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Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (1) and, in particular, Article 10 (4) thereof,

Whereas Regulation (EEC) No 793/93 envisages a system of evaluation and control of the risk of existing substances and whereas Article 10 thereof requires that it shall be for the Member States to carry out such risk assessment on existing substances having priority;

Whereas, given that the responsibility for risk assessment lies with the Member States, it is, however, appropriate that the principles of such assessment be adopted at Community level to avoid disparities between Member States which would not only affect the functioning of the internal market but would also fail to guarantee the same level of protection of man and the environment;

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

Whereas, having regard to the classification of a given substance in accordance with 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 (2), as last amended by Commission Directive 93/105/EC (3), 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 the results of a risk assessment should be the principal basis of decisions under appropriate legislation to reduce the risks arising from manufacture, transport, storage, formulation into a preparation or other processing, use and disposal or recovery of existing substances;

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, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (4);

Whereas the provisions of this Regulation 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 (5), 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 Regulation are in accordance with the opinion of the Committee set up pursuant to Article 15 of Regulation (EEC) No 793/93,

HAS ADOPTED THIS REGULATION:

Article 1

Objectives This Regulation lays down general principles for the assessment of the risks posed by existing substances to man and the environment as required by Article 10 of Council Regulation (EEC) No 793/93.

Article 2

Definitions 1. The definitions contained in Article 2 of Regulation (EEC) No 793/93 are applicable to this Regulation.

2. For the purposes of this Regulation:

(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 spheres (water, soil and air) 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 sphere due to actual or predicted exposure to a substance, and may include 'risk estimation', i.e. the quantification of that likelihood.

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 be based on the information on the substance submitted in accordance with Articles 3, 4, 7 (1) and (2), 9 (1) and (2) and 10 (2) of Regulation (EEC) No 793/93 and on other available information and shall normally be conducted in accordance with the procedures set out in Articles 4 and 5 of this Regulation.

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 rapporteur shall include a full description and justification of such assessments in the written report submitted to the Commission in accordance with Article 6.

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

4. Where a substance for which a risk assessment has already been carried out in accordance with Article 10 of Regulation (EEC) No 793/93 appears again on a priority list, the subsequent risk assessment shall take into account the previous risk assessment(s).

Article 4

Risk assessment: human health For each substance appearing on the priority lists in accordance with Article 8 of Regulation (EEC) No 793/93, the rapporteur shall carry out a risk assessment in relation to its effects on human health, the first stage of which shall be hazard identification which shall address, at least, the properties and potential adverse effects specified in Annexes I A and II A. Having conducted the hazard identification, the rapporteur shall take the following sequence of actions, which shall be carried out in accordance with the guidelines set out in Annexes I B and II B:

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

(ii) exposure assessment for whichever human population-group (i.e. workers, consumers or man exposed indirectly via the environment) is exposed or likely to be exposed to the substance;

(b) risk characterization.

Article 5

Risk assessment: environment For each substance appearing on the priority lists in accordance with Article 8 of Regulation (EEC) No 793/93, the rapporteur 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 rapporteur 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 spheres exposed or likely to be exposed to the substance;

(b) risk characterization.

Article 6

Risk assessment report Having carried out the risk assessment in accordance with Articles 4 and 5, the rapporteur shall prepare a report containing at least the information set out at Annex V together with all data relevant for the risk assessment. This report, together with a summary thereof, shall be forwarded to the Commission in accordance with Article 10 (3) of Regulation (EEC) No 793/93.

Article 7

Final provisions This Regulation shall enter into force on the 60th day following its publication in the Official Journal of the European Communities.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 June 1994.

For the Commission

René STEICHEN

Member of the Commission

(1) OJ No L 84, 5. 4. 1993, p. 1.

(2) OJ No 196, 16. 8. 1967, p. 1.

(3) OJ No L 294, 30. 11. 1993, p. 21.

(4) OJ No L 358, 18. 12. 1986, p. 1.

(5) OJ No L 183, 29. 6. 1989, p. 1.

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 exposed or liable to be exposed:

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

The objective shall be to identify the effect(s) of concern and to review the (provisional) classification in the light of all data available.

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.

2.5. Where toxicity data derived from observations of human exposure, e.g. information from poison centres or epidemiological surveys, are available, special consideration shall be given to those data when carrying out the risk assessment.

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 is known or 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.

3.2. In particular, the exposure assessment, where appropriate, shall take account of:

- (i) adequately measured exposure data;
- (ii) the quantity in which the substance is produced and/or imported;
- (iii) the form in which the substance is produced and/or imported and/or in which the substance is used (e.g. substance itself or as component of a preparation);
- (iv) use pattern and degree of containment;
- (v) process data, where relevant;
- (vi) physico-chemical properties of the substance including, where relevant, those conferred by the process (e.g. aerosol formation);
- (vii) breakdown products and/or transformation products;
- (viii) likely routes of exposure and potential for absorption;
- (ix) frequency and duration of exposure;
- (x) type and size of specific exposed population(s) where such information is available.

3.3. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall then also be considered.

3.4. If a substance is contained in a preparation, consideration of exposure to the substance in that preparation shall be necessary if the latter is classified on the basis of the toxicological properties of the substance in accordance with Council Directive 88/379/EEC (1), or if there are other reasonable grounds for concern.

4. RISK CHARACTERIZATION

4.1. Where, for any of the effects set out in Annex I A, a Noael or Loael has been identified, the risk characterization in relation to each of those effects shall entail comparison of the Noael or Loael with the estimate of the dose/concentration to which the population(s) will be exposed. If a quantitative estimate of exposure is available, an exposure level /N(L)oa_{el} ratio shall be derived. On the basis of the comparison between the quantitative or qualitative estimate of exposure and the N(L)oa_{el}, the rapporteur shall indicate the results of the risk characterization in relation to those effects.

4.2. Where, for any of the effects set out in Annex I A, a N(L)oa_{el} has not been determined, the risk characterization in relation to each of those effects shall entail an evaluation, on the basis of the quantitative and/or qualitative information on exposure relevant to the human populations under consideration, of the

likelihood that the effect will occur (2). Having made the evaluation, the rapporteur shall indicate the results of the risk characterization in relation to those effects.

4.3. When carrying out the risk characterization, the rapporteur shall take into account, inter alia:

(i) the uncertainty arising, among other factors, from the variability in the experimental data and intra- and inter-species variation;

(ii) the nature and severity of the effect;

(iii) the human population to which the quantitative and/or qualitative information on exposure applies.

5. INTEGRATION

In accordance with the provisions of Article 4, a risk characterization may be carried out in relation to more than one potential adverse effect or human population. The rapporteur shall judge the result of the risk characterization for each effect. Having completed the risk assessment, the rapporteur shall review the various results and produce integrated results in relation to the overall toxicity of the substance.

(1) OJ No L 187, 16. 7. 1988, p. 14.

(2) Where, despite a N(L)oael not having been determined, the test results nevertheless demonstrate a relationship between dose/concentration and the severity of an adverse effect or where, in connection with a test method which entails the use of only one dose or concentration, it is possible to evaluate the relative severity of the effect, such information shall also be taken into account in evaluating the likelihood of the effect occurring.

ANNEX II

RISK ASSESSMENT: HUMAN HEALTH (PSYCHO-CHEMICAL PROPERTIES) Part A Risk assessment in accordance with Article 4 shall take account of the potential adverse effects which may occur in the following human populations exposed or liable to be exposed to substances with the following properties.

PROPERTIES

1. Explosivity
2. Flammability
3. Oxidizing potential

HUMAN POPULATIONS

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

Part B 1. HAZARD IDENTIFICATION

The objective shall be to identify the effect(s) of concern and to review the (provisional) classification in the light of all data available.

2. EXPOSURE ASSESSMENT

If risk characterization has to be conducted in accordance with Article 4, it shall be necessary to determine the known or the reasonably foreseeable conditions of use.

3. RISK CHARACTERIZATION

The risk characterization shall entail an evaluation of the likelihood that an adverse effect will be caused under the known or the reasonably foreseeable conditions of use. The rapporteur shall indicate the results of the risk characterization.

4. INTEGRATION

In accordance with the provisions of Article 4, a risk characterization may be carried out in relation to more than one potential adverse effect or human population. The rapporteur shall judge the results of the risk characterization for each effect. Having completed the risk assessment, the rapporteur shall review the various results and produce integrated results.

ANNEX III

RISK ASSESSMENT: ENVIRONMENT 1. HAZARD IDENTIFICATION

The objective shall be to identify the effect(s) and/or property (properties) of concern and to review the (provisional) classification in the light of all data available.

2. DOSE (CONCENTRATION) - RESPONSE (EFFECT) ASSESSMENT

2.1. The objective shall be to predict the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the predicted no effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) - response (effect) relation would have to be made.

2.2. The PNEC may be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50 per cent inhibition of a given parameter, e.g. growth), NOEL(C) (no observed effect level (concentration)), or LOEL(C) (lowest observed effect level (concentration)) or other appropriate methods.

2.3. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor (1).

3. EXPOSURE ASSESSMENT

3.1. The objective of the exposure assessment shall be to predict the concentration of the substance which is likely to be found in the environment. That concentration is known as the predicted environmental concentration (PEC). However, in some cases, it may not be possible to establish a PEC and a qualitative estimation of exposure would have to be made.

3.2. A PEC or, where necessary, a qualitative estimation of exposure need only be determined for the environmental spheres to which emissions, discharges, disposal or distributions are known or are reasonably foreseeable.

3.3. The PEC or qualitative estimation of exposure shall be determined taking account of, in particular and if appropriate:

- (i) adequately measured exposure data;
- (ii) the quantity in which the substance is produced and/or imported;
- (iii) the form in which the substance is produced and/or imported and/or in which the substance is used (e.g. substance itself or as component of a preparation);
- (iv) use pattern and degree of containment;
- (v) process data, where relevant;
- (vi) physico-chemical properties of the substance, in particular melting point, boiling point, vapour pressure, surface tension, water solubility, partition coefficient n-octanol/water;
- (vii) breakdown products and/or transformation products;
- (viii) likely pathways to environmental spheres and potential for absorption/desorption and degradation;
- (ix) frequency and duration of exposure.

3.4. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure concentrations, adequate models shall be applied. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall then also be considered.

4. RISK CHARACTERIZATION

4.1. For any given environmental sphere, the risk characterization shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived. If the PEC/PNEC ratio is equal to or less than one, the risk characterization shall result that, at present, no further information and/or testing and no risk reduction measures beyond those which are being applied already are necessary. If the ratio is greater than one, the rapporteur shall judge, on the basis of the size of that ratio and other relevant factors, such as:

- (i) indications of bioaccumulation potential;

(ii) the shape of the toxicity/time curve in ecotoxicity testing;

(iii) indications of other adverse effects on the basis of toxicity studies, e.g. classification as a mutagen, toxic or very toxic or as harmful with risk phrase R40 ('Possible risk of irreversible effects') or R48 ('Danger of serious damage to health by prolonged exposure');

(iv) data on structurally analogous substances;

if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary.

4.2. If it has not been possible to derive a PEC/PNEC ratio, the risk characterization shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure. Having made such an evaluation and taking into account relevant factors such as those listed in paragraph 4 (1), the rapporteur shall indicate the results of the risk characterization in relation to those effects.

5. INTEGRATION

In accordance with the provisions of Article 5, a risk characterization may be carried out in relation to more than one environmental sphere. The rapporteur shall judge the results of the risk assessment for each sphere. Having completed the risk assessment, the rapporteur shall review the different results and produce integrated results in relation to the overall environmental effects of the substance.

(1) An assessment factor of the order of 1 000 is typically applied to an L(E)C50 value derived from the results of testing for acute toxicity but that factor may be reduced in the light of other relevant information. A lower assessment factor is typically applied to an NOEC derived from the results of testing for long-term/chronic toxicity.

ANNEX IV

OVERALL INTEGRATION OF RESULTS 1. The results produced in conformity with section 5 of Annex I B, section 4 of Annex II B and section 5 of Annex III shall be reviewed by the rapporteur and integrated in relation to the totality of risks identified in the risk assessment.

2. Further information/testing requirements or recommendations to consider risk reduction measures shall be justified.