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

Chemicals Decree

(675/1993; amendments up to 555/2001 included)

Section 1 - *Scope of application*

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

1) notification regarding a new substance;

2) assessment of the risk posed by a new substance to human health and the environment;

3) the classification, packaging and labelling of chemicals (substances and preparations); (555/2001)

4) the duty to provide information and the chemical register, and (555/2001)

5) the advertising of a dangerous chemical. (555/2001)

(2) This Decree does not apply to the following preparations that are ready for use by end users:

1) medicinal products intended for humans or for animals;

2) cosmetic products;

3) foodstuffs;

4) alcoholic beverages;

5) animal feedingstuffs;

6) radioactive substances; or

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. (555/2001)

(3) The requirements concerning packaging safety and labelling referred to in sections 15 and 16 do not apply to explosives. (555/2001)

(4) Similarly, the Decree does not apply to waste.

Section 2 – *Definitions*

In this Decree,

1) *substance* means chemical elements and their compounds, including the additives necessary to preserve the stability of the substance and the impurities deriving from the production process, but excluding solvents which may be separated without affecting the stability of the substance or changing its composition;

2) *preparation* means a mixture consisting of two or more substances;

3) *polymer* means a substance consisting of molecules characterized by the sequence of one or more types of monomer units; most of the polymer molecules must consist of at least three monomer units covalently bound to another monomer unit or to some other molecule group; most of the weight of a polymer must consist of molecules of different weights, and the polymer molecules must be distributed over a range of molecular weights, with the differences in the molecular weights mostly deriving from differences in the number of monomer units;

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; (555/2001)

5) *notification* of a new substance means documents presented to the competent authorities of the parties to the Agreement on the European Economic Area (EEA Agreement) in accordance with the European Communities (EC) Council Directive (67/548/EEC) on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; the documents are supplied by:

a) the manufacturer of a new substance that is manufactured within the area of the contracting parties of the EEA Agreement and that is placed on the market either as such or as part of a preparation; or

b) for a new substance that is manufactured outside the area of the contracting parties to the EEA Agreement and that is placed on the market either as such or as part of a preparation, an undertaking that places the substance on the market or an undertaking that the manufacturer of the substance has designated to submit the notification of the substance as his sole representative;

1) *notifier* means an undertaking that submits the notification referred to above in paragraph 5; depending on the amount of the substance, the notification is called a full or a reduced notification;

2) *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; (555/2001)

3) *scientific research and development* means scientific experimentation, analysis or chemical research carried out under controlled conditions, including determination of intrinsic properties, performance and efficacy of a substance, and scientific investigation related to product development;

4) *process-orientated research and development* means operations related to product development, during which the field of application of the substance is tested by means of production trials or pilot plants;

10) *inventory of existing commercial chemical substances* (EINECS; European Inventory of Existing Commercial Chemical Substances) means a list of the substances deemed to be on the Community market on September 18, 1981.

Section 3 - *Categories of dangerous chemicals*

(1) Dangerous chemicals (substances and preparations) referred to in section 11 of the Chemicals Act are divided into the following categories:

1) *explosive chemicals*: solid, liquid, pasty or gelatinous substances and preparations which may, without an external source of oxygen, react exothermically thereby quickly evolving gases, and which, under defined test conditions, explode when they are heated in a partly closed space or for some other reason;

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

3) *extremely flammable chemicals*: liquid substances and preparations having an extremely

low flash-point and a low boiling point, and gaseous substances and preparations that form a flammable mixture in contact with air at ambient temperature and pressure;

4) *highly flammable chemicals*:

a) substances and preparations that may become hot and catch fire in contact with air at ambient temperature without any application of energy;

b) solid substances and preparations that may readily catch fire after brief contact with a source of ignition and continue to burn after removal of the source of ignition;

c) liquid substances and preparations that have a very low flash-point; or

d) substances and preparations that, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

5) *flammable chemicals*: liquid substances and preparations having a low flash-point;

6) *very toxic chemicals*: 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;

7) *toxic chemicals*: substances and preparations which in low quantities cause death or acute or

chronic damage to health when inhaled, swallowed or absorbed via the skin;

8) *harmful chemicals*: substances and preparations that may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

9) *corrosive chemicals*: substances and preparations which may, on contact with living tissue, destroy it;

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

11) *sensitizing chemicals*: substances and preparations which may, when inhaled or absorbed via the skin, be capable of eliciting sensitization so that further exposure to the substance or preparation results in characteristic adverse effects;

12) *carcinogenic chemicals*: substances and preparations which may induce cancer or increase its incidence when inhaled, ingested or absorbed via the skin;

13) *mutagenic chemicals*: substances and preparations that may induce heritable genetic defects or increase their incidence when inhaled, ingested or absorbed via the skin;

14) *chemicals toxic for reproduction*: substances and preparations which may produce, or increase the incidence of, non-heritable adverse effects in the progeny or an impairment of male or female reproductive functions and capacity when inhaled, ingested or absorbed via the skin; and

15) *chemicals dangerous for the environment*: substances and preparations which may present an immediate or delayed danger to the environment or to a component of it on entering the environment.

(2) The chemicals referred to above in subsection 1(1-5) pose a danger of fire or explosion, the chemicals referred to in subsection 1(6-14) pose a danger to health, and the chemicals referred to in subsection 1(15) pose a danger to the environment.

Section 4 - *Testing and evaluation of properties* (555/2001)

(1) Chemicals testing referred to in this Decree must 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 must 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 undertaking 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 5 - *Classification and labelling*

(1) A manufacturer, importer, distributor or any other undertaking responsible for placing of the chemical on the market or its supply for use must classify the chemical in accordance with the categories referred to in section 3 and label the packaging of the chemical as stipulated in this Decree.

(2) A chemical mentioned in the list (*list of substances*) referred to in section 11(4) of the Chemicals Act must be classified and labelled as stipulated in the list.

(3) When a substance is classified, impurities are taken into account when their contents exceed the limits given in the Ministry of Social Affairs and Health decision on classification principles and labelling or in the list of substances.

Section 6 - *Duty to obtain information* (555/2001)

(1) Manufacturers, importers and distributors must 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 7 - *Notification of a new substance*

(1) In a notification referred to in section 20 of the Chemicals Act, the notifier must provide the following information:

1) technical dossier needed for assessing the risk caused by the substance;

2) a declaration concerning the unfavourable effects that may be related to the various foreseeable uses of the substance;

3) proposed classification and labelling of the substance;

4) a proposal for a safety data sheet for a dangerous substance;

5) the notifier’s identity; and

6) other data required in the Ministry of Social Affairs and Health decision.

(2) The Ministry of Social Affairs and Health shall issue more detailed regulations on the notification procedure and on the technical dossier to be included in the notification, and on the detailed contents of the notification, based on the amounts of substance manufactured and imported.

(3) If at least 10 years have passed since the first notification concerning a new substance, the notification must only contain data on the identity and use of the substance and on the safety precautions related to its use, as stipulated by decision of the Ministry of Social Affairs and Health.

Section 8 (1153/1994) - *Placing a new notified substance on the market* (555/2001)

(1) A substance on which the full notification has been submitted may be placed on the market no sooner than 60 days after the National Product Control Agency for Welfare and Health has received the information and studies required by the Decree, unless otherwise informed by the Product Control Agency. If the notification is deficient, the substance may be placed on the market 60 days after the Product Control Agency has received a new notification supplemented to comply with the requirements of this Decree.

(2) A substance on which a reduced notification has been submitted may be placed on the market no sooner than 30 days after the National Product

Control Agency for Welfare and Health has received the information and studies required by this Decree, unless otherwise informed by the Product Control Agency. If the notification is deficient, the substance may be placed on the market 30 days after the Product Control Agency has received a new notification supplemented to comply with the requirements of this Decree. If the notifier has, however, received information that the notification is in conformity with the requirements of the Decree, the substance may be placed on the market no sooner than 15 days after the Product Control Agency has received the notification.

Section 9 – *Exceptions concerning the notification of a new substance* (555/2001)

(1) The notification referred to in section 20 of the Chemicals Act need not be submitted on the following substances:

1) substances which appear in the inventory of existing commercial substances;

2) additives and substances for exclusive use in animal feedingstuffs;

3) substances used exclusively as additives in foodstuffs and substances used exclusively as flavourings in foodstuffs;

4) active ingredients used exclusively in medicinal products; these substances do not, however, include chemical intermediates;

5) substances used exclusively in certain product sectors when these products are covered by other notification and approval procedures and the relevant requirements for data submission are equivalent to those requirements stipulated in this Decree.

(2) The Ministry of Social Affairs and Health shall issue detailed regulations on the application of the notification duty to substances referred to in subsection 1(5), polymers, small amounts of substances, scientific research and development and process-orientated research and development.

Section 10 - *Follow-up data on a new substance* (555/2001)

(1) The notifier must submit the following information to the National Product Control Agency for Welfare and Health in writing: (1153/1994)

1) changes in the annual quantities or total quantities of the substance placed on the market within the European Economic Area, or if the substance that the notifier represents as the sole representative is manufactured outside the European Economic Area, changes in the quantities of substance placed on the market by the notifier or other parties;

2) any new knowledge on the effects of the substance on health or the environment that the notifier can reasonably be expected to have become aware of;

3) new uses that the notifier can reasonably be expected to have become aware of;

4) changes in the composition of the substance; and

5) changes in the status of the notifier as manufacturer or importer.

(2) If the substance is manufactured outside the European Economic Area and the manufacturer’s sole representative has previously submitted a notification on the substance, any other importer importing the substance on the basis of the same notification must provide the manufacturer’s sole representative with up-to-date information on the quantities of substance it places on the European Economic Area market.

Section 11 - *Reference to the notification of a new substance* (555/2001)

(1) A notifier need not submit data on the physical and chemical properties of a substance or on its effects on health or the environment if the notifier can show that the notification concerns a substance that, in both its degree of purity and nature of impurities, is identical with a substance on which someone has already made a notification.

(2) The new notifier must obtain written agreement from the first notifier for use of the submitted data.

(3) The Ministry of Social Affairs and Health shall issue more detailed regulations on reference to a notification, on how to avoid duplicating laboratory animal testing required for the notification, and on the related procedures.

Section 12 - *Handling the notification of a new substance* (555/2001)

(1) Within 60 days of receiving a full notification and within 30 days of receiving a reduced notification, the National Product Control Agency for Welfare and Health shall decide whether the notification is in conformity with the requirements. If the notification is deficient, the Product Control Agency shall inform the notifier about what further information is required to supplement the notification. If the notification is in conformity with the requirements, the Product Control Agency shall advise the notifier of the official number which has been allocated for the notification within the same period of time. (1153/1994)

(2) When necessary, the National Product Control Agency for Welfare and Health shall request statements from the Finnish Environment Institute and other supervisory authorities referred to in the Chemicals Act in order to assess the danger posed by the new substance. (864/2000)

(3) The National Product Control Agency for Welfare and Health and the authorities giving their statements in their respective fields shall assess the risks posed by the new substance. If an authority

mentioned in subsection 2 demands that additional studies be made, this authority shall also make a recommendation on the test method to be used. In addition, the authorities shall, when necessary, give a recommendation for measures whereby the risk to health and the environment resulting from placing of the substance on the market can be reduced. If additional information is provided on a new substance, the risks caused by the substance must be reassessed if necessary. (1153/1994)

(4) The Ministry of Social Affairs and Health publishes an annual list (*list of notified substances*) on the substances on which notification has been submitted to the competent authorities of the European Economic Area. In this publication, the Ministry of Social Affairs and Health may refer to the corresponding European Economic Community list.

Section 13 was repealed by Decree 697/1999.

Section 14 (1153/1994) – *Listing of notified substances* (697/1999)

(1) Substances appearing in the list of notified substances and which are not classified as dangerous in accordance with this Decree may be included on the list under their trade names for a maximum of three years. The National Product Control Agency for Welfare and Health may decide that the substance may be recorded on the list under its trade name for more than three years if publication of a chemical name in accordance with the IUPAC (International Union of Pure and Applied

Chemistry) nomenclature could reveal the notifier’s business or trade secrets.

(2) The National Product Control Agency for Welfare and Health may request to keep dangerous substances on the list under their trade names only until the substances are included in the list of substances.

Subsection 3 was repealed by Decree 697/1999.

Section 15 – *Packaging*

Dangerous chemicals must not be placed on the market or supplied for use unless their packaging meets the following requirements:

1) the packaging must be designed and constructed so that its contents cannot escape;

2) the packaging and the fastenings must be made of materials that are not affected adversely by the contents and do not form dangerous compounds with the contents;

3) the packaging and the fastenings must be strong and solid enough to ensure that they do not loosen and that they are able to withstand the strains and stress caused by normal handling:

4) a packaging with a replaceable fastening device must be so designed and constructed that the packaging can be refastened repeatedly without the contents escaping;

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 (555/2001)

6) a packaging containing a dangerous chemical may not be offered or sold to consumers if the shape or graphic decoration on the packaging could attract a child or arouse the curiosity of a child or could mislead the user of the chemical, or if the appearance or design of the packaging is similar to the packaging of a foodstuff or some other product intended for ingestion, an animal feedingstuff, a medical product or a cosmetic product.

(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. (555/2001)

Section 16 – *Labelling*

(1) A dangerous chemical may not be placed on the market or supplied for use unless the labelling on its packaging meets the requirements laid down in this section. (555/2001)

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

1) the trade name or some other designation of the preparation; in the case of a substance, the packaging must show the name given in the list of substances, and if the substance is not included in the list of substances, the name must be given in accordance with an internationally recognised nomenclature;

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; (555/2001)

3) dangerous substances contained in the preparation as laid down by Ministry of Social Affairs and Health decree; (555/2001)

4) danger symbols and indications of danger;

5) risk phrases (R phrases);

6) safety phrases (S phrases);

7) the EC number of the substance, which means an indication used for the substance in the European Community and appearing in the list of substances, provided that an indication of this kind has been allocated for the substance in the list of substances or in the list of existing commercial substances; in addition, the label on the packaging of substances included in the list of substances must carry the words ‘EY-merkintä, EG-märkning’ (EC

label); however, this requirement does not apply to the labelling of a preparation; (287/1998)

8) the quantity of the contents of a preparation (mass or volume) if the preparation is intended for retail sale; and

9) other labelling required for safe use of the chemical as laid down by Ministry of Social Affairs and Health decree. (555/2001)

(3) The packaging of chemicals referred to in this Decree may 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 must display the labelling laid down in subsection 1(1),(2) and (9). Such labels must 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 must also be displayed on preparations referred to in paragraph 9 that are not classified as dangerous. (555/2001)

(5) In addition to the above-mentioned information, the packaging of pesticides referred to in the

Pesticides Act must 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). (555/2001)

(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. (555/2001)

Section 17 – *Advertising*

(1) Advertising a substance classified as dangerous is prohibited, unless the advertisement includes information on the danger associated with the substance, in accordance with the definition of danger in section 3.

(2) In distance marketing, in which a purchase contract can be concluded without first seeing the labelling on a preparation, consumer advertising of preparations must 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 the legislation covering consumer protection in distance marketing. (555/2001)

Section 18 - *Safety data sheet*

(1) An undertaking responsible for the placing of a chemical referred to in section 17(3) of the Chemicals Act on the market or its supply for use must 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 must supply a safety data sheet on request. (555/2001)

(3) The safety data sheet must include the following headings and the corresponding information:

1) identification details of the chemical and of the undertaking located in the European Community; (555/2001)

2) composition of the chemical and information on its ingredients;

3) description of hazardous properties;

4) first-aid measures;

5) measures in the event of fire;

6) instructions for preventing release;

7) handling and storage;

8) exposure prevention and personal protection; (555/2001)

9) physical and chemical properties;

10) stability and reactivity;

11) data related to health effects;

12) data on the risk posed by the chemicals to the environment;

13) disposal considerations;

14) transport information;

15) regulatory information; and

16) other information. (555/2001)

Section 19 - *Supplying information on a chemical*

(1) The information referred to in section 48a(1) and (2) of the Chemicals Act must be submitted to the National Product Control Agency for Welfare and Health for registration when the chemical is placed on the market or supplied for use. (369/1998)

(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. (555/2001)

(3) On the basis of section 47(1) of the Chemicals Act, the manufacturer or importer of a chemical shall inform the product register of the chemical register about the quantities of dangerous chemicals manufactured or imported.

Section 20 (864/2000) - *Sub-registers in the chemical register*

The register of chemicals referred to in section 58 of the Chemicals Act will contain the following sub-registers:

1) *A product register*, containing the data referred to in section 48a of the Chemicals Act, section 40a of the Occupational Safety Act (299/1958) and section 19(3) of this Decree;

2) *A chemical preservatives register*, containing data on the chemical preservatives referred to in section 25 of the Chemicals Act and on the notifications regarding chemical preservatives referred to in section 26 of the Chemicals Act;

3) *A permit register*, containing data on the permits and notifications referred to in section 32 of the Chemicals Act.

Section 21 - *Upkeep of the register*

(1) The authorities responsible for the upkeep of sub-registers in the chemical register are as follows:

1) the National Product Control Agency for Welfare and Health is responsible for the product register;

2) the Finnish Environment Institute is responsible for the chemical preservatives register; and

3) the Safety Technology Authority is responsible for the permit register. (369/1998)

(2) The authorities responsible for the upkeep of a sub-register in the chemical register have the right to receive information from other sub-registers.

Section 22 - *Supervision of the import of a chemical*

It is the duty of the Customs authority to see that chemicals whose handling is prohibited in Finland are not imported into the country, and that the notification referred to in section 20 of the Chemicals Act is made regarding new substances imported.

Section 23 (555/2001) - *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.

Section 24 (256/1997) - *Detailed regulations*

The Ministry of Social Affairs and Health may issue more detailed regulations on the enforcement of this Decree.

Section 25 - *Entry into force*

(1) This Decree enters into force on August 1, 1993.

(2) However, section 2(1)(4-6), and sections 7-14 enter in force on January 1, 1994. The requirements concerning a preparation dangerous to the environment, as specified in section 5(1), will enter into force on a date to be stipulated separately. (1308/1993)

(3) The requirements of sections 15 and 16 of this Decree concerning the packaging and labelling of butane, propane and liquefied petroleum gas enter in force on October 1, 1997. (256/1997)

(4) This Decree repeals the Chemicals Decree (620/90) issued on June 29, 1990, as amended. The provisions of sections 34-39 of the previous decree on the advance approval of chemical preservatives, and of

sections 43-46 on the notification duty will continue to apply until separately provided otherwise. (441/1994)

(5) Decisions issued by the Ministry and the National Board of Labour Protection by virtue of the previous decree will be valid until otherwise provided or stipulated. (441/1994)

(6) Measures needed to enforce this Decree can be taken before it enters into force. (441/1994)

Section 26 - *Transitional provisions*

(1) The manufacturer, importer, distributor or any other undertaking responsible for placing a chemical on the market or supplying it for use may place the chemical on the market or supply it for use until the end of June 1994 even if its labelling, packaging or safety data sheet do not meet the provisions of this Decree, provided that the labelling, packaging or safety data sheet comply with the regulations in force when this Decree enters into force.

(2) If the data referred to in section 19(1) on a chemical have been submitted to the National Board of Labour Protection before this Decree enters into force using a safety data sheet that conformed to the provisions of section 18, as it appeared when the Act on the Amendment of the Chemicals Act (1412/1992) entered into force, and the information has not changed, the information required on the chemical according to this Decree shall be

submitted by the end of 1995. Should changes occur to the data submitted to the National Board of Labour Protection, the new information must be submitted to the Ministry of Labour in accordance with section 18 of this Decree as of January 1, 1994.