20, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods, where it has been established that the disadvantages of the implementation outweigh the advantages expected for the marketing of seed.';

12. Article 14 is replaced by the following:

*'Article 14*

1. Member States shall provide that seed of oil and fibre plants

- which has been produced directly from basic seed or certified seed of the first generation officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 15 (1) (b), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and
- which has been harvested in another Member State,

shall, on request and without prejudice to the provisions of Directive 70/457/EEC, be officially certified as

certified seed in any Member State if that seed has undergone field inspection satisfying the conditions laid down in Annex I for the relevant category and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied.

Where in such cases the seed has been produced directly from officially certified seed of generations prior to basic seed, Member States may also authorize official certification as basic seed, if the conditions laid down for that category are satisfied.

2. Seed of oil and fibre plants which has been harvested in another Member State, and which is intended for certification in accordance with the provisions laid down in paragraph 1, shall:

- be packed and labelled with an official label satisfying the conditions laid down in Annex V (A) and (B), in accordance with the provisions laid down in Article 9 (1), and
- be accompanied by an official document satisfying the conditions laid down in Annex V (c).

3. The Member States shall also provide that seed of oil and fibre plants

- which has been produced directly from basic seed or certified seed of the first generation officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 15 (1) (b), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and
- which has been harvested in a third country,

shall, on request, be officially certified as certified seed in any of those Member States where the basic seed was either produced or officially certified, if the seed has undergone field inspection satisfying the conditions laid down in an equivalence decision made under Article 15 (1) (a) for the relevant category and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied. Other Member States may also authorize official certification of such seed.';

13. Article 22 is replaced by the following:

*'Article 22*

Upon application by a Member State, which will be dealt with as provided in Article 20, that State may be wholly or partially released from the obligation to apply the provisions of this Directive, with the exception of Article 13 (1):

- (a) in respect of the following species:
  - Safflower;
- (b) in respect of other species which are not normally reproduced or marketed in its territory.';

14. in the first paragraph of the table in Annex I (2), '*Helianthus annuus*' is deleted;

15. in the table in Annex I (2) the following is added:

| 1                                                                  | 2       |
|--------------------------------------------------------------------|---------|
| <i>Helianthus annuus</i>                                           |         |
| — for the production of basic seed of hybrids                      | 1 500 m |
| — for the production of basic seed of varieties other than hybrids | 750 m   |
| — for the production of certified seed                             | 500 m'  |

16. Annex I (3) is replaced by the following:

3. The crop shall have sufficient varietal identity and varietal purity or, in the case of a crop of an inbred line of *Helianthus annuus*, sufficient identity and purity as regards its characteristics.

For the production of seed of hybrid varieties of *Helianthus annuus*, the abovementioned provisions shall also apply to the characteristics of the components, including male sterility or fertility restoration.

In particular, crops of *Brassica juncea*, *Brassica nigra*, *Cannabis sativa*, *Carthamus tinctorius*, *Carum carvi*, *Gossypium* spp. and hybrids of *Helianthus annuus* shall conform to the following standards or other conditions:

- A. *Brassica juncea*, *Brassica nigra*, *Cannabis sativa*, *Carthamus tinctorius*, *Carum carvi* and *Gossypium* spp.:

The number of plants of the crop species which are recognizable as obviously not being true to the variety shall not exceed:

- one per 30 m<sup>2</sup> for the production of basic seed,
- one per 10 m<sup>2</sup> for the production of certified seed.

- B. Hybrids of *Helianthus annuus*:

- (a) the percentage by number of plants which are recognizable as obviously not being true to the inbred line or to the component shall not exceed:

- (aa) for the production of basic seed:

- |                                                                                                            |     |
|------------------------------------------------------------------------------------------------------------|-----|
| (i) inbred lines                                                                                           | 0,2 |
| (ii) simple hybrids                                                                                        |     |
| — male parent, plants which have shed pollen while 2 % or more of the female plants have receptive flowers | 0,2 |
| — female parent                                                                                            | 0,5 |

- (bb) for the production of certified seed:

- |                                                                                                               |     |
|---------------------------------------------------------------------------------------------------------------|-----|
| — male component, plants which have shed pollen while 5 % or more of the female plants have receptive flowers | 0,5 |
| — female component                                                                                            | 1,0 |

- (b) the following other standards or conditions shall be satisfied for the production of seed of hybrid varieties:

- (aa) sufficient pollen shall be shed by the plants of the male component while the plants of the female component are in flower;
- (bb) where the female component plants have receptive stigmas, the percentage by number of female component plants which have shed pollen or are shedding pollen shall not exceed 0,5;
- (cc) for the production of basic seed the total percentage by number of plants of the female component which are recognizable as obviously not being true to the component and which have shed pollen or are shedding pollen shall not exceed 0,5;

(dd) where the condition laid down in Annex II (I) (1a) cannot be satisfied, the following condition shall be satisfied: a male-sterile component shall be used to produce certified seed by using a male component which contains a specific restorer line or lines so that at least one-third of the plants grown from the resulting hybrid will produce pollen which appears normal in all respects.';

17. Annex I (5) (B) is replaced by the following:

'B. In cases other than crops of hybrids of sunflower there shall be at least one field inspection. In the case of hybrids of sunflower there shall be at least two field inspections.;

18. the following is inserted after Annex II (1):

'1a. Where the condition laid down in Annex I (3) (B) (b) (dd) cannot be satisfied, the following condition shall be met: where for the production of certified seed of hybrids of sunflower a female male-sterile component and a male component which does not restore male fertility have been used, the seed produced by the male-sterile parent shall be blended with seed produced by the fully fertile seed parent. The ratio of male-sterile parent seed to male-fertile parent shall not exceed two to one.';

19. the following is added to Annex IV (A) (a) (5):

'; indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters.'

20. the following is added to Annex IV (A) (a):

'In accordance with the procedure laid down in Article 20, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.';

21. the following is added to Annex IV (A) (a) (6):

'; indicated at least in roman characters';

22. the following is inserted after Annex IV (A) (a) (10):

'10a. In the case of varieties which are hybrids or inbred lines:

— for basic seed where the hybrid or inbred line to which the seed belongs has been officially accepted under Council Directive 70/457/EEC:

the name of this component, under which it has been officially accepted, with or without reference to the final variety, accompanied, in

the case of hybrids or inbred lines which are intended solely as components for final varieties, by the word "component",

— for basic seed in other cases:

the name of the component to which the basic seed belongs, which may be given in code form, accompanied by a reference to the final variety, with or without reference to its function (male or female), and accompanied by the word "component",

— for certified seed:

the name of the variety to which the seed belongs, accompanied by the word "hybrid".';

23. the following is added to Annex IV (A) (b) (6):

'; indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters.';

24. the following sentence is added to Annex IV (A) (b):

'In accordance with the procedure laid down in Article 20, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.';

25. the following Annex is added:

#### 'ANNEX V

**Label and document provided in the case of seed not finally certified, harvested in another Member State**

##### A. Information required for the label

- authority responsible for field inspection and Member State or their initials,
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in Roman characters,
- variety, indicated at least in roman characters; in the case of varieties (inbred lines, hybrids), which are intended solely as components for hybrid varieties, the word "component" shall be added,

- category,
- in the case of hybrid varieties, the word "hybrid",
- field or lot reference number,
- declared net or gross weight,
- the words "seed not finally certified".

In accordance with the procedure laid down in Article 20, Member States may be released from the requirement to indicate the botanical name in respect of individual species and, where appropriate, for limited periods where it has been established that the disadvantages of its implementation outweigh the advantages expected for the marketing of seed.

#### B. *Colour of the label*

The label shall be grey.

#### C. *Information required for the document*

- authority issuing the document
- species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters,
- variety, indicated at least in roman characters,
- category,
- reference number of the seed used to sow the field and name of the country or countries which certified that seed,
- field lot or reference number,
- area cultivated for the production of the lot covered by the document,
- quantity of seed harvested and number of packages,
- number of generations after basic seed, in the case of certified seed,
- attestation that the conditions to be satisfied by the crop from which the seed comes have been fulfilled,
- where appropriate, results of a preliminary seed analysis.'

#### Article 6

Directive 70/457/EEC is hereby amended as follows:

##### 1. the following paragraph is inserted in Article 3:

'1. In the case of varieties (inbred lines, hybrids) which are intended solely as components for final varieties, the provisions of paragraph 1 apply only to the extent that the seeds which belong to them are to be marketed under their names.'

After 1 July 1992, the conditions under which the provisions of paragraph 1 shall apply also to other component varieties may be determined in accordance with the procedure laid down in Article 23. In the mean time, in the case of cereals other than maize,

Member States may themselves apply those provisions to other component varieties in respect of seed intended for certification in their territories.

Component varieties shall be indicated as such.;

##### 2. the following is added to Article 4 (2):

'(c) for the acceptance of varieties (inbred lines, hybrids) which are intended solely as components for hybrid varieties satisfying the requirements of paragraph 1.'

##### 3. the following paragraph is added to Article 4:

'3. In the case of varieties to which paragraph 2 (a) applies, it may be decided, in accordance with the procedure laid down in Article 23, and to the extent that this is justified in the interest of free circulation of seed within the Community, that the varieties have to be shown by appropriate examination to be suitable for the purpose for which they are declared to be intended. In such cases, the conditions for the examination shall be determined.;

##### 4. the following sentence is inserted in Article 10 (2) after the first sentence:

'This provision shall not apply in the case of varieties (inbred lines, hybrids) which are intended solely as components for final varieties.;

##### 5. the following is added to Article 15 (2):

'With regard to Greece and in respect of varieties which have been accepted before 1 January 1986 in one or more of the other Member States and which have never been allowed for marketing in Greece before that date, applications submitted by that Member State not later than 31 December 1986 shall be taken into consideration, without prejudice to the provisions laid down in paragraph 1, provided that the applications are made on the grounds referred to in paragraph 3 (c), first alternative.;

##### 6. the following is added to Article 15 (7):

'With regard to Greece and in respect of applications submitted by that Member State not later than 31 December 1985 and made on the grounds referred to in paragraph 3 (c), second alternative, the period provided for in paragraph 1 may be extended to 30 June 1989.'

#### Article 7

Directive 70/458/EEC is hereby amended as follows:

##### 1. In Article 2 (1) (A),

'*Brassica pekinensi*  
(Lour.) Rupr.

Chinese cabbage'

is inserted after  
'*Brassica oleracea* L.  
convar. *acephala* (DC)  
Alef var. *gongylodes*

Kohlrabi'

'chicory' is replaced by  
'Witloof chicory, large-  
leaved chicory  
(Italian chicory)',

and

'*Cichorium intybus* L.  
(*partim*)

Industrial chicory'

is inserted after

'*Cichorium intybus* L.  
(*partim*)

Witloof chicory, large-  
leaved chicory  
(Italian chicory)'

2. in Article 2 (1a) of the English version, 'descriptions' is replaced by 'names';

3. former Article 2 (1b) becomes Article 2 (1c);

4. the following paragraph is inserted in Article 2:

'1b. The different types of varieties, including the components, may be specified and defined in accordance with the procedure laid down in Article 40.';

5. the following subparagraph is added to Article 4:

'In the case of industrial chicory, the variety must be of satisfactory value for cultivation and use.';

6. the following sentence is inserted in Article 9 (3) after the first sentence:

'With regard to Greece, the dates of 30 June 1975 and 1 July 1972 referred to above shall be replaced by the dates 31 December 1988 and 1 January 1986 respectively.';

7. the following is added to Article 10 (2):

'In the case of varieties which are derived from varieties whose official acceptance has been determined pursuant to Article 13 (3), second and fourth sentences, and which have been accepted in one or more Member States as a result of the official measures referred to in that provision, it may be decided, in accordance with the procedure laid down in Article 40, that all Member States of acceptance shall ensure that the varieties bear names determined under the same procedure and complying with the above principles.';

8. the following is added to Article 13 (2):

'In the case of varieties referred to in the second sentence of Article 12 (1) the acceptance may only be renewed

where, without prejudice to the provisions of Article 37, the name of the person or persons responsible for the maintenance has been officially registered and published in accordance with the provisions of Article 10 (1).';

9. the following is added to Article 13 (3):

'In the case of varieties for which acceptance has been granted before 1 July 1972, the period mentioned in the second sentence of paragraph 1 may be extended, in accordance with the procedure laid down in Article 40, until 30 June 1990 at the latest for individual varieties, where official measures organized on a Community basis have been taken before 1 July 1982 in order to ensure that the conditions for the renewal of their acceptance or for the acceptance of varieties derived from them are met.

With regard to Denmark, Ireland and the United Kingdom, the date 1 July 1972 referred to above shall be replaced by the date 1 January 1973.

With regard to Greece, Spain and Portugal, the expiry of the acceptance period for certain varieties for which acceptance has been granted in those Member States before 1 January 1986 may, at the request of those Member States, also be fixed for 30 June 1990, in accordance with the procedure laid down in Article 40, and the varieties concerned may be included in the aforementioned official measures organized on a Community basis.';

10. the following is added to Article 16:

'5. With regard to Greece and in respect of varieties which have been accepted before 1 January 1986 in one or more of the other Member States and which have never been allowed for marketing in Greece before that date, the period provided for in paragraph 2 shall expire on 31 December 1988.';

11. Article 20 (1) is replaced by the following:

'1. The Member states shall provide that seed of industrial chicory may not be placed on the market unless it has been officially certified as "basic seed" or "certified seed" and unless it satisfies the conditions laid down in Annex II.

1a. The Member States shall provide that seed of other vegetable species may not be placed on the market unless it has been officially certified as "basic seed" or "certified seed", or is standard seed, and unless it satisfies the conditions laid down in Annex II.';

12. Article 26 (2) is replaced by the following:

'2. In the case of varieties which are widely known on 1 July 1970, reference may also be made on the label to any maintenance of the variety which has been or will be declared in accordance with the provisions of Article 37 (2). It shall be prohibited to refer to any special properties which might be connected with such maintenance. With regard to Denmark, Ireland and the United Kingdom, the date 1 July 1970 referred to above

shall be replaced by 1 January 1973. With regard to Spain, it shall be replaced by 1 March 1986.

This reference shall follow the varietal name, from which it shall be clearly separated, preferably by means of a dash. It shall not be given greater prominence than the varietal name.

After a date to be determined before 1 July 1992 in accordance with the procedure laid down in Article 40, only maintenances declared before the date so determined may be referred to on the label.;

13. in Article 26, paragraph 3 becomes paragraph 1b and the following is added:

'Save in the case of small packages of standard seed up to a maximum net weight of 100 grams, the information prescribed or authorized under this provision shall be kept clearly separate from any other information given on the label or the package, including that provided for in Article 28.

After 30 June 1992 it may be decided, in accordance with the procedure laid down in Article 40, that small packages of standard seed up to a maximum net weight of 100 grams should be subjected to this requirement or that the information prescribed or authorized be distinct in some other way from any other information if the distinctive feature is expressly declared as such on the label or package.;

14. former Article 28 becomes Article 28 (1);
15. the following paragraph is added to Article 28:

'2. In the case of basic and certified seed the label or the printing referred to under paragraph 1 shall be drawn up in such a manner that it cannot be confused with the official label referred to in Article 26 (1).';

16. the following Article 29a is inserted:

*'Article 29a*

For the purpose of seeking improved alternatives to certain elements of the certification scheme adopted under this Directive, it may be decided to organize temporary experiments under specified conditions at Community level in accordance with the procedures laid down in Article 40.

In the framework of such experiments, Member States may be released from certain obligations laid down in this Directive. The extent of that release shall be defined with reference to the provisions to which it applies. The duration of an experiment shall not exceed seven years.;

17. the fifth and sixth indents of Article 30 (3) (c) are replaced by the following:

— species, indicated at least in roman characters, under its botanical name, which may be given

in abridged form and without the authorities' names, or under its common name, or both,

— variety, indicated at least in roman characters,;

18. Article 31 is replaced by the following:

*'Article 31*

1. Member States shall provide that vegetable seed

— which has been produced directly from basic seed or certified seed officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 32 (1) (d), or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and

— which has been harvested in another Member State,

shall, on request and without prejudice to the other provisions of this Directive, be officially certified seed in any Member State if that seed has undergone field inspection satisfying the conditions laid down in Annex I for the relevant category and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied.

Where in such cases the seed has been produced directly from officially certified seed of generations prior to basic seed, Member States may also authorize official certification as basic seed, if the conditions laid down for that category are satisfied.

2. Vegetable seed which has been harvested in another Member State, and which is intended for certification in accordance with the provisions laid down in paragraph 1, shall:

— be packed and labelled with an official label satisfying the conditions laid down in Annex V (A) and (B), in accordance with the provisions laid down in Article 25 (1), and

— be accompanied by an official document satisfying the conditions laid down in Annex V (C).

3. The Member States shall also provide that vegetable seed

— which has been produced directly from basic seed or certified seed officially certified either in one or more Member States or in a third country which has been granted equivalence under Article 32 (1) (d) or which has been produced directly from the crossing of basic seed officially certified in a Member State with basic seed officially certified in such a third country, and

— which has been harvested in a third country,

shall, on request, be officially certified as certified seed in any of those Member States where the basic seed was

either produced or officially certified, if the seed has undergone field inspection satisfying the conditions laid down in an equivalence decision made under Article 32 (1) (a) for the relevant category, and if official examination has shown that the conditions laid down in Annex II for the same category are satisfied. Other Member States may also authorize official certification of such seed.';

19. in Article 37 (2) of the English version, 'to methods for the maintenance' is replaced by 'to a given maintenance';

20. in Article 42 (a), 'Chinese cabbage' is inserted after 'Cauliflower' and 'Chicory' is replaced by

'Witloof chicory, large-leaved chicory (Italian chicory), industrial chicory';

21. the following is inserted after Annex I (4) (A):

**'Aa Industrial chicory**

- |                                                        |         |
|--------------------------------------------------------|---------|
| 1. From other species of the same genera or subspecies | 1 000 m |
| 2. From another variety of industrial chicory:         |         |
| — for basic seed                                       | 600 m   |
| — for certified seed                                   | 300 m   |

22. in Annex II (3) (a), '*Beta vulgaris* (Cheltenham beet variety)' is replaced by '*Beta vulgaris* (Cheltenham beet)' and '*Beta vulgaris* (all species)' by '*Beta vulgaris* (other than Cheltenham beet)' respectively;

23. in Annex II (3) (a), '*(partim)* (Witloof chicory, large-leaved chicory (Italian chicory))' is added after '*Cichorium intybus*' and the following is inserted after '*Brassica oleracea* (other species)' and '*Cichorium intybus (partim)* (Witloof chicory, large-leaved chicory (Italian chicory))' respectively:

|                                                           |    |   |      |
|-----------------------------------------------------------|----|---|------|
| <i>Brassica pekinensis</i>                                | 97 | 1 | 75'  |
| and                                                       |    |   |      |
| <i>Cichorium intybus (partim)</i><br>(industrial chicory) | 97 | 1 | 80'; |

24. in Annex III (2), '*(partim)* (Witloof chicory, large-leaved chicory (Italian chicory))' is inserted after '*Cichorium intybus*' and the following is inserted after '*Brassica*

*oleracea*' and '*Cichorium intybus*' (*partim*) (Witloof chicory, large-leaved chicory (Italian chicory))' respectively:

|                                                        |      |
|--------------------------------------------------------|------|
| <i>Brassica pekinensis</i>                             | 20'  |
| and                                                    |      |
| <i>Cichorium intybus (partim)</i> (industrial chicory) | 50'; |

25. the following is added to Annex IV (A) (a) (5):

‘, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities’ names, or its common name, or both.’;

26. the following is added to Annex IV (A) (a) (6):

‘, indicated at least in roman characters.’;

27. the following is inserted after Annex IV (A) (a) (10):

‘10a. In the case of varieties which are hybrids or inbred lines:

- for basic seed where the hybrid or inbred line to which the seed belongs has been officially accepted under this Directive:

the name of this component, under which it has been officially accepted, with or without reference to the final variety, accompanied, in the case of hybrids or inbred lines which are intended solely as components for final varieties, by the word “component”,

- for basic seed in other cases:

the name of the component to which the basic seed belongs, which may be given in code form, accompanied by a reference to the final variety, with or without reference to its function (male or female), and accompanied by the word “component”,

- for certified seed:

the name of the variety to which the seed belongs, accompanied by the word “hybrid”.’;

28. the following is added to Annex IV (B) (a) (4):

‘, indicated at least in roman characters.’;

29. the following is added to Annex IV (B) (a) (5):

‘, indicated at least in roman characters.’;

30. the following Annex is added:

## ANNEX V

## Article 8

**Label and document provided in the case of seed not finally certified, harvested in another Member State****A. Information required for the label**

- authority responsible for field inspection and Member State or their initials,
- species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both,
- variety, indicated at least in roman characters,
- category,
- field or lot reference number,
- declared net or gross weight,
- the words "seed not finally certified".

**B. Colour of the label**

The label shall be grey.

**C. Information required for the document**

- authority issuing the document,
- species, indicated at least in roman characters, under its botanical name, which may be given in abridged form and without the authorities' names, or under its common name, or both
- variety, indicated at least in roman characters,
- category,
- reference number of the seed used to sow the field and name of the country or countries which certified that seed,
- field lot or reference number,
- area cultivated for the production of the lot covered by the document,
- quantity of seed harvested and number of packages,
- attestation that the conditions to be satisfied by the crop from which the seed comes have been fulfilled,
- where appropriate, results of a preliminary seed analysis.'

Directive 86/155/EEC is hereby amended as follows:

in the second indent of Article 7, '1 July 1987' is replaced by '31 December 1988'.

## Article 9

Directive 86/320/EEC is hereby amended as follows:

in Article 2, '1 July 1987' is replaced by '31 December 1988'.

## Article 10

Member States shall adopt the laws, regulations and administrative provisions necessary to comply:

- with Article 3 (11) and Article 7 (9), with effect from 1 July 1982,
- with Article 3 (12), with effect from 1 January 1983,
- with Article 6 (5) and (6) and Article 7 (6) and (10), with effect from 1 January 1986,
- with Article 2 (8), (17), (20) and (28), Article 3 (18), (31) and (37) and Article 5 (10), (19), (23) and (25) in so far as those provisions require the botanical name of a species to be indicated on the label of seed, and also with Articles 1 (8), 2 (10), 3 (20), 5 (12) and 7 (18), not later than 1 July 1992,
- with the other provisions of this Directive, not later than 1 July 1990.

They shall immediately inform the Commission thereof.

## Article 11

This Directive is addressed to the Member States.

Done at Luxembourg, 13 June 1988.

*For the Council*  
*The President*  
I. KIECHLE