

L.N. 318 of 2001

**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)**

The Dangerous Substances (Notification) Regulations, 2001

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and
Commencement.

1.1 The title of this Order is the Dangerous Substances (Notification) Regulations, 2001.

1.2 These regulations shall come into effect as from 1st January 2002, with the exception of regulations 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18, which shall come into effect on such date as the Minister responsible for consumer affairs may, by notice in the Government Gazette, determine.

Applicability.

2.1 These regulations concern:

- (a) the notification of substances;
- (b) the exchange of information on notified substances;
- (c) the assessment of the potential risk to man and the environment of notified substances;
- (d) the classification, packaging and labelling of substances dangerous to man or the environment,

where such substances are placed on the market.

2.2 These regulations shall not apply to the following preparations in the finished state, intended for the final user:

- (a) medicinal products for human or veterinary use, as defined in the Act;
- (b) cosmetic products as defined by the Cosmetic Products Order, 2000 (L.N. 204 of 2000);
- (c) mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC¹ and 78/319/EEC²;

¹OJ No L 194, 15.7.1975, p.39.

²OJ No L 84, 31.3.1978, p.43.

- (d) foodstuffs;
- (e) animal feedingstuffs;
- (f) pesticides;
- (g) radioactive substances as defined by Directive 80/836/EEC³;
- (h) other substances or preparations for which European Community notification or approval procedures exist and for which requirements are equivalent to those laid down in these regulations.

2.3 In addition, these regulations shall not apply to:

- the carriage of dangerous substances by rail, road, inland waterway, sea or air,
- substances in transit which are under customs supervision, provided they do not undergo any treatment or processing.

3.1 In these regulations, the following definitions shall apply, *Definitions.* unless the context otherwise requires:

- (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 products 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) “polymer” means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a “monomer unit” means the reacted form of a monomer in a polymer;

³OJ No L 246, 17.9.1980, p.1.

(d) “notification” means the documents, with the requisite information, presented to the competent authority of a Member State of the European Community:

- for substances manufactured within the European Community, by the manufacturer who places a substance either on its own or in a preparation on the market,

- for substances manufactured outside the European Community, by any person established in the European Community who is responsible for placing the substance either on its own or in a preparation on the Community market, or alternatively by the person established within the European Community who is, for the purposes of submitting a notification for a given substance placed on the Community market, either on its own or in a preparation, designated by the manufacturer as his sole representative. The person submitting the notification, as described above, shall be referred to as “the notifier”.

(e) “placing on the market” means the making available to third parties. Importation into European Community customs territory shall be deemed to be placing on the market for the purposes of these Regulations;

(f) “scientific research and development” means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

(g) “process-orientated research and development” means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance;

(h) “EINECS” means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the European Community market on 18 September, 1981.

(i) “Directive” shall mean Council Directive 67/548/EEC⁴ on the approximation of the laws, regulations and administrative

⁴OJ No L 196, 16.8.1967, p.1

provisions relating to the classification, packaging and labelling of dangerous substances, as amended by the following Directives:

- Directive 71/144/EEC (OJ L 074, 29.3.1971, p.15)
- Directive 73/146/EEC (OJ L 167, 25.6.1973, p.1)
- Directive 75/409/EEC (OJ L 183, 14.7.1975, p.22)
- Directive 76/907/EEC (OJ L 360, 30.12.1976, p.1)
- Directive 79/370/EEC (OJ L 088, 7.4.1979, p.1)
- Directive 79/831/EEC (OJ L 259, 15.10.1979, p.10)
- Directive 80/1189/EEC (OJ L 366, 31.12.1980, p.1)
- Directive 81/957/EEC (OJ L 351, 7.12.1981, p.5)
- Directive 82/232/EEC (OJ L 106, 21.4.1982, p.18)
- Directive 83/467/EEC (OJ L 257, 16.9.1983, p.1)
- Directive 84/449/EEC (OJ L 251, 19.9.1984, p.1)
- Directive 86/431/EEC (OJ L 247, 1.9.1986, p.1)
- Directive 87/432/EEC (OJ L 239, 21.8.1987, p.1)
- Directive 88/490/EEC (OJ L 259, 19.9.1988, p.1)
- Directive 90/517/EEC (OJ L 287, 19.10.1990, p.37)
- Directive 91/410/EEC (OJ L 228, 17.8.1991, p.67)
- Directive 91/632/EEC (OJ L 338, 10.12.1991, p.23)
- Directive 92/32/EEC (OJ L 154, 5.6.1992, p.1)
- Directive 92/37/EEC (OJ L 154, 5.6.1992, p.30)
- Directive 93/21/EEC (OJ L 110, 4.5.1993, p.20)
- Directive 93/72/EEC (OJ L 258, 16.10.1993, p.29)
- Directive 93/101/EEC (OJ L 013, 15.1.1993, p.1)
- Directive 93/105/EEC (OJ L 294, 30.11.1993, p.21)
- Directive 94/69/EC (OJ L 381, 31.12.1994, p.1)
- Directive 96/54/EC (OJ L 248, 30.9.1996, p.1)
- Directive 96/56/EC (OJ L 236, 18.9.1996, p.35)
- Directive 97/69/EC (OJ L 343, 13.12.1997, p.19)
- Directive 98/73/EC (OJ L 305, 16.11.1998, p.1)
- Directive 98/98/EC (OJ L 355, 30.12.1998, p.1)
- Directive 99/33/EC (OJ L 199, 30.7.1999, p.57)
- Directive 2000/32/EC (OJ L 136, 8.6.2000, p.1)
- Directive 2000/33/EC (OJ L 136, 8.6.2000, p.90)
- Directive 2001/59/EC (OJ L 136, 21.8.2001, p.1)

(j) “competent authority” for the purposes of these regulations shall mean the Foodstuffs, Chemicals and Cosmetics Directorate within the Malta Standards Authority.

3.2 The following are “dangerous” within the meaning of these regulations:

(a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also

⁴ OJ Numru L 196, 16.8.1967, p.1

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react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

(b) oxidizing substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

(c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

(d) highly flammable substances and preparations:
- substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

- solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

- liquid substances and preparations having a very low flash-point, or

- substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(e) flammable substances and preparations: liquid substances and preparations having a low flash-point;

(f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

(k) sensitizing substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced;

(l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

(m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

(n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

(o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment.

4.1 Tests on chemicals carried out within the framework of these regulations shall as a general principle be conducted according to the methods laid down in Annex V of the Directive. The physico-chemical properties of substances shall be determined according to the methods specified in Annex VA of the Directive; their toxicity shall be determined according to the methods specified in Annex VB and their ecotoxicity according to the methods specified in Annex VC.

Testing and
Assessment of the
properties of
substances.

4.1.1 However, for some of the substances in the EINECS it is possible that test data exist which have been generated by methods other

- packaged and labelled in accordance with regulations 23 to 26 and with the criteria in Annex VI of the Directive, and in accordance with the results of the tests provided for in Annexes VII and VIII of the same Directive, save in the case of preparations where other provisions exist.

6.1.1 In addition, the provisions concerning safety data sheets as laid down in regulation 28 shall be observed.

6.2 The measures referred to in the second indent of regulation 6.1 shall apply until the substance is listed in Annex I of the Directive or until a decision not to list it has been taken in accordance with the procedure laid down in Article 29 of the Directive.

7.1 Manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I of the Directive shall carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules laid down in regulations 23 to 26 and the criteria in Annex VI of the Directive.

Obligation to carry out investigations.

8.1 Without prejudice to regulations 2.2, 9.1, 14 and 17.1, any notifier of a substance is required to submit to the competent authority a notification including:

Full notification.

- a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose. As a minimum, the dossier shall contain the information and results of the studies referred to in Annex VII A of the Directive, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them,

- a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses,

- the proposed classification and labelling of the substance in accordance with these Regulations,

- in the case of dangerous substances only, a proposal for a safety data sheet as provided for in regulation 24,

- in the case of a manufacturer located outside the European Community, the notifier shall, in accordance with regulation 3.1

(d), second indent, include, if appropriate, a statement from the manufacturer to the effect that, for the purpose of submitting a notification for the substance in question, he is designated as the manufacturer's sole representative,

- if so desired, a statement by the notifier requesting, on reasoned grounds, that the notification be exempted from the provisions of regulation 16.2 for a maximum period which shall not in any case exceed one year following the date of notification.

Besides the information referred to above, the notifier may also provide the authority with a preliminary assessment of the risks, which he has made in accordance with the principles laid down in regulation 4.2.

8.2 Without prejudice to regulation 15, any notifier of a substance already notified shall inform the competent authority:

- when the quantity of the substance placed on the market reaches 10 tonnes per year per manufacturer or when the total quantity placed on the market reaches 50 tonnes per manufacturer; in this case, the competent authority may require some or all of the additional tests/studies laid down in Annex VIII of the Directive, level 1, to be carried out within a time limit it will determine,

- when the quantity of the substance placed on the market reaches 100 tonnes per year per manufacturer or when the total quantity placed on the market reaches 500 tonnes per manufacturer; in this case, the competent authority shall require the additional tests/studies laid down in Annex VIII of the Directive, level 1, to be carried out within a time limit it will determine, unless the notifier can give good reason why a given test/study is not appropriate or an alternative scientific test/study would be preferable,

- when the quantity of a substance placed on the market reaches 1 000 tonnes per year per manufacturer or when the total quantity placed on the market reaches 5 000 tonnes per manufacturer; in this case, the competent authority shall draw up a programme of tests/studies according to Annex VIII of the Directive, level 2, to be carried out by the notifier within a time limit which the competent authority will determine.

8.3 When additional testing is carried out either in accordance with the requirements of regulation 3 or voluntarily, the notifier shall provide the competent authority with the results of the studies carried out.

9.1 Without prejudice to regulations 2.2, 14.1 and 17.1, any notifier intending to place a substance on the European Community market in quantities of less than one tonne per annum per manufacturer is required to submit to the competent authority a notification including:

Reduced notification requirements for substances placed on the market in quantities of less than one tonne per annum per manufacturer.

- a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose. As a minimum, the dossier shall contain the information and results of the studies referred to in Annex VII B of the Directive, together with a full and detailed description of the studies conducted and of the methods used or a bibliographical reference to them if the competent authority so requires,
- all the other information referred to in regulation 8.1.

9.2 When the quantities to be placed on the market are below 100 kg per year per manufacturer the notifier may, without prejudice to regulation 17.1, restrict the information in the technical dossier of the said notification above to that provided for in Annex VII C of the Directive.

9.3 In the case of a notifier who has submitted a reduced notification dossier in conformity with regulation 9.2, he shall, before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer or before the total quantity placed on the market reaches 500 kg per manufacturer, provide the competent authority with the additional information necessary to complete the technical dossier to the level of Annex VII. B of the Directive.

9.4 Similarly, when a notifier has submitted a reduced notification dossier in conformity with regulation 9.1 he shall, before the quantity of the substance placed on the market reaches 1 tonne per year per manufacturer, or before the total quantity placed on the market reaches 5 tonnes per manufacturer, submit a full notification according to the requirements of regulation 8.

9.5 The substances notified in conformity with regulations 9.1 and 9.2 must, in so far as the notifier may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled in accordance with the rules laid down in regulations 19 to 22 and with the criteria imposed in Annex VI of the Directive. Where it is not yet possible to label them in accordance with the principles set out in regulation 20, the label should bear, in addition to the label deriving from the tests already carried out, the warning "Caution - substance not yet fully tested".

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Substances already notified (10-year rule).

10.1 A notifier need not supply the information required under regulations 8 and 9 for the technical dossiers in Annexes VII A, VII B, VII C and VII D of the Directive with the exception of items 1 and 2 thereof, if the data were originally submitted at least 10 years previously.

Placing of notified substances on the market.

11.1 Substances notified under regulation 8 may, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 60 days after receipt by the authority of a dossier in conformity with the requirements of these regulations.

If the competent authority considers that the dossier is not in conformity with these regulations and advises the notifier accordingly, as provided for in regulation 17.2, the substance may be placed on the market only 60 days after receipt by the authority of the information necessary to bring the notification into conformity with these regulations.

11.2 Substances notified under regulation 9.1 or 9.2 may, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 30 days after receipt by the authority of a dossier in conformity with the requirements of these regulations.

If the competent authority considers that the dossier is not in conformity with these regulations and advises the notifier accordingly, as provided for in regulation 17.3, the substance may be placed on the market only 30 days after receipt by the authority of the information necessary to bring the notification into conformity with these Regulations. However, if the notifier has received notice in accordance with regulation 17.3 that the dossier has been accepted, the substance may be placed on the market no sooner than 15 days after receipt of the dossier by the competent authority.

Substances manufactured outside the Community.

12.1 Where, for substances manufactured outside the Community, more than one notification exists for a substance manufactured by the same manufacturer, the cumulative yearly tonnages placed on the Community market shall be those determined by the Commission and the national authorities on the basis of the information submitted under Articles 7 (1), 8 (1) and 14 of the Directive. The obligation to carry out supplementary testing in accordance with Article 7 (2) of the Directive will fall collectively on all notifiers.

Polymers

13.1 For polymers, the specific provisions concerning the technical dossiers contained in the notifications and referred to in regulations 8.1 and 9.1 shall be those laid down in Annex VII of the Directive, in the form of Annex VII. D, in accordance with the procedure referred to in Article 29 (4) (b) of the Directive.

14.1 The following substances shall be exempted from the provisions of regulations 8, 9, 15 and 16: ^{Exemptions.}

- substances which appear on the EINECS inventory,
- additives and substances for exclusive use in animal feedingstuffs as covered by Directives 70/524/EEC⁷ and 82/471/EEC⁸,
- substances used exclusively as additives in foodstuffs, as covered by the Additives in Food Regulations, 1994 (L.N. 89 of 1994) and substances used exclusively as flavourings in foodstuffs and which are covered by the Flavourings for Use in Foodstuffs and Source Materials for their Production Regulations, 1998 (L.N. 257 of 1998)
- active ingredients used exclusively in the medicinal products referred to in regulation 2.2(a), excluding chemical intermediates,
- substances for exclusive use in other product sectors for which European Community notification or approval procedures exist and for which the requirements for data submission are equivalent to those laid down in the Directive.

14.2 The substances listed below shall be considered as having been notified within the meaning of the Directive when the following conditions are fulfilled:

- polymers, with the exception of those which contain in combined form 2 % or more of any substance which is not on EINECS,
- substances placed on the market in quantities of less than 10 kg per year per manufacturer, provided the manufacturer/importer satisfies all the conditions imposed by the competent authority. These conditions shall not exceed the information provided for in Annex VII C of the Directive, points 1 and 2,
- substances placed on the market in limited quantities, and in any case not exceeding 100 kg per manufacturer per year, and intended solely for purposes of scientific research and development carried out under controlled conditions. Any manufacturer or

⁷OJ No L 270, 14.12.1970, p.1

⁸OJ No L 213, 21.7.1982, p.8

importer making use of this exemption must maintain written records containing the identity of the substance, labelling data, quantities and a list of customers; this information must be available upon request to the competent authority,

- substances placed on the market for the purposes of process-orientated research and development with a limited number of registered customers in quantities which are limited to the purpose of process-orientated research and development. These substances shall qualify for an exemption for a period of one year provided that the manufacturer or importer communicates their identity, labelling data, quantity, the justification for the quantity and a list of customers and the research and development programme to the competent authority and complies with any conditions imposed by the competent authority or any other national authorities on such research and development. After one year, these substances will normally be subject to notification. The manufacturer or importer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled only by customers' staff in controlled conditions and will not be made available to the general public at any time either on its own or in a preparation. In addition, if the competent authority considers that there may exist an unacceptable risk for man and the environment, it may extend the restriction referred to above to include any products containing the new substances which were produced during the process-orientated research and development.

The one-year exemption period referred to above may in exceptional circumstances be extended for a further year if the person submitting the request can demonstrate, to the satisfaction of the competent authority, that such an extension is justified.

14.3 The substances referred to in regulation 14.2 must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in regulations 19 to 22 and with the criteria imposed in Annex VI of the Directive.

14.3.1 If it is not possible to label the substances completely, and in accordance with the principles set out in regulation 20, because the results of tests provided for in Annex VII A of the Directive are not all available, the label should bear, in addition to the label deriving from tests already carried out, the warning "Caution - substance not yet fully tested".

14.4 Where a substance as referred to in regulation 9.2, labelled in accordance with the principles set out in regulation 20, is very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic, the manufacturer or importer of such a substance must transmit to the competent authority any appropriate information as regards Annex VII A of the Directive, Sections 2.3, 2.4 and 2.5. Moreover, acute toxicity data shall be given where available.

15.1 Any notifier of a substance already notified in conformity with regulations 8.1 or 9.1 shall be responsible on his own initiative for informing in writing the competent authority of:

Follow-up
information

- changes in the annual or total quantities placed on the Community market by him or, in the case of a substance manufactured outside the Community for which the notifier has been designated as sole representative, by him and/or others,
- new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware,
- new uses for which the substance is placed on the market of which he may reasonably be expected to have become aware,
- any change in the composition of the substances as given in Annex VII A, B or C, section 1.3 of the Directive,
- any change in his status (manufacturer or importer).

15.2 Any importer of a substance produced by a manufacturer established outside the Community who imports the substance within the framework of a notification previously submitted by a sole representative in accordance with regulation 3.1 (d) is required to ensure that the sole representative is provided with up-to-date information concerning the quantities of the substance introduced by him on to the Community market.

16.1 In the case of a substance which has already been notified in accordance with regulations 8.1 or 9.1, the competent authority may agree that the subsequent notifier of that substance may, for the purposes of sections 3, 4 and 5 of Annex VII A and B of the Directive and sections 3 and 4 of Annex VIII C of the Directive, refer to the results of the tests/studies forwarded by the first notifier, in so far as the subsequent notifier can provide evidence that the substance renotified is the same as the one previously notified, including the degree of purity and the nature of impurities. The first notifier must give his agreement in writing to the

Renotification of
the same substance
and avoidance of
duplicating testing
on vertebrate
animals.

reference to the results of the tests/studies he has forwarded before such reference can be made.

16.2 Before carrying out testing on vertebrate animals for the purpose of submitting a notification in conformity with regulations 8.1 or 9.1, and without prejudice to regulation 16.1, prospective notifiers shall enquire of the competent authority as to:

(a) whether or not the substance they intend to notify has already been notified; and

(b) the name and address of the first notifier.

This enquiry shall be supported by evidence that the prospective notifier has intention to place the substance on the market and of the quantities he intends to place on the market.

In the event that:

(a) the competent authority is satisfied that the prospective notifier intends to place the substance on the market in the quantities stated; and

(b) the substance has been notified previously; and

(c) the first notifier has not requested and been granted a temporary exemption from the provisions of this regulation,

the competent authority shall provide the prospective notifier with the name and address of the first notifier and shall inform the first notifier of the name and address of the prospective notifier.

The first notifier and the prospective notifier shall take all reasonable steps to reach an agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

16.3 Notifiers of the same substance who have agreed to share information relating to Annex VII of the Directive in accordance with regulations 16.1 and 16.2 shall also take all necessary steps to reach an agreement on the sharing of information derived from testing on vertebrate animals submitted in conformity with regulation 8.2.

Rights and Duties of
the Competent
Authority.

17.1 The competent authority shall be responsible for receiving the information provided for in regulations 8 to 15 and examining its conformity with the requirements of these regulations.

Moreover, if it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, the competent authority may ask for further information, verification and/or confirmatory tests concerning the substances or their transformation products, of which it has been notified or has received information under these regulations; this may also include requesting any of the information referred to in Annex VIII of the Directive earlier than provided for in regulation 8.2.

Additionally, the competent authority may:

- carry out such sampling as is necessary for control purposes,
- require the notifier to supply such quantities of the notified substance as it deems necessary for the carrying out of verification tests,
- take appropriate measures relating to safe use of a substance pending the introduction of Community provisions.

In the case of substances notified in accordance with regulations 8.1 and 9.2 and 9.4, the competent authority shall carry out an assessment of the risks in accordance with the general principles laid down in regulation 4.2. The assessment shall include recommendations on the most appropriate method for testing the substance and, where appropriate, also include recommendations on measures which will enable the risk for man and the environment in connection with the marketing of the substance to be lessened. The assessment shall be updated from time to time in the light of additional information provided under this regulation or regulations 8.2, 9.3 and 15.1.

17.2 In the case of notifications submitted in conformity with regulation 8, within a period of 60 days following receipt of the notification, the competent authority shall inform the notifier in writing as to whether the notification has, or has not, been accepted as being in conformity with these regulations.

If the dossier is accepted, the authority shall at the same time advise the notifier of the official number which has been allocated to the notification. If the dossier is not accepted, the authority shall inform the notifier as to what further information he is required to provide in order to bring the dossier into conformity with these regulations.

17.3 For notifications submitted in accordance with regulation 9, the competent authority shall, within a period of 30 days following receipt of the notification, decide whether the notification is in

conformity with these regulations and, where the notification is adjudged not to be in conformity, inform the notifier as to what further information he is required to provide in order to bring the dossier into conformity with these regulations. Where the notification is in conformity with these regulations, the authority shall, within the same period, advise the notifier of the official number which has been allocated to his notification.

17.4 For substances manufactured outside the Community for which more than one notification has been submitted for the substance produced by one manufacturer, the competent authority, together with the European Commission and the competent authorities of the other Member States, shall be responsible for calculating the annual and cumulative tonnages placed upon the Community market. If the tonnage thresholds detailed in regulation 8.2 are attained, the competent authority shall contact each notifier informing them of the identity of the other notifiers and drawing their attention to their collective responsibility as outlined in regulation 12.

17.5 Without prejudice to regulation 18.1, the competent authority shall ensure that any information concerning commercial exploitation or manufacturing brought to its attention is kept secret.

Confidentiality of data.

18.1 If he considers that there is a confidentiality problem, the manufacturer or importer may indicate the information provided for in regulations 8, 9 and 15 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 the competent authority, the competent authorities of other Member States and the European Commission. Full justification must be given in such cases.

18.1.1 With respect to the notifications and information submitted in conformity with regulations 8.1 and 8.2, 9.1, 9.2 and 9.3,

Industrial and commercial secrecy shall not apply to:

- (a) the trade name of the substance;
- (b) the name of the manufacturer and the notifier;
- (c) physico-chemical data concerning the substance in connection with section 3 of Annexes VII A, VII B and VII C of the Directive;
- (d) the possible ways of rendering the substance harmless;

(e) the summary results of the toxicological and ecotoxicological tests;

(f) if essential to classification and labelling for the purpose of introducing the substance into Annex I of the Directive, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous within the meaning of regulation 3.2;

(g) the recommended methods and precautions referred to in Annex VII of the Directive, section 2.3, and the emergency measures referred to in Annex VII of the Directive, sections 2.4 and 2.5;

(h) the information contained in the safety data sheet;

(i) in the case of substances in Annex I of the Directive, 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.

If the notifier, manufacturer or importer should himself later disclose previously confidential information, he shall inform the competent authority accordingly.

18.2 The competent authority shall decide on its own responsibility which information is covered by industrial and commercial secrecy in accordance with regulation 18.1.

18.3 Confidential information brought to the attention of the competent authority shall be kept secret. In all cases such information:

- may be brought to the attention only of the authorities whose responsibilities are specified in Article 16(1) of the Directive,
- may, however, be divulged to persons directly involved in administrative or legal proceedings involving sanctions which are undertaken for the purpose of controlling substances placed on the market and to persons who are to participate or be heard in legislative proceedings.

19.1 Dangerous substances cannot be placed on the market unless ^{Packaging.} their packaging satisfies the following requirements:

- (a) it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;

(b) the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents;

(c) packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

(e) every container of whatever capacity, containing substances sold or made available to the general public and labelled "very toxic", "toxic" or "corrosive", as defined in these Regulations, must have a child-resistant fastening and a tactile warning of danger;

(f) every container, of whatever capacity, containing substances sold or made available to the general public and labelled "harmful", "extremely flammable" or "highly flammable" as defined in these regulations must bear a tactile warning of danger.

19.2 The technical specifications relating to the devices referred to in regulation 19.1 (e) and (f) are to be found in points A and B of Annex IX to the Directive.

Labelling.

20.1 Dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the requirements in this regulation.

20.2 Every package shall show clearly and indelibly the following:

(a) the name of the substance under one of the designations given in Annex I of the Directive. If the substance is not yet listed in Annex I of the Directive, the name must be given using an internationally recognized designation;

(b) the name and full address including the telephone number of the person established in the European Community who is responsible for placing the substance on the market whether it be the manufacturer, the importer or the distributor;

(c) danger symbols, when laid down, and indication of the danger involved in the use of the substance. The design of the

danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II of the Directive. The symbol shall be printed in black on an orange-yellow background. The danger symbols and indications of danger to be used for each substance shall be those indicated in Annex I of the Directive. For dangerous substances not yet appearing in Annex I the danger symbols and indications of danger shall be assigned according to the rules laid down in Annex VI of the Directive.

When more than one danger symbol is assigned to a substance:

- the obligation to indicate the symbol T makes the symbols X and C optional, unless Annex I of the Directive provides otherwise,
- the obligation to indicate the symbol C makes the symbol X optional,
- the obligation to indicate the symbol E makes the symbol F and O optional;

(d) standard phrases (R-phrases) indicating the special risks arising from the dangers involved in using the substance. The wording of those R-phrases shall comply with that laid down in Annex III of the Directive. The R-phrases to be used for each substance shall be as indicated in Annex I of the Directive. For dangerous substances not yet appearing in Annex I of the Directive the R-phrases to be used shall be assigned according to the rules laid down in Annex VI of the Directive;

(e) standard phrases relating to the safe use of the substance (S-phrases). The wording of these S-phrases shall comply with that laid down in Annex IV of the Directive. The S-phrases to be used for each substance shall be as indicated in Annex I of the Directive. For dangerous substances not yet appearing in Annex I of the Directive, the S-phrase to be used shall be assigned according to the rules laid down in Annex VI of the Directive;

(f) the EC number, when allocated. The EC number shall be obtained from the EINECS or from the list referred to in Article 21 (1) of the Directive. In addition, as regards substances appearing in Annex I of the Directive, the label shall also include the words "EC label".

20.3 In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of R-phrases and S-phrases need not be given where the package does not contain more than 125 ml.

This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

20.4 Indications such as “non-toxic”, “non-harmful” or any other similar indications must not appear on the label or packaging of substances subject to this Directive.

Implementation of
Labelling
Requirements.

21.1 Where the particulars required by regulation 20 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

| <i>Capacity of the package</i> | <i>Dimensions (in millimetres)</i> |
|---|--|
| not exceeding 3 litres | at least 52 x 74 |
| greater than 3 litres but not exceeding 50 litres | at least 74 x 105 |
| greater than 50 litres but not exceeding 500 litres | at least 105 x 148 |
| greater than 500 litres | at least 148 x 210 |

Each symbol shall cover at least one-tenth of the surface area of the label but not be less than 1 cm². The entire surface of the label shall adhere to the package immediately containing the substance.

These dimensions are intended solely for provisions of the information required by these regulations and if necessary of any supplementary health or safety indications.

21.2 A label is not required where the particulars are clearly shown on the package itself, as specified in regulation 21.1.

21.3 The colour and presentation of the label - or, in the case of regulation 21.2, of the package - shall be such that the danger symbol and its background stand out clearly.

21.4 The information required on the label under regulation 20 shall stand out clearly from its background and shall be of such size and spacing as to be easily read. Any specific provisions regarding the presentation and dimensions of this information laid down in Annex VI of the Directive shall be observed.

21.5 Dangerous substances may only be placed on the market if they are labelled in at least one of the official languages of Malta.

21.6 For the purpose of these regulations, 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 substances and the inner package or packages are labelled in accordance with these regulations;

(b) in the case of a single package:

- if such a package is labelled in accordance with international rules on the transport of dangerous substances and with regulation 20.2 (a), (b), (d), (e) and (f), and

- where appropriate, for particular types of packaging such as mobile gas cylinders, in accordance with the specific requirements referred to in Annex VI of the Directive.

Where dangerous substances do not leave the territory of Malta, labelling which complies with national rules instead of with international rules on the transport of dangerous substances shall be permitted.

22.1 Regulations 19, 20 and 21 shall not apply to the provisions governing munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect. Exemptions from labelling and packaging requirements.

23.1 Any advertisement for a substance which belongs to one or more of the categories referred to in regulation 3.2 is prohibited if no mention is made therein of the category or categories concerned. Advertisement.

24.1 To enable professional users in particular to take the necessary measures as regards the protection of the environment and health and safety at the workplace, at, or if appropriate, before the first delivery of a dangerous substance, any manufacturer, importer or distributor shall communicate to the recipient a safety data sheet. This sheet must contain the information necessary for protection of man and the environment. Safety Data Sheet.

It may be communicated on paper or electronically. Subsequently, the manufacturer, importer or distributor shall forward to the recipient of the safety data sheet any new relevant information on the substance which has become known to him.

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Safeguard Clausc.

25.1 Where, in the light of new information, the competent authority has justifiable reasons to consider that a substance, which has been accepted as satisfying the requirements of these Regulations, nevertheless constitutes a danger for man or the environment, by reason of classification, packaging or labelling which is no longer appropriate, it may temporarily reclassify or, if necessary, prohibit the placing on the market of that substance or subject it to special conditions.