L.N. 323 of 2004

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Further Provisions for Product Withdrawal and Recall Regulations, 2004

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Competitiveness and Communications, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Further Provisions for Product Withdrawal and Recall Regulations, 2004.

Scope.

2. These regulations shall apply to any product as defined by the Act.

Definitions.

3. For the purposes of these regulations, all the definitions of the Act shall apply, and in addition:

"dangerous product" means any product which does not meet the definition of "safe product" in article 2 of the Act;

"MSA Directorates [1]" means the Consumer and Industrial Goods Directorate and the Foodstuffs Chemicals and Cosmetics Directorates of the Malta Standards Authority;

"RAPEX" means the European Community Rapid Information System;

"recall" means any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor;

"serious risk" means any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities;

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[1] L.N. 213 of 2000 – Malta Standards Authority (Establishment of Directorates) Order, 2000, published in Government Gazette No. 17,002 of 20th October, 2002.

"the Directive" means Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety;

"under normal or foreseeable conditions of use" also includes, where applicable, the putting into service, the installation and the maintenance requirements;

"withdrawal" means any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer.

Information on non-compliant products.

4. (1) In order to ensure compliance with the general safety requirements under article 7(1) of the Act or under any other requirement of the Community rules on the product in question, any producer or distributor shall immediately forward to the Director any information in their possession in terms of article 7(1) of the Act.

(2) In the event of serious risks, this information shall at least include the following:

(a) information enabling a precise identification of the product or batch of products in question;

(b) a full description of the risk that the products in question present;

(c) all available information relevant for tracing the product;

(d) a description of the action undertaken to prevent risks to consumers.

Exchanges of information and rapid intervention situations.

5. (1) Where the Director takes measures which restrict the placing on the market of products, or which require their withdrawal or recall, including those provided for in Part III of the Act, he shall, subject to the provisions of regulation 6 hereunder or any specific Community legislation, inform the Director of Market Surveillance of any such measures and of any modification or lifting thereof.

(2) If the Director considers that the effects of the risk do not or cannot go beyond the Maltese territory, he shall inform the Director of Market Surveillance who shall notify such measures

to the Commission as long as such information would be relevant with regards to product safety, and in particular, if such measures would have been occasioned by the necessity to respond to a new risk which has not yet been reported in other notifications.

(3) Where the Director adopts or decides to adopt, recommends or agrees with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within the Maltese territory, of products by reason of a serious risk, he shall immediately notify the Director of Market Surveillance of such measures or actions and of any modification or lifting thereof.

(4) If the Director considers that the effects of the risk do not, or cannot go beyond, its territory he shall follow the procedure laid down in sub-regulations (1), and (2) hereof, taking into account the relevant criteria established in regulation 6 (7) of these regulations.

(5) In the case of a serious risk, the Director shall notify the Director of Market Surveillance of the voluntary measures laid down in Article 5 of the Directive and in article 6 (2) of the Act, as taken by producers and distributors.

(6) Without prejudice to sub-regulation (1) and (3) of these regulations, before deciding to adopt any measures or take any action, the Director shall pass on any information in his possession regarding the existence of a possible serious risk to the MSA Directorates and to the Director of Market Surveillance.

(7) When the Director, after analysing all technical details including any possible technical advice given by the MSA Directorates and after consultation with the Director of Market Surveillance, decides that there is a serious risk, he shall communicate such decision to the MSA Directorates and to the Director of Market Surveillance who in turn shall communicate such notification to the Commission through the RAPEX system.

Procedures for the application of RAPEX.

6. (1) RAPEX shall cover products as defined in article 2 of the Act that pose a serious risk to the health and safety of consumers.

(2) RAPEX is essentially aimed at a rapid exchange of information between Member States in the event of a serious risk. Regulation 6 (7) of these regulations, define specific criteria for identifying serious risks.

(3) When a notification is being effected under regulation 5 (3) of these regulations, all available details shall be provided in such manner that -

(a) in particular, the notification shall contain the information stipulated in the guidelines referred to in regulation 6 (7) of these regulations, and including:

(i) information enabling the product to be identified;

(ii) a description of the risk involved, including a summary of the results of any tests and, or analyses and of their conclusions which are relevant to assessing the level of risk;

(iii) the nature and the duration of the measures or action taken or decided on, if applicable;

(iv) information on supply chains and distribution of the product, in particular on destination countries;

(b) such information shall be transmitted using the special standard notification form and by the means stipulated in the guidelines in regulation 6 (7) of these regulations;

(c) when the measure notified pursuant to regulations 5 (1) or 5 (3) of these regulations seeks to limit the marketing or use of a chemical substance or preparation, either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available, shall be provided as soon as possible. The anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93(3) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC – LN 318 of 2001, as last amended - in the case of a new substance shall also be communicated. The guidelines referred to in regulation 6 (7) of these regulations, shall define the details and procedures for the information requested in that respect.

(4) When the Director has informed the Director of Market Surveillance, in accordance with regulation 5 (5) of these regulations, of a serious risk before deciding to adopt measures, the

Director of Market Surveillance shall inform the Commission within 45 days whether this information has been confirmed or modified.

(5) Upon receipt of any notification referred to in regulation 5 of these regulations, the Director of Market Surveillance shall inform the Commission, at the latest within the set period of time stipulated in the guidelines referred to in regulation 6 (7) of these regulations, of the following:

(a) whether the product has been marketed in the Maltese territory;

(b) what measures concerning the product in question are being adopted in the light of the country's circumstances, stating the reasons, including any differing assessment of risk or any other special circumstance justifying the decision, in particular lack of action or of follow-up;

(c) any relevant supplementary information he has obtained on the risk involved, including the results of any tests or analyses carried out:

Provided that the guidelines, referred to in regulation 6 (7) of these regulations, shall provide precise criteria for notifying measures limited to the national territory and shall specify how to deal with notifications concerning risks which are considered by the Member State not to go beyond its territory.

(6) The Commission shall be immediately informed of any modification or lifting of any measure or action in question.

(7) Guidelines concerning the management of RAPEX by the Commission and the Member States shall be prepared and regularly updated. The procedure used shall be that laid down in Article 15 (3) of the Directive.

7. (1) Any export from Malta of dangerous products may be prohibited: Export ban.

Provided that any export from Malta of dangerous products which have been the subject of a decision referred to in paragraph 1 of Article 13 of the Directive, shall be prohibited unless the decision provides otherwise.

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