L.N. 40 of 2002

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

Dangerous Substances (Risk Assessment) Regulations, 2002

IN exercise of the powers conferred by article 38 of the Product Safety Act, 2001 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 these regulations is the Dangerous Substances (Risk Assessment) Regulations, 2002.

1.2 These regulations shall come into effect as from 1st March, 2002.

Applicability.

2.1 These regulations lay down general principles for the assessment of the risks posed by substances to man and the environment as required by regulation 4.2 of the Dangerous Substances (Notification) Regulations, 2001. L.N. 318 of 2001.

Definitions.

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

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

"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;

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

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

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

modifications to the classification, packaging or labelling of the substance proposed by the notifier in the notification submitted in accordance with regulations 8.1, 9.1 or 9.2 of the Dangerous Substances (Notification) Regulations, 2001;

modifications to the safety data sheet proposed by the notifier in the notification submitted in accordance with regulations 8.1, 9.2 or 9.2 of the Dangerous Substances (Notification) Regulations, 2001;

modifications to the recommended methods and precautions or emergency measures, as set out in sections 2.3, 2.4 and 2.5 of Annex VIIA, VIIB or VIIC of Directive 67/548/EEC, proposed by the notifier in the technical dossier of the notification submitted in accordance with regulations 8.1, 9.2 or 9.2 of the Dangerous Substances (Notification) Regulations, 2001;

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

"competent authority" shall mean the Directorate responsible for chemicals within the Malta Standards Authority;

"Directive" shall mean Commission Directive 93/67/EEC of the European Community.

Principles of risk assessment.

4.1 The risk assessment shall entail hazard identification and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterization. It shall normally be conducted in accordance with the procedures set out in regulations 5 and 6.

4.2 Notwithstanding regulation 4.1, in relation to particular effects, such as ozone depletion, for which the procedures set out in regulations 5 and 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis.

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

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

4.4.1 The substance is of no immediate concern and need not be considered again until further information is made available in accordance with regulation 8.2, 9.3, 9.4 or 15.1 of the Dangerous Substances (Notification) Regulations, 2001.

4.4.2 The substance is of concern and the competent authority shall decide what further information is required for revision of the assessment but shall defer a request for that information until the quantity placed on the market reaches the next tonnage threshold as indicated in regulation 8.2, 9.3 or 9.4 of the Dangerous Substances (Notification) Regulations, 2001.

4.4.3 The substance is of concern and further information shall be requested immediately.

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

4.5 When the risk assessment indicated that the conclusions at regulation 4.4.2, 4.4.3 or 4.4.4 above apply, the notifier may be informed by the competent authority of its conclusions and be given the opportunity to comment on those conclusions and to provide additional information.

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

Risk assessment: human health.

5.1 For each substance notified in accordance with regulation 8.1, regulation 9.1 or regulation 9.2 of the Dangerous Substances (Notification) Regulations, 2001, the competent authority shall carry out a risk assessment, the first stage of which shall be hazard

identification which shall address, as a minimum, the properties and potential adverse effects specified in Annexes IA and IIA of the Directive. Having conducted the hazard identification, the competent authority shall proceed to the following sequence of actions which shall be carried out in accordance with the guidelines set out in Annexes IB and IIB of the Directive:

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

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

5.1.2 risk characterization.

5.2 In derogations from regulation 5.1:

5.2.1 if the test appropriate to hazard identification in relation to a particular effect or property has been conducted and the results have not led classification of the substance in accordance with the Dangerous Substances (Notification) Regulations, 2001, the risk assessment in relation to that effect or property need not include the actions at regulation 5.1.1 and 5.1.2 and the conclusion at regulation 4.4.1 shall apply, unless there are other reasonable grounds for concern; and

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

Risk assessment: environment.

6.1 For each substance notified in accordance with regulation 8.1, 9.1 or 9.2 of the Dangerous Substances (Notification) Regulations, 2001, the competent authority shall carry out a risk assessment in relation to its environmental effects, the first stage of which shall be hazard identification. Having conducted the hazard identification, the competent authority shall proceed to the following sequence of actions which shall be carried out in accordance with the guidelines set out in Annex III of the Directive:

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

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

6.1.2 risk characterization.

6.2 In derogation from regulation 6.1:

6.2.1 for substances notified in accordance with regulation 8.1 of the Dangerous Substances (Notification) Regulations, 2001 but not classified dangerous for the environment, the risk assessment need not include the actions at regulation 6.1.1 and 6.1.2 and the conclusion at regulation 4.4.1 shall apply, unless there are other reasonable grounds for concern; and

6.2.2 for substances notified in accordance with regulation 9.1 or 9.2 of the Dangerous Substances (Notification) Regulations, 2001, if there are insufficient data to determine whether classification as dangerous for the environment is appropriate, the hazard identification shall entail consideration of whether there are any reasonable grounds for concern in relation to environmental effects on the basis of other data, e.g. data on physico-chemical and toxic properties. Unless there are such reasonable grounds, the risk assessment need not include the actions at regulation 6.1.1 and 6.1.2 and the conclusion at regulation 4.4.1 shall apply.

Risk assessment: conclusions.

7.1 Having carried out a risk assessment in accordance with regulations 5 and 6 and in conformity with Annexes I, II and III of the Directive, the competent authority shall determine, in conformity with Annex IV of the Directive, which of the four conclusions of regulation 4.4 is or are applicable and take action as described in regulation 4.5 if appropriate.

7.2 Where additional information is received in accordance with regulations 8.2, 9.3, 9.4, 15.1 or 17 of the Dangerous Substances (Notification) Regulations, 2001 or otherwise, the risk assessment carried out in accordance with regulations 5 and 6 and in conformity with Annexes I, II and III of the Directive shall be reviewed and, if necessary, revised.