NB: Unofficial translation; legally binding texts are those in Finnish and Swedish

Government Decree amending the Chemicals Decree

555/2001

Section 1 - Scope of application

(1) This Decree contains provisions on the application of the Chemicals Act to:

- 3) the classification, packaging and labelling of chemicals (substances and preparations);
- 4) the duty to provide information and the chemical register, and
- 5) the advertising of dangerous chemicals.
- (2) This Decree does not apply to the following preparations that are ready for use by end users:

7) medical equipment installed inside the human body (invasive equipment) or medical equipment used in direct contact with the human body in cases where special legislation covering such equipment provides the same level of protection concerning these chemicals in respect of labelling and safety data sheets as in the chemicals legislation.

(3) The requirements concerning packaging safety and labelling referred to in sections 15 and 16 do not apply to explosives.

Section 2 - Definitions

The following definitions are used in this Decree:

4) intermediate means a chemical substance that is solely produced and fully consumed or used in a chemical process with the aim of converting the substance into another chemical substance;

6) placing on the market means making the substance available to third parties; placing on the market also includes importation into the customs territory of the European Community;

Section 4 - Testing and evaluation of properties

(1) Chemicals testing referred to in this Decree shall be carried out in accordance with generally accepted testing methods, as stipulated in more detail by Ministry of Social Affairs and Health decree.

Laboratory tests shall be carried out in compliance with good laboratory practice, as stipulated in section 57 of the Chemicals Act. Proof of good laboratory practice is not, however, required in the testing of the physical-chemical properties of preparations.

- (2) When information on an existing substance has been acquired through testing methods other than those referred to above, the establishment must decide whether the chemical can be classified and labelled on the basis of such information.
- (3) After consulting the Ministry of the Environment, the Ministry of Social Affairs and Health may issue instructions on the procedure to be used in assessing the risk posed by the new substance to health and the environment.

Section 6 - Duty to obtain information

Manufacturers, importers and distributors shall obtain the essential information available on the properties of dangerous substances that are included in a list of commercially used substances but not mentioned in the list of substances referred to in section 5. Using this information as a basis, the chemicals must be classified, packed and labelled in accordance with the provisions of this Decree.

- (2) Classifications and labelling made by the manufacturer, importer or distributor as referred to in subsection 1 are valid until otherwise laid down in the list of substances.
- Section 8 Placing a new notified substance on the market
- Section 9 Exceptions concerning the notification of a new substance

Section 10 - Follow-up data on a new substance

Section 11 - Reference to the notification of a new substance

Section 12 - Handling the notification of a new substance

Section 15 - Packaging

(1) Dangerous chemicals shall not be placed on the market or supplied for use unless their packaging meets the following requirements:

5) packaging that contains a chemical specified by Ministry of Social Affairs and Health decree and intended for retail sale must have a child-resistant fastening (safety fastening) and a tactile warning of danger for the visually impaired as laid down by Ministry of Social Affairs and Health decree; and

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(2) Except for the special packaging requirements laid down in paragraph 5, packaging of preparations is deemed to be in accordance with this Decree if it meets the requirements covering transport of dangerous substances by rail, road, sea or air or on inland waterways.

Section 16 - Labelling

(1) A dangerous chemical shall not be placed on the market or supplied for use unless the labelling on its packaging meets the requirements laid down in this section.

(2) The following information shall be marked clearly and indelibly on the packaging:

- 2) the name, address and telephone number of the undertaking located in the European Community that is responsible for the placing of the chemical on the market or its supply for use;
- 3) dangerous substances contained in the preparation as laid down by Ministry of Social Affairs and Health decree;

- 9) other labelling required for safe use of the chemical as laid down by Ministry of Social Affairs and Health decree.
- (3) The packaging of chemicals referred to in this Decree shall not carry the indications 'non-toxic', 'harmless', 'environmentally friendly', 'ecological' or other such labelling suggesting that the chemical is not dangerous. However, this does not apply to labelling on pesticides referred to in the Pesticides Act for which separate provisions in the pesticide legislation apply.
- (4) The packaging of dangerous chemicals referred to in section 17(3)(2) of the Chemicals Act shall display the labelling laid down in subsection 1(1),(2) and (9). Such labels shall also be displayed on preparations not classified as dangerous but that must be equipped with a safety fastening or a tactile warning of danger for the visually impaired. The information contained in paragraphs 1 and 2 shall

- also be displayed on preparations referred to in paragraph 9 that are not classified as dangerous.
- (5) In addition to the above-mentioned information, the packaging of pesticides referred to in the Pesticides Act shall also display the labelling specified in conjunction with the approval of the pesticide concerned and the text: 'Noudata käyttöohjeita ihmisille ja ympäristölle aiheutuvien vaarojen välttämiseksi'. 'För att undvika risker för människor och miljö, följ bruksanvisningen'(Follow the instructions so that danger to humans and the environment can be minimized).
- (6) An exception can be made to the displaying of danger symbols on separately specified preparations dangerous to the environment, as laid down by Ministry of Social Affairs and Health decree, if the preparation can be shown to be environmentally sound.

Section 17 - Advertising

(2) In distance marketing, in which a purchase contract can be concluded without first seeing the labelling on a preparation, consumer advertising of preparations shall state the name or names of the danger symbols as laid out in the provisions on labelling. However, this requirement does not restrict the application of consumer protection legislation in distance marketing.

Section 18 - Safety data sheet

(1) An establishment responsible for the placing of a dangerous chemical referred to in section 17(3)(1) of the Chemicals Act on the market or its supply for use shall submit a safety data sheet to the recipient of the chemical when the chemical is supplied for the first time.

- (2) When placing a dangerous, non-classified preparation referred to in section 17(3)(2) of the Chemicals Act on the market or supplying it for use, the undertaking shall supply a safety data sheet on request.
- (3) The safety data sheet shall include the following headings and the corresponding information:
 - 1) identification details of the chemical and of the establishment located in the European Community;

8) exposure prevention and personal protection.

Section 19 - Supplying information on chemicals

(2) The National Product Control Agency for Welfare and Health may transmit the confidential information thus received on the composition of the preparation to the Poison Information Centre for the issue of instructions on how to treat poisoning.

Section 23 - Local supervision

It is the duty of the municipal supervisory authority for chemicals to see that:

- 1) chemicals to be placed on the market are classified and packed, and their packages labelled as laid down in the Decree;
- 2) safety data sheets are drawn up on chemicals and that notifications of new substances are submitted; and that
- 3) the information on chemicals referred to in section 17(3) of the Chemicals Act has been supplied to the product register of the chemical register.

This Decree enters into force on July 1, 2001.