II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 93/67/EEC

of 20 July 1993

laying down the principles for assessment of risks to man and the environment of subtances notified in accordance with Council Directive 67/548/EEC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 67/548/EEC of 27 June 1967, on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1), as amended by Directive 93/21/EEC (2) and, in particular, Article 3 thereof,

Whereas, in accordance with the provisions of Directive 67/548/EEC, any new substance placed on the market should be notified to the competent authorities to Member States by means of a notification containing certain information;

Whereas Article 16 of Directive 67/548/EEC requires the competent authorities receiving notification of a new substance to carry out an assessment of its risks to man and the environment in accordance with general principles;

Whereas, given that the responsibility for risk assessment lies with the Member States, it is, however, appropriate that general principles be adopted at Community level to avoid disparities between Member States which not only affect the functioning of the internal market but also do not guarantee the same level of protection of man and the environment thorughout the Community and whereas, therefore, Article 3 of Council Directive 67/548/EEC provides that the Commission shall lay down the general principles;

Whereas the assessment of risks should be based on a comparison of the potential adverse effects of a substance with the reasonably foreseeable exposure of man and the environment to that substance;

Whereas, having regard to its classification in accordance with Directive 67/548/EEC, the assessment of risks to man should take account of the physico-chemical and toxicological properties of a substance;

Whereas, having regard to its classification in accordance with Directive 67/548/EEC, the assessment of risks to the environment should take account of the environmental effects of a substance;

Whereas, where the assessment of risks indicates that a substance is of concern, the competent authority may acquire further information including the results of further tests to determine the substance's intrinsic hazardous properties in accordance with Council Directive 67/548/EEC;

Whereas the results of a risk assessment should be the principal basis of decisions under appropriate legislation to reduce the risks arising from the placing of substances on the market;

Whereas it is appropriate that, having carried out an assessment of risks, the competent authority may inform the notifier of a dangerous substance of its conclusions and that, further, the competent authority should forward a written report thereon to the Commission;

Whereas it is appropriate to reduce to a minimum the number of animals used for experimental purposes in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of the laws,

(1) OJ No 196, 16. 8. 1967, p. 1.
(2) OJ No L 110, 4. 5. 1993, p. 20.

regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (1);

Whereas the provisions of this Directive shall be without prejudice to specific Community legislation concerning the safety and protection of health of workers at work, in particular Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the health and safety of workers at work (2), which places an obligation on employers to evaluate the risks to the health and safety of workers arising from the use of new and existing chemical substances and, as necessary, to take measures to ensure an appropriate protection of workers;

Whereas the measures set out in this Directive are in accordance with the opinion of the committee set up pursuant to Article 29 of Directive 67/548/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Objectives

This Directive lays down general principles for the assessment of the risks posed by substances to man and the environment as required by Article 3 of Directive 67/548/EEC.

Article 2

Definitions

1. The definitions contained in Article 2 of Directive 67/548/EEC are applicable to this Directive.

2. For the purposes of this Directive:

(a) 'hazard identification' is the identification of the adverse effects which a substance has an inherent capacity to cause;

(b) 'dose (concentration) — response (effect) assessment' is the estimation of the relationship between dose, or level of exposure to a substance, and the incidence and severity of an effect;

(c) 'exposure assessment' is the determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentrations/doses to which human populations or environmental compartments are or may be exposed;

(d) 'risk characterization' is the estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include 'risk estimation', i.e., the quantification of that likelihood;

(e) 'recommendations for risk reduction' is the recommendation of measures which would enable the risks for man and/or the environment in connection with the marketing of the substance to be lessened. They may include:

(i) modifications to the classification, packaging or labelling of the substance proposed by the notifier in the notification submitted in accordance with Article 7 (1), 8 (1) or 8 (2) of Directive 67/548/EEC;

(ii) modifications to the safety data sheet proposed by the notifier in the notification submitted in accordance with Article 7 (1), 8 (1) or 8 (2) of Directive 67/548/EEC;

(iii) modifications to the recommended methods and precautions or emergency measures, as set out in sections 2.3, 2.4 and 2.5 of Annex VIIA, VIIB or VIIC, proposed by the notifier in the technical dossier of the notification submitted in accordance with Article 7 (1), 8 (1) or 8 (2) of Directive 67/548/EEC;

(iv) advice to the relevant control authorities that they should consider appropriate measures for the protection of man and/or the environment from the risks identified.

Article 3

Principles of risk assessment

1. The risk assessment shall entail hazard identification and, as appropriate, dose (concentration) — response (effect) assessment, exposure assessment and risk characterization. It shall normally be conducted in accordance with the procedures set out in Articles 4 and 5.

2. Notwithstanding paragraph 1, in relation to particular effects, such as ozone depletion, for which the procedures set out in Articles 4 and 5 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the competent authority shall include a full description and justification of such assessments in the written report submitted to the Commission in accordance with Article 7.

3. In conducting an exposure assessment, the competent authority shall take into account those human populations or environmental compartments for which exposure to the substance is reasonably foreseeable in the light of available information on the substance, with particular regard to storage, formulation into a preparation or other processing, use and disposal or recovery.

(1) OJ No L 358, 18. 12. 1986, p. 1.
(2) OJ No L 183, 29. 6. 1989, p. 1.

4. The risk assessment shall indicate one or more of the following conclusions:

(i) The substance is of no immediate concern and need not be considered again until further information is made available in accordance with Article 7 (2), 8 (3), 8 (4) or 14 (1) of Directive 67/548/EEC.

(ii) The substance is of concern and the competent authority shall decide what further information is required for revision of the assessment but shall defer a request for that information until the quantity placed on the market reaches the next tonnage threshold as indicated in Article 7 (2), 8 (3) or 8 (4) of Directive 67/548/EEC.

(iii) The substance is of concern and further information shall be requested immediately.

(iv) The substance is of concern and the competent authority shall immediately make recommendations for risk reduction.

5. When the risk assessment indicated that the conclusions at paragraph 4 (ii), (iii) or (iv) above apply, the notifier may be informed by the competent authority of its conclusions and be given the opportunity to comment on those conclusions and to provide additional information. The competent authority shall use any relevant information to revise the risk assessment before sending it to the Commission in accordance with Article 17 of Directive 67/548/EEC.

6. In making recommendations for risk reduction in relation to a substance, the competent authority shall take account of the possibility that reducing the exposure of certain human populations or environmental compartments may increase the exposure of other human populations or environmental compartments.

Article 4

Risk assessment: human health

1. For each substance notified in accordance with Article 7 (1), Article 8 (1) or Article 8 (2) of Directive 67/548/EEC, the competent authority shall carry out a risk assessment, the first stage of which shall be hazard identification which shall address, as a minimum, the properties and potential adverse effects specified in Annexes IA and IIA. Having conducted the hazard identification, the competent authority shall proceed to the following sequence of actions which shall be carried out in accordance with the guidelines set out in Annexes IB and IIB:

(a) (i) dose (concentration)-response (effect) assessment, where appropriate;

(ii) exposure assessment for whichever of the human populations (i.e., workers, consumers and man exposed indirectly via the environment) is likely to be exposed to the substance;

(b) risk characterization.

2. In derogations from paragraph 1:

(i) if the test appropriate to hazard identification in relation to a particular effect or property has been conducted and the results have not led classification of the substance in accordance with Directive 67/548/EEC, the risk assessment in relation to that effect or property need not include the actions at paragraph 1 (a) and (b) and the conclusion at Article 3 (4) (i) shall apply, unless there are other reasonable grounds for concern; and

(ii) if the test appropriate to hazard identification in relation to a particular effect or property has not yet been conducted, that effect or property shall not be considered in the risk assessment unless there are other reasonable grounds for concern.

Article 5

Risk assessment: environment

1. For each substance notified in accordance with Article 7 (1), 8 (1) or 8 (2) of Directive 67/548/EEC, the competent authority shall carry out a risk assessment in relation to its environmental effects, the first stage of which shall be hazard identification. Having conducted the hazard identification, the competent authority shall proceed to the following sequence of actions which shall be carried out in accordance with the guidelines set out in Annex III:

(a) (i) dose (concentration)-response (effect) assessment, where appropriate;

(ii) exposure assessment for the environmental compartments (i.e. aquatic environment, terrestrial environment and air) likely to be exposed to the substance;

(b) risk characterization.

2. In derogation from paragraph 1:

(i) for substances notified in accordance with Article 7 (1) of Directive 67/548/EEC but not classified dangerous for the environment, the risk assessment need not include the actions at paragraph 1 (a) and (b) and the conclusion at Article 3 (4) (i) shall apply, unless there are other reasonable grounds for concern; and

(ii) for substances notified in accordance with Article 8 (1) or 8 (2) of Directive 67/548/EEC, if there are insufficient data to determine whether classification as dangerous for the environment is appropriate, the hazard identification shall entail consideration of whether there are any reasonable grounds for concern

in relation to environmental effects on the basis of other data, e.g. data on physico-chemical and toxic properties. Unless there are such reasonable grounds, the risk assessment need not include the actions at paragraph 1 (a) and (b) and the conclusion at Article 3 (4) (i) shall apply.

Article 6

Risk assessment: conclusions

1. Having carried out a risk assessment in accordance with Articles 4 and 5 and in conformity with Annexes I, II and III, the competent authority shall determine, in conformity with Annex IV, which of the four conclusions of Article 3 (4) is/are applicable and take action as described in Article 3 (5) if appropriate.

2. Where additional information is received in accordance with Articles 7 (2), 8 (3), 8 (4), 14 (1) or 16 of Directive 67/548/EEC or otherwise, the risk assessment carried out in accordance with Articles 4 and 5 and in conformity with Annexes I, II and III shall be reviewed and, if necessary, revised.

Article 7

Content of written report to the Commission

1. Having carried out the risk assessment in accordance with Articles 4 and 5 and made conclusions in accordance with Article 6, the competent authority shall prepare a written report containing at least the information set out at Annex V. That report shall be sent to the Commission in accordance with Article 17 of Directive 67/548/EEC. It shall be updated following any revision of the assessment in the light of additional information and the updated report shall be sent to the Commission.

2. When, in accordance with Article 18 of Directive 67/548/EEC, the competent authorities have reached agreement on the written report of the risk assessment or any revision thereof, a copy shall be made available to the notifier on request.

Article 8

Final provisions

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 31 October 1993 and shall forthwith inform the Commission.

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 9

This Directive is addressed to the Member States.

Done at Brussels, 20 July 1993.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

ANNEX I

RISK ASSESSMENT: HUMAN HEALTH (TOXICITY)

PART A

The risk assessment conducted in accordance with Article 4 shall take account of the following potential toxic effects and populations liable to exposure:

Effects

1. Acute toxicity
2. Irritation
3. Corrosivity
4. Sensitization
5. Repeated dose toxicity
6. Mutagenicity
7. Carcinogenicity
8. Toxicity for reproduction

Human populations

1. Workers
2. Consumers
3. Man exposed indirectly via environment

PART B

1. Hazard identification

1.1. In those cases where the test appropriate to hazard identification in relation to a particular potential effect has been conducted but the results have not led to classification (Article 4 (2) (i)), risk characterization in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. positive *in vitro* test results for mutagenicity.

1.2. In those cases where the test appropriate to hazard identification in relation to a particular potential effect has not yet been conducted (Article 4 (2) (ii)), risk characterization in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. exposure considerations or indications of potential toxicity from structure activity relationships.

2. Dose (concentration)-response (effect) assessment

2.1. For repeated-dose toxicity and reproductive toxicity, the dose-response relationship shall be assessed and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest dose/concentration associated with an adverse effect, i.e., the lowest-observed-adverse-effect level (LOAEL), shall be identified.

2.2. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of the results of tests conducted in accordance with the requirements of Directive 67/548/EEC. For acute toxicity, the LD50 or LC50 value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects, it shall be sufficient to determine whether the substance has an inherent capacity to cause such effects.

2.3. For mutagenicity and carcinogenicity, it shall be sufficient to determine whether the substance has an inherent capacity to cause such effects. However, if it can be demonstrated that a substance identified as a carcinogen is non-genotoxic, it will be appropriate to identify a NOAEL/LOAEL as described in paragraph 2.1.

2.4. With respect to skin sensitization and respiratory sensitization, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitized to a given substance, it shall be sufficient to evaluate whether the substance has an inherent capacity to cause such effects.

3. Exposure assessment

3.1. An exposure assessment shall be conducted for each of the human populations (workers, consumers and man liable to exposure indirectly *via* the environment) for which exposure to the substance can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which a population is or may be exposed. Such estimation shall take account of spatial and temporal variations in the exposure pattern.