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

## Government Decree

# On prohibitions and restrictions on carcinogenic, mutagenic and reprotoxic substances

(610/2000)

## Section 1

- (1) This Decree contains provisions on prohibitions and restrictions on carcinogenic, mutagenic and reprotoxic substances as laid down in Appendix 1.
- (2) This Decree does not apply to research, development work or analyses or exports outside the European Economic Area.

## Section 2

- (1) This Decree enters into force on July 1, 2000.
- (2) Chemicals that do not accord with the requirements of this Decree may not be placed on the market after January 1, 2001.
- (3) This Decree repeals the Government Decision of November 25, 1998 on prohibitions and restrictions on carcinogenic, mutagenic and reprotoxic substances (858/1998).

#### APPENDIX 1

Substance or category of substance

1.a. Substances classified as carcinogens of category 1 or 2 in the list of dangerous substances (list of substances) referred to in section 11(4) of the Chemicals Act that carry at least the label 'Myrkyllinen (T)' ('toxic (T)') and the risk phrase R 45 'Aiheuttaa syöpäsairauden vaaraa' ('May cause cancer') or risk phrase R 49 'Aiheuttaa syöpäsairauden vaaraa hengitettynä' ('May cause cancer by inhalation').

Substances referred to in paragraph a are listed in Appendix 2 as follows:

- carcinogens of category 1 in list 1 and
- carcinogens of category 2 in list 2.
- b. Substances classified as mutagens of category 1 or 2 in the list of dangerous substances (list of substances) referred to in section 11(4) of the Chemicals Act that carry at least the risk phrase R 46 'Saattaa aiheuttaa periytyviä perimävaurioita' ('May cause heritable genetic damage').

Substances referred to in paragraph b are listed in Appendix 2 as follows:

- mutagens of category 1 in list 3 and
- mutagens of category 2 in list 4.

c. Substances classified as toxic to reproduction of category 1 or 2 in the list of dangerous substances (list of substances) referred to in section 11(4) of the Chemicals Act that carry the risk phrase R 60 'Voi heikentää hedelmällisyyttä' ('May impair fertility') and/or R 61 'Vaarallista sikiölle' ('May cause harm to the unborn child').

Substances referred to in paragraph c shall be listed in Appendix 2 as follows:

- toxic to reproduction of category 1 in list 5 and
- toxic to reproduction of category 2 in list 6.

#### Prohibition or restriction

A carcinogenic, mutagenic or reprotoxic substance mentioned in Appendix 2 may not be used in a chemical intended to be sold to the general public if the concentration of a substance in it is at least as high as

- the concentration limit defined for the substance in the list of substances, or
- the concentration limits of categories 1 and 2 in Tables 6 and 6a, 7 and 7a, and 8 and 8a of Appendix 2 to the Decision on the classification basis of chemicals and on labelling issued under section 19(2) of the Chemicals Act, in the event that no concentration limit is given in the list of substances.

In addition to other markings, packaging of such chemicals shall be clearly and indelibly labelled 'Vain ammattikäyttöön – Endast för yrkesmässigt bruk' ('Only for professional use').

The restriction does not apply to:

- a) medicinal or veterinary products
- b) cosmetic products
- c) the following fuels:
  - motor fuel, such as petrol,
  - mineral oil products that are intended for use in mobile or fixed combustion plants,
  - fuels sold in closed systems (such as liquid gas bottles); or
- d) artists' paints.

#### APPENDIX 2

Introduction

Name of substance:

The name used in the Decree is the same as that used for the substance in the Ministry of Social Affairs and Health Decree on the list of dangerous substances. Whenever possible, dangerous substances have been defined using the names entered in the European Inventory of Existing Commercial Chemical Substances (EINECS) or the European List of Notified Chemical Substances (ELINCS). Substances not entered in the above lists have been named using an internationally recognized nomenclature (such as ISO or IUPAC). In a few cases, a commonly used name has also been used.

Index number:

The index number is the identification code denoting a substance in the list of dangerous substances. The substances are listed in alphabetical order.

#### EC number:

The European Inventory of Existing Commercial Chemical Substances (EINECS) gives each substance an identification code. The codes start from the number 200-001-8.

Notified substances are given an identification code, which is specified and published in the European List of Notified Chemical Substances (ELINCS). The codes start from the number 400-010-9.

#### CAS number:

For easier identification, each substance is given a CAS (Chemical Abstracts Service) number.

#### Notes:

The full text of the notes is given in the introduction to Appendix 1 of the Ministry of Social Affairs and Health Decree on the list of dangerous substances (paragraph 6, notes).

The following notes apply to this Decree:

#### Note J:

A substance is not classified as carcinogenic if it can be shown that its benzene content is less than 0.1% by mass weight (EINECS number 200-753-7).

#### Note K:

A substance is not classified as carcinogenic if it can be shown that its 1,3-butadiene content is less than 0.1% by weight (EINECS number 203-450-8).

#### Note L:

A substance is not classified as carcinogenic if it can be shown that its content of dimethyl sulphoxide extract (DMSO-extract) is less than 3%, as measured using the IP 346 method.

#### Note M:

A substance is not classified as carcinogenic if it can be shown that its benzo(a)pyrene content is less than 0.005% by mass weight (EINECS number 200-028-5).

## Note N:

A substance is not classified as carcinogenic if all stages of its processing are known and if it can be shown that the substance from which it is produced is not carcinogenic.

## Note P:

A substance is not classified as carcinogenic if it can be shown that its benzene content is less than 0.1% by mass weight (EINECS number 200-753-7