

*The text the Swedish Chemicals Agency reproduces here is a translation of the Swedish text contained in the Swedish Code of Statutes*

In any matters of dispute, the Swedish text only shall apply.

## **The Chemical Products and Biotechnical Organisms Ordinance (1998:941)**

issued 25 June 1998.

The Government stipulates<sup>1</sup> the following:

### **Introductory provisions**

#### **Section 1**

In this Ordinance, “manufacturer” also refers to a party that, in its own name and for further transfer, packages, re-packages or changes the name of a chemical product or biotechnical organism without having imported it into Sweden, manufactured it or otherwise made it.

#### **Section 2**

Particularly dangerous chemical products are divided into extremely dangerous and very dangerous products for the application of Sections 14-20. The Swedish Chemicals Agency shall issue detailed regulations regarding which chemical products will be considered extremely dangerous and very dangerous, respectively.

#### **Section 3**

The Swedish Chemicals Agency may stipulate that the provisions in Chapter 14, Sections 7-9, and Section 24, paragraph 2 of the Environmental Code shall also apply to products which contain, or have been treated with, a chemical product and which, due to their properties, may be feared to cause injury to humans or the environment.

Anyone professionally handling or importing into Sweden a product as referred to in the first paragraph shall, even if a specific regulation has not been issued, comply with the provisions in Chapter 14, Section 8 of the Environmental Code.

#### **Section 4**

This Ordinance shall not apply in respect of cosmetic and hygiene products unless otherwise specifically stipulated in the Cosmetic and Hygiene Products Ordinance (1993:1283).

<sup>1</sup> Cf. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L196/1, Celex 367L0548), most recently amended by Commission Directive 97/69/EC (OJ L343/19) and Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L230/1, Celex 391L0414), most recently amended by Commission Directive 97/73/EC (OJ L353/26, Celex 397L0073).

## **Expertise Requirements**

### **Section 5**

The Swedish Chemicals Agency shall issue such further regulations regarding expertise as necessary for the application of Chapter 2, Section 2 of the Environmental Code with respect to handling, importation and exportation of chemical products and biotechnical organisms.

## **Precautions and product selection**

### **Section 6**

The Swedish Chemicals Agency may, with respect to chemical products and biotechnical organisms, issue further regulations about precautions and product selection pursuant to Chapter 2, Sections 3 and 6 of the Environmental Code.

With respect to the transportation of chemical products, the transport authority concerned shall issue such regulations as referred to in the first paragraph, pursuant to the Transport of Dangerous Goods Ordinance (2006:311) and following consultation with the Swedish Chemicals Agency. *Ordinance (2006:314)*

## **Environmental and health impact assessments**

### **Section 7**

The Swedish Chemicals Agency may issue further regulations about environmental and health impact assessments pursuant to Chapter 14, Section 7 of the Environmental Code.

## **Product information**

### **Section 8**

The Swedish Chemicals Agency shall issue such further regulations about product information as necessary for the application of Chapter 14, Section 8 of the Environmental Code.

## **Obligation to provide information**

### **Section 9**

The Swedish Chemicals Agency shall issue such further regulations about the obligation to provide information as are necessary for the application of Chapter 14, Section 9 of the Environmental Code.

## **Product register**

### **Section 10**

Chemical products and biotechnical organisms which are professionally produced in or imported into Sweden must be registered in the product register in accordance with the provisions in Section 11.

The product register shall be maintained by the Swedish Chemicals Agency.

The provisions of the first paragraph shall not apply in respect of chemical products and biotechnical organisms governed by the Food Act (2006:804), the Medicinal Products Act (1992:859), or the Feeding-Substances Act (2006:805). *Ordinance (2006:847)*.

### **Section 11**

Any chemical product or biotechnical organism which is attributable to any of the types of goods listed in the Annex to this Ordinance shall be reported to the Swedish Chemicals Agency by means of a product report, for registration in the product register.

The product report shall be submitted by the manufacturer or, with respect to chemical products or biotechnical organisms which have been imported into Sweden, by the party responsible for such importation. The Swedish Chemicals Agency may, in individual cases and if it is acceptable from a health and environment perspective, allow a commercial agent to fulfil the obligation to submit the product report in lieu of the party responsible for importation.

A party that annually manufactures or imports into Sweden less than 100 kilogrammes of a chemical product or biotechnical organism need not report the product or organism, unless otherwise stipulated by the Swedish Chemicals Agency.

The obligation to report arises upon the production or importation into Sweden of a chemical product or biotechnical organism.

## **Section 12**

The Swedish Chemicals Agency shall issue such further regulations as are necessary concerning the product register. The Swedish Chemicals Agency may make stipulations about exceptions or, in individual cases, grant exemptions from the provisions in Sections 10 and 11.

## **Prior notification**

### **Section 13**

The Swedish Chemicals Agency shall issue such regulations about prior notification of chemical products as are necessary pursuant to Chapter 14, Section 11 of the Environmental Code.

## **Permits, etc.**

### **Section 14**

Permits, as referred to in Chapter 14, Section 12 of the Environmental Code, are required for:

- 1) the professional importation of extremely dangerous chemical products from countries which are not members of the European Union;
- 2) the professional transfer of particularly dangerous chemical products;
- 3) the importation, other than professional, of particularly dangerous chemical products from countries which are not members of the European Union;
- 4) the handling, other than professional, of particularly dangerous chemical products.

The provisions of the first paragraph do not apply to chemical products and biotechnical organisms governed by the Food Act (2006:804), the Medicinal Products Act (1992:859), or the Feeding-Substances Act (2006:805). *Ordinance (2006:847)*.

### **Section 15**

Heads of institutions or corresponding bodies at universities or higher education units, or of such research laboratories, research institutes or similar as are owned by or receive support from the State, from county councils or municipalities, may import extremely dangerous chemical products necessary for their activities without permits as referred to in Section 14, paragraph 1. Permits for the importation of extremely dangerous chemical products are further not required for parties that are authorised to produce medicinal products in general under the Medicinal Products Act (1992:859).

### **Section 16**

Permits as referred to in Section 14, paragraph 1, item 2) are not required for parties entitled to conduct retail trade in pharmaceutical products pursuant to Section 4 of the Medicinal Products (Trading) Act (1996:1152).

Permits as referred to in Section 14, paragraph 1, items 3) and 4) may be issued only to persons who have attained the age of 18 and who need the products for an artistic, technical, scientific or similar purpose.

### **Section 17**

Matters regarding permits as referred to in Section 14 shall be reviewed, if the applicant conducts a business, by the county administrative board of the county in which the business is conducted, and otherwise by the county administrative board of the county in which the applicant resides. Permits shall be valid for a maximum of five years.

### **Section 18**

Within Sweden, extremely dangerous or very dangerous chemical products may only be transferred to a party that uses such products for professional purposes or holds a permit for other handling. The party that transfers such products shall maintain records regarding the sale, in accordance with regulations issued by the Swedish Chemicals Agency.

### **Section 19**

An extremely dangerous chemical product may not be taken charge of in the manner laid down in Chapter 4, Section 2 of the Customs Act (2000:1281) by any person other than the person entitled to import such a product.

In respect of chemical products which have not cleared Customs, the Transport, Storage, and Destruction of Regulated Imported Goods, etc. Act (1973:980) shall otherwise apply. The Swedish Chemicals Agency shall determine how to deal with an extremely dangerous chemical product which may not be sold under Section 4 of the said Act. *Ordinance (2000:1318)*.

### **Section 20**

The Swedish Chemicals Agency may, if special cause exists, stipulate that the provisions in Sections 14-19 shall also apply to chemical products which are not deemed to be extremely dangerous or very dangerous.

### **Section 21**

The Swedish Chemicals Agency may issue further regulations pursuant to Chapter 14, Section 24, paragraph 2 of the Environmental Code with regard to permit requirements or special conditions for the handling, importation or exportation of chemical products and biotechnical organisms.

## **Authorisation to issue regulations about exceptions and grant exemptions**

**Section 22** The Swedish Chemicals Agency may, if special cause exists, issue regulations about exceptions to the provisions in Sections 14-19. In individual cases, if extraordinary cause exists, the Agency may grant exemptions from the provisions.

Chapter 14, Section 16 of the Environmental Code states that such regulations or decisions regarding exemptions may include requirements for notification before a chemical product is offered for sale or used.

## **Obligation to notify regarding adverse effects**

### **Section 23**

The Swedish Chemicals Agency is the authority which shall be notified with regard to adverse effects, pursuant to Chapter 14, Section 23 of the Environmental Code.

## **Authorisation to issue further regulations**

### **Section 24**

The Swedish Chemicals Agency may issue regulations about such restrictions as are needed due to:

- Regulation (EC) No. 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals;
- Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, most recently amended by Commission Directive 2004/98/EC; and
- Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC. *Ordinance (2005:709)*.

### **Section 25**

The Swedish Chemicals Agency may issue such regulations as are necessary for the implementation of this Ordinance. The Swedish Chemicals Agency may also issue regulations regarding the handling, importation and exportation of chemical products necessary for the implementation of Regulation (EC) No. 304/2003 of the European Parliament and of the Council concerning the export and import of dangerous chemicals. *Ordinance (2004:716)*

### **Section 26**

The Environmental Protection Agency, the National Board of Housing, Building and Planning, and the National Food Administration may, after consultation with the Swedish Chemicals Agency, issue such regulations as referred to in Sections 3, 6, 8, 9, 21 and 25, first sentence, subject to the following conditions:

1) for the Environmental Protection Agency: if cause exists with particular regard to the protection of the environment;

2) for the National Board of Housing, Building and Planning: with respect to construction products, if regulations are needed for the protection of the indoor environment;

3) for the National Food Administration: with respect to materials and products which are intended to come into contact with food, and with respect to dummies. *Ordinance (2006:847)*.

### **Section 27**

Prior to the issuance of restrictions or regulations with implications for transports by any authority other than such transportation authority as referred to in Section 6, paragraph 2, consultation shall take place with the relevant transportation authority pursuant to the Transportation of Dangerous Goods Ordinance (2006:311). *Ordinance (2006:314)*.

## **Competent authority and reporting under EC legislation**

### **Section 28**

The Swedish Chemicals Agency is the competent authority as referred to in

- Article 13 of Council Regulation (EEC) No. 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances;
- Article 4 of Regulation (EC) No. 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals;
- Article 8 of Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents; and
- Article 5 of Directive 2004/42/EC of the European Parliament and of the Council, and
- Article 121 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. (*Ordinance (2007:274)*).

### **Section 28 a**

The Swedish Chemicals Agency shall be responsible for such reporting as is referred to in Article 7 of Directive 2004/42/CE of the European Parliament and of the Council. (*Ordinance (2005:709)*).

## **Supervision and fees**

### **Section 29**

Provisions regarding supervision and fees are laid down in the Environmental Code (Supervision) Ordinance (1998:900), the Environmental Code Fees (Examination/Determination and Supervision) Ordinance (1998:940) and the Chemical Charges Etc. Ordinance (1998:942).

### **Section 30**

Governmental supervisory authorities shall notify the Consumer Ombudsman if it is the authority's judgement that there are reasons, from a health or environment perspective, for intervention against the marketing of a chemical product or biotechnical organism pursuant to the Marketing Act (1995:450). Authorities other than the Swedish Chemicals Agency shall consult with the Agency before making the notification.

## **Appeals**

### **Section 31**

Provisions regarding appeals are laid down in Chapter 19, Section 1 of the Environmental Code.

## **Penalties and forfeiture**

### **Section 32**

Provisions regarding penalties and forfeiture are laid down in Chapter 29 of the Environmental Code.

The Annex – Chemical products and biotechnical organisms obliged to be reported in accordance with Section 10 – is not included here.