

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 793/93**of 23 March 1993****on the evaluation and control of the risks of existing substances**

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 (1), In co-operation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee(3),

Whereas disparities between the laws, regulations and administrative provisions relating to the risk evaluation of existing substances which are in effect or in preparation in the Member States are liable to hinder trade between Member States and create unequal conditions of competition;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market must, in so far as they concern health, safety, environmental and consumer protection, take a high level of protection as a basis;

Whereas, in order to ensure the protection of man, including workers and consumers, and of the environment, it is necessary to carry out at Community level a systematic evaluation of the risks involving existing substances appearing in the Einesc (European Inventory of Existing Commercial Substances)(4);

Whereas, in the interests of efficiency and economy, it is necessary to establish a Community policy which will ensure a sharing and co-ordination of responsibilities between Member States, the Commission and industrialists;

Whereas a Regulation is the appropriate legal instrument as it imposes directly on manufacturers and importers precise requirements to be implemented at the same time and in the same manner throughout the Community;

Whereas, in order to undertake a preliminary risk evaluation of existing substances and to identify priority substances requiring immediate attention, it is necessary to collect certain information and test data on existing substances;

Whereas the requirement to provide such information should not apply to certain substances which, on the basis of their intrinsic properties, involve only risks generally recognised as minimal;

Whereas the information should be submitted by manufacturers and importers to the Commission, which will send copies to all Member States; whereas, however, it should be possible for a Member State to ask manufacturers and importers established in its territory to submit the same information at the same time to its competent authorities;

Whereas, for the purpose of the risk evaluation of certain existing substances, it is necessary, in certain cases, to require manufacturers or importers to submit further data or to carry out further testing on given existing substances;

Whereas it is necessary to draw up, at Community level, lists of priority substances which require special attention; whereas the Commission should submit not later than one year after the entry into force of this Regulation an initial priority list;

Whereas the risk evaluation of substances on the priority lists should be carried out by the Member States; whereas the latter should be designated at Community level on the basis of a distribution of responsibilities taking account of the situation of the Member States; whereas risk evaluation principles should also be established at Community level;

(1) OJ No C 276, 5. 11. 1990, p. 1.

(2) OJ No C 280, 28. 10. 1991, p. 65 and OJ No C 337, 21. 12. 1992.

(3) OJ No C 102, 18. 4. 1991, p. 42.

(4) OJ No C 146, 15. 6. 1990, p. 1.

Whereas, in the priority-setting process and risk evaluation of existing substances, it is necessary to take into account, in particular, the lack of data on the effects of the substance, the work already carried out in other international organisations, such as the Organisation for Economic Co-operation and Development, and other legislation and/or Community programmes concerning dangerous substances;

Whereas it is necessary to adopt at Community level the results of the risk evaluation and the recommended strategy for limiting risks in respect of substances on the priority lists;

Whereas it is appropriate to reduce to a minimum the number of animals used for experimental purposes in accordance with the provisions of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (5) ; whereas, wherever possible and in consultation, in particular, with the European Centre for Alternative Testing Methods, the use of animals must be avoided by recourse to validated alternative procedures;

Whereas for tests on chemical substances to be carried out in the context of this Regulation it is necessary to follow the good laboratory practices set out in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (6) ;

Whereas the Commission, assisted by a committee made up of representatives of the Member States, should be given the necessary powers to adapt certain Annexes to technical progress and to adopt certain implementing measures in respect of the Regulation;

Whereas the confidential nature of certain information covered by industrial or commercial secrecy should be guaranteed,

HAS ADOPTED THIS REGULATION:

Article 1

Aims and scope

1. This Regulation shall apply to:

- (a) the collection, circulation and accessibility of information on existing substances;

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

(6) OJ No L 15, 17. 1. 1987, p. 29.

- (b) the evaluation of the risks of existing substances to man, including workers and consumers, and to the environment, in order to ensure better management of those risks within the framework of Community provisions.

2. The provisions of this Regulation shall apply without prejudice to Community legislation on the protection of workers and consumers.

Article 2

Definitions

For the purpose of this Regulation:

- (a) *substances* means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- (b) *preparations* means mixtures or solutions composed of two or more substances;
- (c) *importing* means bringing into the customs territory of the Community;
- (d) *producing* means the production of substances which are isolated in a solid, liquid or gaseous form;
- (e) *existing substances* means substances listed in EINECS.

PART 1

SYSTEMATIC DATA REPORTING AND ESTABLISHMENT OF LISTS OF PRIORITY SUBSTANCES

Article 3

Data reporting on high volume production or import of existing substances

Without prejudice to Article 6 (1), any manufacturer who has produced or any importer who has imported an existing substance, as such or in a preparation, in quantities exceeding 1 000 tonnes per year, at least once in the three years preceding the adoption of this Regulation and/or the year following its adoption, must submit to the Commission, in accordance with the procedure laid down in Article 6 (2) and (3), the following information, as specified in Annex III, within 12 months of entry into force of this Regulation in the case of a substance appearing in Annex I and within 24 months in the case of a substance appearing in EINECS but not in Annex I:

- (a) the name and the EINECS number of the substance;
- (b) the quantity of the substance produced or imported;

- (c) the classification of the substance according to Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances (7) or the provisional classification according to the said Directive, including the class of danger, the danger symbol, the risk phrases and the safety phrases;
- (d) information on the reasonably foreseeable uses of the substance;
- (e) data on the physico-chemical properties of the substance;
- (f) data on pathways and environmental fate;
- (g) data on the ecotoxicity of the substance;
- (h) data on the acute and subacute toxicity of the substance;
- (i) data on carcinogenicity, mutagenicity and/or toxicity for reproduction of the substance;
- (j) any other indication relevant to the risk evaluation of the substance.

Manufacturers and importers must make all reasonable efforts to obtain existing data regarding points (e) to (j). However, in the absence of information, manufacturers and importers are not bound to carry out further tests on animals in order to submit such data.

Article 4

Data reporting on lower volume production or import of existing substances

1. Without prejudice to Article 6 (1), any manufacturer who has produced, or any importer who has imported, an existing substance, as such or in a preparation, in quantities exceeding 10 tonnes per year but no greater than 1 000 tonnes per year, at least once in the three years preceding the adoption of this Regulation and/or the year following its adoption, shall submit to the Commission, in accordance with the procedure laid down in Article 6 (2) and (3), the following information, as specified in Annex IV, within a period of 24 months, to start once the Regulation has been in force for three years:

- (a) the name of the substance and the EINECS number;
- (b) the quantity of the substance produced or imported;

(7) OJ 196, 16. 8. 1967, p. 1. Directive as last amended by Commission Directive 91/632/EEC (OJ No L 338, 10. 12. 1991, p. 23).

- (c) the classification of the substance according to Annex I to Directive 67/548/EEC or the provisional classification according to the said Directive, including the class of danger, the danger symbol, the risk phrases and the safety phrases;
- (d) information on the reasonably foreseeable uses of the substance.

2. The Commission, in consultation with the Member States, shall determine the cases in which it is necessary to request the manufacturers and importers of the substances declared in pursuance of paragraph 1 to submit additional information, in the framework of Annex III, on the physico-chemical properties, toxicity, and ecotoxicity of such substances, exposure and any other aspect relevant to the risk evaluation of the substances. However, without prejudice to Article 12 (2), manufacturers and importers are not bound to carry out further tests on animals for that purpose.

The specific information to be submitted and the procedure to be followed for this submission shall be determined in accordance with the procedure laid down in Article 15

Article 5

Exemptions

The substances listed in Annex II shall be exempt from the provisions of Articles 3 and 4. However, information on the substances listed in Annex II may be requested by a procedure laid down in accordance with the procedure referred to in Article 15.

Article 6

Procedure for data reporting

1. In the case of a substance produced or imported by several manufacturers or importers, the information referred to in Article 3 and Article 4 (2) may be submitted by one manufacturer or importer acting, with their agreement, on behalf of other manufacturers or importers concerned. The latter shall nevertheless submit to the Commission the information specified in points 1.1 to 1.19 of the data set laid down in Annex III and, in doing so, shall make reference to the data set submitted by the manufacturer or importer.

2. In submitting the information referred to in Article 3 and in Article 4 (1), the manufacturers and importers shall use only the special software package on diskette made available free of charge by the Commission.

3. Member States may provide that manufacturers and importers established in their territory shall be required to submit simultaneously to their competent authorities the same information as that forwarded to the Commission pursuant to Articles 3 and 4.

4. On receipt of the data referred to in Articles 3 and 4 respectively, the Commission shall forward copies to all the Member States.

Article 7

Updating of the reported information and obligation to submit certain information spontaneously

1. Manufacturers and importers who have submitted information on a substance in accordance with Articles 3 and 4 shall update the information forwarded to the Commission.

In particular, they shall submit, where appropriate:

- (a) new uses of the substance which substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance;
- (b) new data obtained on the physico-chemical properties, toxicological or ecotoxicological effects where this is likely to be relevant to the evaluation of the potential risk presented by the substance;
- (c) any change in the provisional classification under Directive 67/548/EEC. They shall also be required to update the information regarding the production and import volumes referred to in Articles 3 and 4 every three years, if there is a change in relation to the volumes specified in Annex III or Annex IV.

2. Any manufacturer or importer of an existing substance who acquires knowledge which supports the conclusion that the substance in question may present a serious risk to man or the environment shall immediately report such information to the Commission and to the Member State in which he is located.

3. Upon receipt of the data referred to in paragraphs 1 and 2, the Commission shall submit copies thereof to all the Member States.

Article 8

Priority lists

1. On the basis of the information submitted by manufacturers and importers in accordance with Articles 3 and 4, and on the basis of the national lists of priority substances, the Commission, in consultation with Member States, shall regularly draw up lists of priority substances or groups of substances (hereinafter referred to as priority lists) requiring immediate attention because of their potential effects on man or the environment. These lists shall be adopted in accordance with the procedure laid down in Article 15 and shall be published by the Commission for the first time in the course of the year following the entry into force of the Regulation.

2. The factors to be taken into account in drawing up the priority lists shall be:

- the effects of the substance on man or the environment,
- the exposure of man or the environment to the substance,
- the lack of data on the effects of the substance on man and the environment,
- work already carried out in other international fora,
- other Community legislation and/or programmes relating to dangerous substances.

A substance subject to evaluation under other Community legislation should be placed on a priority list only if that evaluation fails to cover risk to the environment or risk to man, including workers and consumers, or if those risks have not been adequately evaluated. An equivalent evaluation carried out under other Community legislation should not be repeated under this Regulation. Special attention shall be given to substances which may have chronic effects, in particular substances known or suspected to be carcinogenic, toxic to reproduction and/or mutagenic or known or suspected to increase the incidence of these effects.

Article 9

Data to be supplied for substances appearing on the priority lists

1. For the substances included in the priority lists referred to in Article 8 (1), manufacturers and importers who have submitted information on a substance in accordance with Articles 3 and 4 shall, within six months of publication of the list, submit to the rapporteur designated in accordance with Article 10 (1) all relevant available information and corresponding study reports for risk assessment of the substance concerned.

2. In addition to the requirement specified in paragraph 1, and without prejudice to the testing which may be required under Article 10 (2), if any of the particulars listed in Annex VII A to Directive 67/548/EEC are not available for a given priority substance, the manufacturers and importers who have submitted information on a substance in accordance with Articles 3 and 4 shall be obliged to carry out the testing necessary to obtain the missing data and to provide the test results and test reports to the rapporteur within 12 months.

3. By way of derogation from paragraph 2, manufacturers and importers may request of the rapporteur that they

be exempted from some or all of the additional testing on the grounds that a given piece of information is either unnecessary for risk assessment or is impossible to obtain; they may also request a longer period where circumstances so require. Full justification must be provided to support such derogation and the rapporteur shall decide whether the request should be accepted. Where derogations are allowed in conformity with this Article, the rapporteur shall immediately inform the Commission of his decision. The Commission shall inform the other Member States. If the decision of the rapporteur is contested by one of the other Member States, a final decision shall be taken in conformity with the committee procedure laid down in Article 15.

PART 2

RISK EVALUATION

Article 10

Risk evaluation of the substances on the priority lists at the level of the Member State designated as rapporteur

1. For each substance on the priority lists a Member State shall be given responsibility for its evaluation in accordance with the procedure laid down in Article 15, whilst ensuring fair burden sharing between Member States.

The Member State shall designate a rapporteur for that substance from among the competent authorities referred to in Article 13.

The rapporteur shall be responsible for evaluating the information submitted by the manufacturer(s) or importer(s) in conformity with the requirements of Articles 3, 4, 7 and 9 and any other available information, and for identifying, after consultation of the producers or importers concerned, whether, for the purpose of the risk evaluation, it is necessary to require the above manufacturers or importers of priority substances to submit further information and/or to carry out further testing.

2. Where the rapporteur considers it necessary to request further information and/or testing, it shall inform the Commission accordingly. The decision to impose on the above importers or manufacturers a request for further information and/or testing and the time limits for responding to that request shall be taken in accordance with the procedure laid down in Article 15.

3. The rapporteur for a given priority substance shall evaluate the risk of that substance to man and the environment. Where appropriate, it shall suggest a strategy for limiting these risks, including control measures and/or surveillance programmes. Where such control measures include recommendations for restrictions on the marketing or use of the substance in question, the rapporteur shall submit an

analysis of the advantages and drawbacks of the substance and of the availability of replacement substances.

The recommended risk evaluation and strategy shall be forwarded to the Commission by the rapporteur.

4. The real or potential risk to man and the environment shall be assessed on the basis of principles adopted, by 4. June 1994, in accordance with the procedure laid down in Article 15. These principles shall be regularly reviewed and, where appropriate, revised in accordance with the same procedure.

5. When manufacturers or importers are asked for further information and/or testing, they must also check, in view of the need to limit practical experiments on vertebrates, whether the information needed to evaluate the substance is not available from former manufacturers or importers of the declared substance and cannot be obtained, possibly against payment of costs. Where experiments are essential, it must be checked whether tests on animals cannot be replaced or limited by using other methods.

Necessary laboratory tests must be performed with due respect for the principles of 'good laboratory practice' as laid down in Directive 87/18/EEC and for the provisions of Directive 86/609/EEC.

Article 11

Risk evaluation of the substances on the priority lists at Community level

1. On the basis of the risk evaluation and measures recommended by the rapporteur, the Commission shall submit to the Committee referred to in Article 15 (1) a proposal concerning the results of the risk evaluation of the priority substances and, if necessary, a recommendation for an appropriate strategy for limiting those risks.

2. The results of the risk evaluation of the priority substances, and the recommended strategy shall be adopted at Community level in accordance with the procedure laid down in Article 15, and shall be published by the Commission.

3. On the basis of the risk evaluation and the recommended strategy referred to in paragraph 2, the Commission shall decide, where necessary, to propose Community measures in the framework of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (8) or in the framework of other relevant existing Community instruments.

(8) OJ No L 262, 27. 9. 1976, p. 201. Directive as last amended by Directive 91/659/EEC (OJ No L 363, 31. 12. 1991, p. 36).

*Article 12***Obligations relating to the provision of further information and to further testing**

1. Any manufacturer or importer of a substance appearing on the priority lists referred to in Article 8 (1) and who has submitted the information under Articles 3 and 4 must, within a given time limit, supply the rapporteur with the data and test results concerning that substance referred to in Article 9 (1) and (2) and those referred to in Article 10 (2).
2. Without prejudice to Article 7 (2), where there are valid reasons for believing that a substance appearing in Einesc may present a serious risk to man or the environment, a decision to ask the manufacturer(s) and importer(s) of the said substance to supply the information which they possess and/or to subject the existing substance to testing and provide a report thereon shall be taken in accordance with the procedure laid down in Article 15.
3. In the case of a substance produced or imported as such or in a preparation by several manufacturers or importers, testing in pursuance of paragraphs 1 and 2 may be performed by one or more manufacturers or importers acting on behalf of other manufacturers or importers concerned. The other manufacturers or importers concerned shall make reference to the tests carried out by that or those manufacturers or importers and shall make a fair and equitable contribution to the cost.

*Article 13***Collaboration between the Member States and the Commission**

Member States shall designate one or more competent authorities to participate in the implementation of this Regulation in collaboration with the Commission, in particular for the work referred to in Articles 8 and 10. The Member States shall also designate the authority or authorities to which the Commission shall send the copy of the data received.

PART 3

MANAGEMENT, CONFIDENTIALITY, MISCELLANEOUS AND FINAL PROVISIONS

*Article 14***Amendment and adaptation of the Annexes**

1. The amendments necessary for adapting Annexes I, II, III and IV to technical progress shall be adopted in accordance with the procedure laid down in Article 15.
2. The amendments and adaptations to Annex V shall be adopted by the Commission.

*Article 15***Committee**

1. The Commission shall be assisted by a Committee composed of the representatives of the Member States and chaired by the representative of the Commission.
2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decision which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.
3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

4. (a) Except in the cases referred to in subparagraph (b) below, if, on the expiry of a period of two months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.
- (b) In the case of decisions referred to in Article 11 (2) and Article 14 (1) if, on the expiry of a period of two months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

*Article 16***Confidentiality of data**

1. If he considers that there is a confidentiality problem, the manufacturer or importer may indicate the information provided for in Articles 3, 4, 7 and 12, which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than Member States and the Commission. Full justification must be given in such cases.

Industrial and commercial secrecy shall not apply to:

- the name of the substance, as given in EINECS,
- the name of the manufacturer or importer,
- data on physico-chemical properties of the substance and on pathways and environmental fate,
- the summary results of the toxicological and ecotoxicological tests, in particular data on carcinogenicity, mutagenicity and/or the substance's toxicity for reproduction,
- any information relating to the methods and precautions relating to the substance and the emergency measures,
- any information which, if withheld, might lead to animal experiments being carried out or repeated needlessly,
- analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans to the substance. If the manufacturer or importer should himself later disclose previously confidential information, he shall inform the competent authority accordingly.

2. The authority receiving the information shall decide on its own responsibility which information is covered by industrial and commercial secrecy in accordance with paragraph 1.

Information accepted as being confidential by the authority receiving the information shall be treated as being confidential by the other authorities.

Article 17

Not later than one year following adoption of this Regulation, Member States shall establish appropriate legal or administrative measures in order to deal with non-compliance with the provisions of this Regulation.

Article 18

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, 23 March 1993.

For the Council

The President

S. AUKEN

*ANNEX I*LIST OF EXISTING SUBSTANCES PRODUCED OR IMPORTED WITHIN THE
COMMUNITY IN QUANTITIES EXCEEDING 1 000 TONNES PER YEAR (*) (*)

The petroleum products are grouped into 31 groups identified by a number or a number and a letter (group 1, group 2, group 3A, group 3B, group 3C, group 4A, group 4B, etc.)

For any one particular group of substances, manufacturers or importers may decide to submit only one set of information, but only in so far as points 2 to 6 inclusive of the information as laid down in Annex III are concerned; this information will then be taken as applying to all substances contained within that particular group.

ANNEX II

LIST OF SUBSTANCES EXEMPT FROM THE PROVISIONS OF ARTICLES 3 AND 4

ANNEX III

INFORMATION REFERRED TO IN ARTICLE 3

1. General information

- 1.1. Name of substance
- 1.2. Einesc No
- 1.3. CAS No
- 1.4. Synonyms
- 1.5. Purity
- 1.6. Impurities
- 1.7. Molecular formula
- 1.8. Structural formula
- 1.9. Type of substance
- 1.10. Physical state
- 1.11. Please indicate who is submitting the data set
- 1.12. Quantity produced or imported, greater than 1 000 tonnes per year
- 1.13. Indicate if the substance has been produced during the last 12 months
- 1.14. Indicate if the substance has been imported during the last 12 months
- 1.15. Classification and labelling
- 1.16. Use pattern
- 1.17. Has the complete data set already been submitted by another manufacturer or importer ?
- 1.18. Specify if you are acting on behalf of another concerned manufacturer or importer
- 1.19. Other remarks: (e. g. options for disposal)

2. Physical-chemical data

- 2.1. Melting point
- 2.2. Boiling point
- 2.3. Density
- 2.4. Vapour pressure
- 2.5. Partition coefficient (log₁₀ POW)
- 2.6. Water solubility
- 2.7. Flash point
- 2.8. Auto flammability
- 2.9. Flammability
- 2.10. Explosive properties
- 2.11. Oxidizing properties
- 2.12. Other data and remarks

3. Environmental fate and pathways

- 3.1. Stability
 - 3.1.1. Photodegradation
 - 3.1.2. Stability in water
 - 3.1.3. Stability in soil
- 3.2. Monitoring data (environment)
- 3.3. Transport and distribution between environmental compartments including estimated environmental concentrations and distribution pathways
 - 3.3.1. Transport
 - 3.3.2. Distribution among environmental compartments
- 3.4. Biodegradation
- 3.5. Bioaccumulation
- 3.6. Other remarks

4. Ecotoxicity

- 4.1. Toxicity to fish
- 4.2. Toxicity to daphnia and other aquatic invertebrates
- 4.3. Toxicity to algae
- 4.4. Toxicity to bacteria
- 4.5. Toxicity to terrestrial organisms
- 4.6. Toxicity to soil dwelling organisms
- 4.7. Other remarks

5. Toxicity

- 5.1. Acute toxicity
 - 5.1.1. Acute oral toxicity
 - 5.1.2. Acute inhalation toxicity
 - 5.1.3. Acute dermal toxicity
 - 5.1.4. Acute toxicity (other routes of administration)
- 5.2. Corrosiveness and irritation
 - 5.2.1. Skin irritation
 - 5.2.2. Eye irritation
- 5.3. Sensitization
- 5.4. Repeated dose toxicity
- 5.5. Genetic toxicity in vitro
- 5.6. Genetic toxicity in vivo
- 5.7. Carcinogenicity
- 5.8. Toxicity to reproduction
- 5.9. Other relevant information
- 5.10. Experience with human exposure

6. List of references*ANNEX IV*

INFORMATION REFERRED TO IN ARTICLE 4 (1)

1. General information

- 1.1. Name of substance
- 1.2. Eines No
- 1.3. CAS No
- 1.4. Synonyms
- 1.5. Purity
- 1.6. Impurities
- 1.7. Molecular formula
- 1.8. Structural formula
- 1.9. Type of substance
- 1.10. Physical state
- 1.11. Please indicate who is submitting the data set
- 1.12. Quantity produced or imported exceeding 10 tonnes per year but not greater than 1 000 tonnes
- 1.13. Indicate if the substance has been produced during the last 12 months
- 1.14. Indicate if the substance has been imported during the last 12 months
- 1.15. Classification and labelling
- 1.16. Use pattern
- 1.17. Other remarks

ANNEX V

COMMUNITY INFORMATION OFFICES

The special software packages are available, on diskette, at the following information offices in the Community

Germany

Bonn

Kommission der Europaeischen Gemeinschaften

Vertretung in der Bundesrepublik Deutschland

Zitelmannstrasse 22

D-5300 Bonn

Telex 88 66 48 EUROP D

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REACH COMPLIANCE



REGULATION (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

DIRECTIVE 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

About B-Lands Consulting

B-Lands Consulting provides consultancy services and **LEAP AHEAD®** services designed to help worldwide organisations comply with European Union regulations.

Our company provides business friendly services on the following European Union environmental regulations:

- **REACH** (Registration, Evaluation and Authorisation of **C**hemicals) legislation
- **ELV / VHU** (End of Life Vehicle:/ Vehicules **H**ors d'**U**sage) legislation
- **EuP** (Energy Using Products) legislation
- **WEEE** (Waste **E**lectrical and **E**lectronic Equipment) legislation
- **RoHS** (Restriction of the use of **H**azardous **S**ubstances) legislation

As some EU compulsory requirements are country specific, such as for the WEEE legislation, our services are designed to adapt and conform to each country's rules and regulations, while serving both business-to-business (B2B) and business-to-consumer (B2C) companies.

We assist our customers in determining proper regulation compliance schemes, including collaborative schemes involving other businesses such as Substance Information Exchange Forums (SIEFs).

Performed services

B-Lands Consulting offers one-stop EU regulations compliance solutions throughout all 27-EU Member States.

Services include:

- EU relevant regulations monitoring.
- Suppliers chain compliance analysis.
- Information on products labelling and other manufacturer's obligations.
- Analysis of the company products distribution system through all EU states (Subsidiaries, distributors, retailers).
- Audits on manufactured products, chemical substances & preparations (Classifications, exemption conditions, etc.).
- REACH Compliance requirements, risks assessment reports, substances full registration process
- Design of proposal for cooperation between the client and its EU distributors in any EU member state.
- Conveying products testing through a third party (Testing Labs, certifications)
- Filling of exemptions petitions on behalf of our clients to the European Commission.
- A pan European WEEE registration and recycling service for all 27-EU Member States.
- Handling of all the required paperwork. Contracts, powers of attorney are to be submitted to the client for approval and signature.

Additional benefits are:

- The implementation and execution of smooth and on schedule compliance overhauls.
- A single and a consistent corporate solution for all EU compliance requirements.
- A single entry point for reporting to the EU bodies and registries.