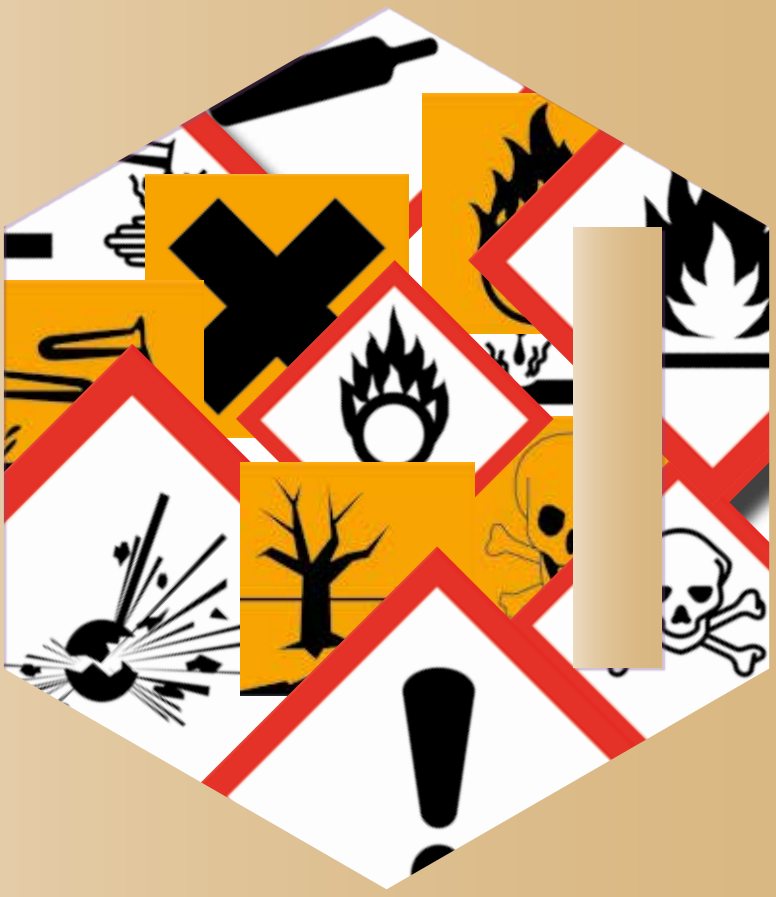

CHEMICALS LEGISLATION
AND SUPERVISION IN FINLAND

KEMK

PUBLICATION NO. 9 OF THE ADVISORY BOARD ON CHEMICALS (2013)

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Chemicals legislation and supervision in Finland

MINISTRY OF SOCIAL AFFAIRS AND HEALTH
FINLAND'S ADVISORY COMMITTEE ON CHEMICALS

HELSINKI 2013

ISSN-L 1459-5990
ISSN 1798-2286 (online)

ISBN 978-952-00-3651-5 (PDF)

Layout: AT-Julkaisutoimisto Oy

Contents

1 INTRODUCTION

The Finnish chemicals legislation is based on the chemicals legislation of the European Union, which has been implemented in Finland by means of the Chemicals Act (599/2013). The Chemicals Act has recently been updated, and it is now in accordance with the chemicals legislation of the EU.

The obligations of operators manufacturing chemicals and placing them on the market and using chemicals are based on EU regulations, which are binding as legislation.

At national level, the Chemicals Act mainly contains provisions on the tasks of the authorities in the implementation of the EU regulations and on certain national obligations. In Finland, there are national provisions on the notifications submitted to the Chemical Products Register, restrictions concerning retail sales, authorisation of certain biocidal products during a transition period and the qualification requirements for users of certain biocides.

This publication gives a brief description of the current chemicals legislation of Finland and the manner in which it is supervised. Obligations concerning chemicals are also laid down in a number of other Finnish laws, such as the Act on the Safe Handling and Storage of Dangerous Chemicals and Explosives (390/2005), through which Finland has implemented the EU directive on the control of major-accident hazards involving dangerous substances (Seveso Directive). An EU regulation (1005/2009/EC) limits the use of substances that deplete the ozone layer. A Government decree (452/2009) contains provisions on the qualifications of the personnel handling devices containing ozone-depleting substances or fluorinated greenhouse gases

A list of the current legislation can be found on the website of Finland's Advisory Committee on Chemicals at www.kemikaalineuvottelukunta.fi.

2 SCOPE OF APPLICATION OF THE CHEMICALS ACT AND THE MANNER IN WHICH IT RELATES TO OTHER LEGISLATION

The Chemicals Act applies to the national implementation of the European Union chemicals legislation specified in the act and the obligations required as part of the management of chemical risks at national level.

The following pieces of EU legislation come under the scope of the Chemicals Act:

- REACH Regulation (EC) No 1907/2006: registration, evaluation, authorisation and restriction of chemicals and provision of information in the supply chain
- CLP Regulation (EC) No 1272/2008: classification, labelling and packaging of chemicals
- Detergent Regulation (EC) No 648/2004: biodegradability and labelling of surface-active agents in detergents
- PIC Regulation (EC) No 649/2012 (PIC = Prior Informed Consent): export declaration procedure concerning certain substances
- POP Regulation (EC) No 850/2004 (POP=Persistent Organic Pollutant): bans and emission and discharge restrictions concerning certain substances
- Regulation on Export Ban for Mercury (EC) No 1102/2008: banning of the exports of mercury outside the EU
- Biocidal Products Regulation (EU) No 528/2012 and Biocide Directive 98/8/EC: pre-authorisation of active substances of biocides and biocidal products and prerequisites for their use

Principles of the chemicals legislation and its relationship to other legislation

Companies placing chemicals on the market and using them must ensure that they examine the obligations concerning their own operations and comply with them. The legislation is based on the principle that companies are responsible for the safety of the chemicals that they market and use in the application concerned. A central starting point for the legislation is that the companies are familiar with chemicals relevant to their operations, their properties, applications and requirements for safe use.

The chemicals regulation of the European Union is very extensive and comprehensive, and its purpose is to protect human health and the environment, to ensure the free movement of chemicals within the EU and to strengthen competitiveness. Regulation helps to ensure that employees and consumers are provided with clear information about the dangers of chemicals by means of classifications and labelling. EU regulations contain detailed provisions on the operators' obligations in the manufacturing of chemicals and in the placing of chemicals on the market. In matters not provided for in the chemicals legislation, provisions on topics such as consumer safety contained in the Consumer Safety Act, provisions on occupational safety and health contained in the Occupational Safety and Health Act, provisions

on environmental protection contained in the Environment Protection Act and provisions elsewhere in the legislation are applied. Usually companies must comply with obligations contained in many different pieces of legislation. In some cases, it must be determined whether a chemical is considered a cosmetic product or a biocide.

Provisions on the prevention and combating of chemical risks are also contained in the following acts and in the statutes issued under them:

- Act on Cosmetic Products (492/2013);
- Act on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (387/2013);
- Act on Plant Protection Products (1563/2011);
- Act on the Safety of Toys (1154/2011);
- Consumer Safety Act (920/2011);
- Waste Act (646/2011);
- Medical Devices Act (629/2010);
- Environmental Protection Act (86/2000) and the Act on Environmental Protection in Maritime Transport (1672/2009);
- Narcotics Act (373/2008);
- Act on the Safe Handling and Storage of Dangerous Chemicals and Explosives (390/2005);
- Occupational Safety and Health Act (738/2002);
- Act on the Control of Exports of Dual-Use Goods (562/1996);
- Health Protection Act (763/1994);
- Act on the Transport of Dangerous Goods (719/1994)
- Radiation Act (592/1991);
- Medicines Act (395/1987);
- Regulation on substances that deplete the ozone layer (EC) No 1005/2009;
- Regulation on certain fluorinated greenhouse gases (EC) No 842/2006;
- Food Act (23/2006);

Provisions on penalties for violations against chemicals legislation are also laid down in the Criminal Code (39/1889).

3 OBLIGATIONS OF THE OPERATOR

The obligations laid down in the legislation apply to the operator (importer, manufacturer, downstream user, distributor or the manufacturer of an article). It is the obligation of an operator to establish its role in connection with each chemical. The operator may also be a natural person.

3.1 Classification, labelling and packaging of chemicals

The new EU regulation on classification and labelling (CLP Regulation) applies to the classification, labelling and packaging of substances and mixtures and certain articles containing dangerous substances. Substances and mixtures are considered hazardous if they meet the criteria laid down in Annex 1 to the CLP Regulation in which consideration is given to physical, health and environmental hazards. Substances and mixtures classified as hazardous must be labelled and packaged in accordance with the regulation.

The CLP Regulation (EC) No 1272/2008 entered into force on 20 January 2009. The CLP Regulation is directly applicable in all EU Member States. For mixtures, the transition period in compliance with the CLP Regulation expires on 1 June 2015, which means that mixtures may still be classified, labelled and packaged in accordance with the old Chemicals Act (744/1989) until summer 2015.

The responsibility for identifying the hazards of the substances and mixtures and for the decisions concerning their classification lies with the manufacturers, importers and downstream users of the substances and mixtures. Manufacturers, importers and downstream users must classify the substances and mixtures placed on the market. All suppliers, including distributors, are responsible for ensuring that the labelling and packaging are in accordance with the requirements. Hazardous chemicals may only be placed on the market if they are classified, labelled and packaged in a correct manner.

Classification

Manufacturers, importers and downstream users must classify the substances and mixtures before they are placed on the market. Even if a substance is not placed on the market, it must nevertheless be classified if it is subject to registration or notification of substances in articles, as required under the REACH Regulation.

The existing data must be identified and assessed, after which the decision on the classification must be made.

The data must be updated if new information becomes available or the composition of the mixture changes.

Labelling

The supplier of the chemical (=manufacturer, importer, downstream user and distributor) must label hazardous chemicals in accordance with the regulation before it is placed on the market. The labelling is performed using a warning label.

Labelling that is in accordance with the CLP Regulation must include the supplier's contact information, product identifiers of the chemical, a hazard pictogram or pictograms, hazard and precautionary statements and a signal word ('Vaara' or 'Varoitus').

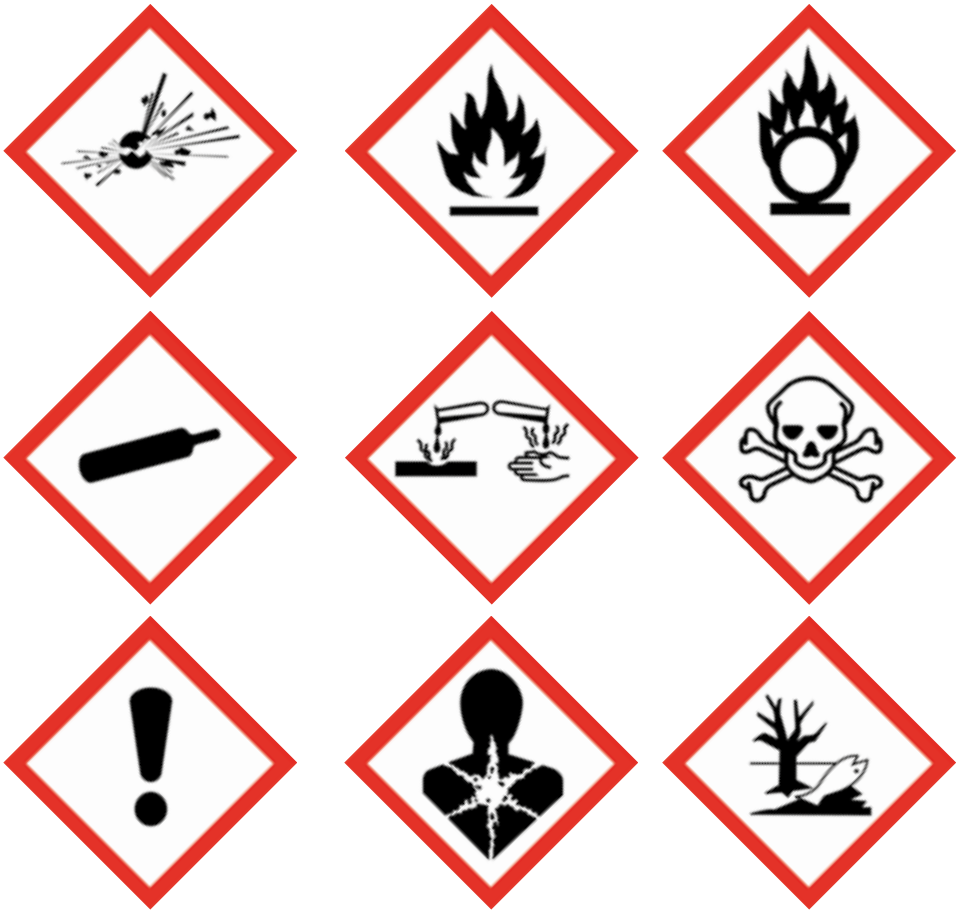
The size of the warning label must be proportional to the size of the packaging. In Finland, the text on the label must always be in Finnish and Swedish.

Hazard pictograms

The orange and black hazard pictograms required under the old legislation will be replaced with new red, white and black pictograms that are in accordance with the CLP Regulation within transition periods.

The new hazard pictograms must have a black symbol on a white field and a red frame that is wide enough so as to be clearly visible. Many of the hazard pictograms apply to more than one hazardous property.

For more information, go to Tukes website at www.tukes.fi.



Hazard pictograms to be phased out

Explosive

Oxidising

Highly flammable

Extremely flammable

Toxic

Very toxic

Harmful

Irritating

Corrosive

Dangerous for the environment

Packaging

The supplier of the chemical (=manufacturer, importer, downstream user and distributor) must package the hazardous chemical in accordance with the CLP Regulation before it is placed on the market.

The packaging must be such that the contents cannot escape, it must be able to withstand the effects of the chemical in question and it may not form hazardous compounds with the contents. The fastenings must withstand normal wear and tear. The packaging requirements contained in the transporting legislation are in accordance with the requirements laid down in the CLP Regulation. However, the CLP Regulation also requires that a packaging intended for the general public may not resemble such products as a drink bottle or otherwise mislead consumers. Child-resistant fastenings and tactile warnings of danger are required for certain hazard classes. The labelling required under the transport legislation is not sufficient as such.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)

3.2 Safety data sheet and supplying the data

The safety data sheet is a document providing information about the properties, risks and safe use of a hazardous substance or mixture in industries or in professional applications. Provisions on the safety data sheet are contained in Article 31 of the REACH Regulation and Annex II to the regulation. Manufacturers, importers, distributors or other operators that are responsible for placing chemicals on the market must compile a safety data sheet of a chemical intended for professional use and submit it to the recipient of the chemical.

A safety data sheet must be prepared for substances and mixtures that are classified as hazardous and unclassified mixtures that contain hazardous substances. A safety data sheet must also be prepared for substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or that are included in the list of substances of very high concern.

A safety data sheet is not required if the chemicals offered or sold to the general public are provided with sufficient information allowing users to take the necessary measures as regards the protection of human health and the environment. A safety data sheet must, however, be supplied if it is requested by a downstream user or a distributor.

A safety data sheet must contain:

- identification of the substance or mixture;
- use of the substance and/or mixture;
- identification of the company;
- identification of the hazard (hazards that the substance or mixture cause to humans and the environment;
- composition and information on ingredients;
- first-aid measures;
- fire-fighting measures;
- accidental release measures;
- information on the handling and storage of the substances at the workplace;
- information required for preventing exposure (such as a reference to the use of personal protection devices);
- physical and chemical properties of the substance/mixture;
- stability and reactivity of the substance/mixture;
- toxicological information;
- ecological information;
- disposal considerations;
- transport information;
- regulatory information (has the chemical safety assessment been carried out).

The introduction of the REACH Regulation means that the safety data sheet will become more extensive and assume a greater importance. The Extended Safety Data Sheet also covers the exposure scenario. The exposure scenario details the operating conditions determined on the basis of the safety assessment and the necessary risk management measures for the safe use of the chemical in question. The operators must comply with these instructions or draw up their own chemical safety assessment and prepare a chemical safety report.

The safety data sheet must be

- dated and it must have standard headings in a specific order;
- updated as new information on the use or properties of the chemical becomes available. The new information must be provided free of charge electronically or in paper form; The recipient of the chemical may choose whether it would like to have the safety data sheet in Finnish or in Swedish or in both languages.

In case updates must be made to the safety data sheet, the new document must be supplied to all those who have received the chemical during the

preceding 12 months. The information contained in the safety data sheet must always also be supplied to the Chemical Products Register of the Finnish Safety and Chemicals Agency (Tukes) in connection with the chemical notification.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)

3.3 Chemical notification

A chemical notification must be submitted to Tukes on those chemicals for which a safety data sheet must be supplied under Article 31 of the REACH Regulation (substances and mixtures that have been classified on the basis of health, environmental or physical hazard). The notification must also be submitted for unclassified chemicals if they contain substances that are hazardous to health or to the environment or substances for which the EU has defined a workplace exposure limit.

The notification must be submitted for chemicals intended for professional use and for those intended for use by the general public. Chemicals that are used on an experimental basis in scientific research or product development or that are supplied in such small amounts that they do not cause any hazard are exempted from the notification obligation.

Notification is not required for harmless chemicals or articles or cosmetics.

As regards its content, the chemical notification corresponds to the safety data sheet. The use category and classification of economic activities code must also be given and the dangerous ingredients must be specified using CAS or EC numbers.

A new chemical notification must be submitted when there are essential changes to the information on the chemical.

Such changes include:

- change in the trade name;
- change in the information on the operator;
- change in the composition;
- new or changed information on the dangerous properties;

Tukes must be notified in writing when a chemical is removed from the market.

The amounts of the chemicals that are manufactured and imported each year must be given in tonnes as accurately as possible. The amounts must be entered in the register for each year by the end of February of the following year.

Further information: www.tukes.fi

3.4 Submitting registrations of substances to the European Chemicals Agency

Registration is a new procedure required under the REACH Regulation. The system is founded on the principle that substances may not be manufactured or placed on the market before they are registered in the database of the European Chemicals Agency. The registration requirement applies to substances that are manufactured or imported within the EU in quantities of more than one tonne/company each year. The registration requires that the manufacturers and importers of the chemicals obtain the information on such matters as the dangerous properties, uses and safe handling of the substances.

The registration will be a phased process based on the tonne quantities and hazardousness of the substance. It will extend to the year 2018 provided that the company has pre-registered the substance and has been authorised to apply transition periods.

The deadlines for registration were as follows: for amounts of more than 1,000 tonnes, for batches of CMR substances amounting to more than one tonne and for batches of substances that are extremely dangerous to the aquatic environment amounting to more than 100 tonnes, 30 November 2010, and for amounts of more than 100 tonnes, 31 May 2013. The final deadline for all other amounts of more than one tonne is 31 May 2018.

Substances that are not registered may not be manufactured or imported within the EU.

In the registration, the manufacturer or EU importer of the substance must obtain the information on the substance, assess the risks concerning the handling of the substance and submit the information to the European Chemicals Agency in electronic form.

A chemical safety assessment must be carried out for the registration if the amount of the substance is more than 10 tonne/registrant. A chemical safety report must be prepared of the assessment. If the substance is classified as hazardous (or is a PBT or a vPvB substance), an exposure assessment and a risk characterisation must also be produced.

The registration also applies to certain substances contained in articles. The registration must be carried out if the substance is intended to be released from an article under normal or reasonably foreseeable conditions of use and if the substance is present in the articles in question in quantities totalling more than one tonne per company per year.

A notification must be submitted to the European Chemicals Agency if a substance of very high concern is present in the article in amounts of more than 0.1 percentage by weight and if it is possible that humans or the environment may become exposed to the substance under normal or reasonably fore-

seeable conditions of use. The notification must be submitted if the substance is present in the articles in question in amounts of more than one tonne per year per company.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)

3.5 Substances of very high concern

Substances of very high concern (SVHC substances) may be carcinogenic, mutagenic or toxic to reproduction. The classification criteria for these substances are laid out in the CLP Regulation. A substance may also be determined as a substance of very high concern if it has endocrine disrupting properties and there is evidence that it has serious health or environmental effects.

Substances of very high concern may also be persistent or very persistent, bioaccumulative or very bioaccumulative and toxic. The classification criteria for these substances are laid out in the REACH Regulation.

If a substance is identified as an SVHC substance it is entered into a candidate list. Some of the substances on the list will be added to the list of substances that are subject to authorisation.

At the time when this publication went to print, there were a total of 144 substances on the candidate list, and the list is continuously updated. There are a number of obligations concerning the substances on the candidate list: a safety data sheet must be compiled on them, the recipient of an article containing a listed substance must be provided with information, and the European Chemicals Agency must be notified of a listed substance contained in an article.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)

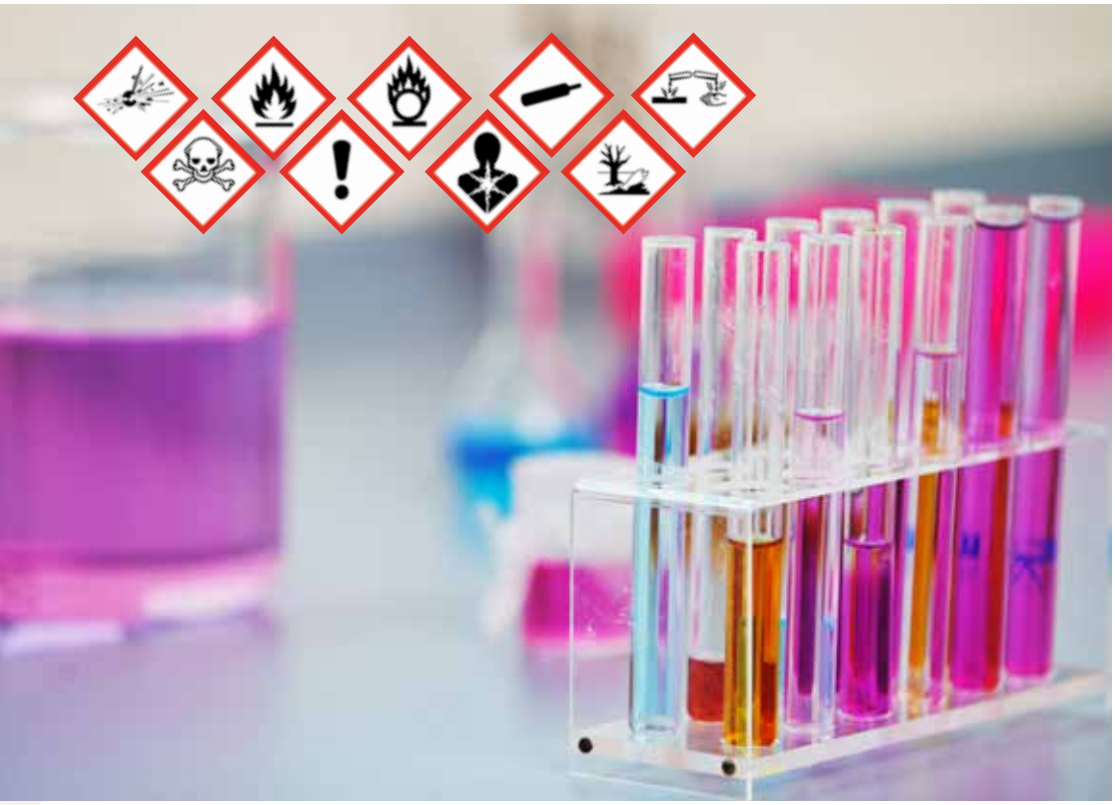
3.6 Authorisation

The purpose of the authorisation is to ensure that the risks contained in substances of very high concern are under control and that the substances are replaced with suitable alternative substances or technologies where these are economically and technically viable.

The substances requiring authorisation are selected from among the substances contained in the candidate list (see section 3.5). A list of the substances subject to authorisation is given in Annex XIV to the REACH Regulation. The manufacturer, importer or downstream user of the substance must apply for an authorisation for the use of substance irrespective of the amounts. A substance subject to authorisation may not be placed on the market or used without authorisation. The authorisation requires that the

user demonstrates that the risks are under control, or that the socio-economic benefits of the use outweigh the risks and that there are no suitable alternatives (substances or technologies). Annex XIV to the REACH Regulation gives a deadline for submitting the application for each substance and another for placing the substance on the market and for ending its use. The authorisation applications are considered by the European Chemicals Agency, and the authorisations are granted by the Commission.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)



The authorities of the Member States assess substances that are suspected to cause a hazard to human health or to the environment. Based on the assessments, the authorities may take measures that are in accordance with the restriction or authorisation procedure.

3.7 Restrictions applying to chemicals

Annex XVII to the REACH Regulation lays down restrictions concerning the manufacturing, placing on the market and use of certain substances,

mixtures and articles. The restrictions apply to substances causing risks that would otherwise be uncontrollable.

The regulation imposes restrictions on the use of thousands of different chemicals. At the moment, the restrictions apply to a total of 105 separate substances, including benzene, benzidine, organic tin compounds, pentachlorophenol, cadmium, lead, mercury, nickel, asbestos, chromate contained in concrete, hexachloroethane and azocolourants in different uses. The consumer use of all CMR substances (carcinogenic, mutagenic and toxic for reproduction) has been restricted as groups. The restrictions are continuously updated.

The restriction procedure allows the EU Commission to impose conditions or bans concerning the manufacturing, use and placing on the market of a substance if the substance causes a substantial hazard to human health or the environment.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)

3.8 Authorisation of biocides

Biocides are chemical substances, products or microbes the purpose of which is to destroy, combat or neutralise harmful organisms, prevent their effects or limit their occurrence.

Provisions on the procedures for authorising biocidal products are laid down in the Regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (EU) No 528/2012. In Finland, the provisions on biocides are contained in the chemicals legislation. Under the Chemicals Act, biocidal products must receive Tukes authorisation before they can be placed on the market in Finland. Placing a product on the market means the sales, imports, storage and use of the product, and the storage relating to its use. The active substances used in biocidal products are authorised at EU level, and the Commission keeps a list of authorised active substances.

One of the most important changes in the scope of the Biocidal Products Regulation compared with the previous regulatory regime is the extension of the regime to cover the placing on the market of articles containing biocides and the provisions on labelling requirements for such articles. The purpose of the labelling is to inform consumers that the articles have been treated with biocidal products and to produce information for the purposes of supervision.

Under the Biocidal Products Regulation, biocidal products are divided into 22 different product groups, depending on their use. Biocidal products

must receive the authorisation required under the regulation before they are made available on the market or before use. Authorisation for products that are already on the market must be sought as the risk assessment programme of active substances progresses and active substances are authorised in accordance with the regulation. The requirement is that the active substances contained in the product are included in the appropriate product group of the assessment programme. Authorisation for products containing new active biocidal substances must be sought before they are made available on the market for the first time.

In addition to the authorisations required under the Biocidal Products Regulation, Finland also has a national pre-authorisation procedure for certain biocidal products for the duration of the transition period. The procedure will expire when it becomes obligatory to seek authorisation in accordance with the regulation.

Further information: Tukes helpdesk: www.kemikaalineuvonta.fi (in Finnish)

3.9 Detergent Regulation, PIC Regulation, POP Regulation, Regulation on Export Ban for Mercury

Detergent Regulation (EC) No 648/2004

Under the Detergent Regulation, laundry detergents sold to households may not contain phosphates used as water softeners. A similar ban will be introduced for household dishwasher detergents in 1.1.2017. Operators must also ensure that the surface-active ingredients contained in the detergents are biodegradable and check the restrictions and prohibitions applied to these ingredients. Operators must also see to it that detergents are appropriately labelled and provide the information that the manufacturers are required hold at the disposal of the authorities and medical personnel.

PIC Regulation (EU) No 649/2012

If the operator exports outside the EU substances subject to prohibition or restrictions in the EU that are listed in Category 1 of Annex 1 to the PIC Regulation or mixtures that contain these substances in such concentrations that they must be labelled in accordance with the CLP Regulation, the operator must submit an export declaration to the Finnish Environment Institute. The export declaration must be submitted no later than 35 days before the first expected export day. Substances that are listed in Categories 2 or 3 of Annex I to the PIC Regulation may not be exported unless the importing country has given its consent to the imports.

POP Regulation (EC) No 850/2004

The regulation on persistent organic pollutants prohibits the manufacturing, use, exports and imports of the substances listed in Annexes A and B to the Stockholm Convention. The operator must also work to reduce, minimise and, ultimately, eliminate the emissions and discharges of certain persistent organic pollutants. Persistent organic pollutants mean substances that are very persistent, toxic and transboundary and accumulate in living organisms.

Regulation on Export Ban for Mercury (EC) No 1102/2008

Operators may not export metallic mercury or certain compounds and mixtures containing mercury outside the Union. Metallic mercury is considered waste in existing areas of use when it is no longer used, at which point the operator must ensure the safe storage of the mercury within the EU.

Fluorinated Gas Regulation (EC) No 842/2006 and Government Decree on the Servicing and Maintenance of Devices Containing Ozone Depleting Substances or Certain Fluorinated Greenhouse Gases (452/2009)

Products and equipment containing fluorinated greenhouse gases listed in Annex II to the Fluorinated Gas Regulation may not be placed on the market. A registered refrigeration equipment company must have at least one responsible person and fitter meeting the qualification requirements laid down in decree 452/2009. Additional restrictions concerning the use of refrigerants that contain fluorinated gases will be introduced when the amendment to the Fluorinated Gas Regulation, currently under preparation, will come into force.

3.10 Other requirements

3.10.1 Qualification requirements for exterminators

Among the provisions in the new Chemicals Act is a requirement for training and a qualification in the use of certain pest control products and a special qualification in the use of biocidal products causing a particular hazard. An company performing pest control must have a responsible person on its payroll who possesses an exterminator's qualification and has received exterminator training or who has equivalent professional skills. The company and the responsible persons are entered into Tukes' register. Companies performing professional pest control must submit a notification to Tukes by 31 December 2016.

Exterminator's qualification

Tukes may decide that certain biocidal products (pest control product groups PT 8, PT 14, PT 18) may only be used by persons that have demonstrated the necessary competence. The requirement is based on the health and environmental hazards caused by the products.

Persons who have taken the required qualification must submit a notification to Tukes (verification of competence) after which the person meeting the qualification requirements will be entered in Tukes' qualification register.

Special qualification

Tukes may also decide that chemicals causing a particular hazard or harm to the environment or health may only be used by persons possessing a special qualification. The requirement may apply to such products as certain fumigated substances. The special qualification may only be taken by persons who already possess the exterminator's qualification. The organiser of the special qualification test is subject to approval by Tukes. The test may also be organised by the manufacturer of the product. The person who has taken the special qualification test is entered in Tukes' qualification register.

3.10.2 Retail sales

The special provisions concerning retail sales apply to the storage of toxic chemicals for sale, prerequisites for supplying them and supplying them from a pharmacy and the refusal to supply them. Under the old chemicals legislation, a toxic chemical is a chemical classified as toxic or very toxic and a chemical that under the CLP Regulation is classified as a chemical with acute toxicity in categories 1–3.

The Government Decree on Retail Sales of Chemicals (644/2013) contains special provisions concerning the retail sales of chemicals.

Under the Retail Sales Decree:

- In a retail outlet or its storage facility, toxic chemicals must be kept in locked space. However, the obligation does not apply to fuels (except for methanol-containing fuels).
- Toxic chemicals may only be supplied to persons over the age of 18 (except for fuels, which may be supplied to all persons irrespective of their age). Methanol-containing motor fuels may, however, only be supplied to persons under the age of 18 with the written consent of their legal guardian.
- When toxic chemicals are supplied from a pharmacy, the recipient must give their personal details and address, the name and amount of the chemical and the intended use of the chemical on a separate

form. The recipient of the chemical must prove their identity and sign the duly dated form. The pharmacy must retain the form for five years.

- No chemicals may be supplied if there are reasons to suspect that the chemical is likely to be purchased for the purpose of intoxication or otherwise be misused so that the use may cause serious health risks.

Further information: www.tukes.fi

4 TASKS OF THE AUTHORITIES SUPERVISING THE CHEMICALS LEGISLATION

Ministries

The Ministry of Social Affairs and Health is responsible for the prevention and combating of the health hazards arising from chemicals and the physical hazards and harm caused by chemicals.

The Ministry of the Environment is responsible for the prevention and combating of the environmental hazards and harm caused by chemicals.

The ministries are responsible for the steering of the supervision concerning compliance with the legislation.

The tasks of the ministries are connected with the overall steering, monitoring and development of the activities.

Further information: www.stm.fi and www.ym.fi

Finnish Safety and Chemicals Agency (Tukes)

The Finnish Safety and Chemicals Agency is responsible for supervising compliance with the Chemicals Act and the provisions issued under it, The REACH Regulation, the CLP Regulation, the Detergent Regulation, the Biocidal Products Regulation and certain provisions of the POP Regulation. The purpose of the market supervision of chemicals is to remove dangerous products or products that otherwise fail to comply with requirements from the market and to ensure that all regulations are complied with. Under the regulations, competent authorities at national level are also required to maintain a national advisory service so that companies can submit questions on such issues as the application of the regulations. Tukes is responsible for providing the advisory service in accordance with the REACH, CLP and Biocidal Product Regulations. Tukes also acts as the competent authority referred to in these regulations.

Further information: www.tukes.fi

Finnish Environment Institute

The Finnish Environment Institute is responsible for supervising compliance with the POP and PIC Regulations and the convention on the international trade in certain hazardous chemicals and pesticides (the Rotterdam Convention).

The authorities supervising compliance with the Environmental Protection Act also manage tasks concerning the POP Regulation and the Regulation on Export Ban for Mercury.

Further information: www.syke.fi

Occupational safety and health authorities

Occupational safety and health authorities are responsible for supervising compliance with the chemicals legislation in all such work where the employer is bound by the Occupational Safety and Health Act. The task of the occupational safety and health authorities is to ensure the safety of the conditions in which chemicals are used.

In their supervisory tasks, the occupational safety and health authorities apply the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces (44/2006).

Further information: www.tyosuojelu.fi

Centres for Economic Development, Transport and the Environment and municipal environmental protection authorities

Centres for Economic Development, Transport and the Environment and municipal environmental protection authorities supervise

- compliance with the Chemicals Act and the provisions issued under it;
- compliance with the terms and conditions and prerequisites laid down for the use of biocidal products;
- compliance with Articles 3 and 4 concerning the use of substances in the POP Regulation;
- compliance with the provisions on the conditions of use and risk reduction measures of substances, use of substances requiring authorisation, and restrictions concerning the use of substances laid down in the REACH Regulation;

The supervision carried out by the two bodies is supervision of activities that pose a threat of environmental pollution to the extent that the supervision concerns the operator's obligation to prevent harmful environmental effects in the use and storing of chemicals.

Further information: www.elykeskus.fi and www.kunnat.net

Finnish Medicines Agency (Fimea)

The task of the Finnish Medicines Agency is to ensure that research activities are carried out in accordance with good laboratory practice (GLP).

Further information: www.fimea.fi Finnish

Customs

The Finnish Customs supervises compliance with the chemicals legislation of the European Union in connection the imports, exports and transit of chemicals and articles containing chemicals.

Further information: www.tulli.fi Finnish

Defence Forces

The Finnish Defence Forces supervises compliance with the chemicals legislation in its military activities, military training and certain other tasks.

5 EUROPEAN CHEMICALS AGENCY

The European Chemicals Agency (ECHA) was established in Helsinki in 2007 under the REACH Regulation. The agency is responsible for tasks concerning the implementation of the REACH, CLP, PIC and Biocidal Products Regulations. The agency is responsible for such tasks as the maintenance of databases containing chemicals information, reception of registration documents, administration of authorisation procedures and preparation of recommendations for reducing risks arising from chemicals.

ECHA is responsible for providing industry and the authorities with the necessary steering and instruments so that they can meet their obligations and for supporting the advisory services established by the Member States. ECHA has the following scientific and technical committees:

- Risk Assessment Committee;
- Committee for Socio-economic Analysis;
- Member State Committee;

ECHA also has

- an enforcement forum for exchanging information concerning implementation.

The committees play a central role in the practical implementation of the chemical regulations of the EU. The members of the committees are appointed by individual Member States. Stakeholder representatives may also take part in the work of the committees as observers.

The work of ECHA is steered and supervised by a Management Board.

Further information: www.echa.europa.eu

Links:

Centres for Economic Development, Transport and the Environment (ELY Centres)
www.elykeskus.fi

European Chemicals Agency (ECHA)
www.echa.europa.eu

European Commission
www.ec.europa.eu

Finland's Advisory Committee on Chemicals
www.kemikaalineuvottelukunta.fi

Municipalities (environmental protection authorities)
www.kunnat.net

Finnish Medicines Agency (Fimea)
www.fimea.fi

Finnish Defence Forces
www.puolustusvoimat.fi

Ministry of Social Affairs and Health (STM)
www.stm.fi

Finnish Environment Institute (SYKE)
www.syke.fi

Finnish Customs
www.tulli.fi

Finnish Safety and Chemicals Agency (Tukes)
www.tukes.fi

Occupational Safety and Health Authority
www.tyosuojelu.fi

Ministry for Foreign Affairs
www.formin.fi

Ministry of the Environment (YM)
www.ym.fi

Operator's checklist:

- Are the chemicals that I manufacture, import or use dangerous to human health or to the environment or do they cause physical hazards? Are the Finnish and Swedish texts in the labelling correct?
- Is the packaging durable? What about the child-resistant fastenings and tactile warnings of danger? Are they required for my chemicals?
- Have I supplied professional users with safety data sheets for the chemicals that I manufacture and import? Has any new information emerged warranting an update of the safety data sheets? I remember to send updated safety data sheets to customers to whom I have supplied products during the past year. If I am a chemicals user I should check whether I have received the latest safety data sheets in Finnish and Swedish.
- I remember to keep the information that I have obtained for compliance with the chemicals legislation for at least ten years after I have last used, supplied, manufactured or imported chemicals.
- Have I clarified the role of my company concerning different chemicals (manufacturer, EU importer, downstream user, distributor)? Has the substance that I have used or imported been registered at the European Chemicals Agency? Do my products contain substances of very high concern (SVHC substances)?
- Has a safety assessment been carried out, and is the manner in which I use the chemicals in accordance with the exposure scenario? Do I comply with safety instructions that are in accordance with the exposure scenario of the safety data sheet?
- Have I submitted to Tukes the information on the chemicals that I have manufactured or imported for registration (chemical notification)? Updated data and data on amounts must also be submitted each year.
- Is the chemical that I manufacture or import a biocidal product? The assessment and authorisation of biocidal products is the responsibility of Tukes.
- Do I have to submit an export declaration for a substance or mixture that I export outside the EU?
- Am I keeping the toxic chemicals in a retail outlet so that they are inaccessible to unauthorised persons? How do I ensure that chemicals that are dangerous to health are not supplied for intoxication purposes or misuse? Remember that toxic chemicals may not be sold to persons under the age of 18. The ban does not apply to methanol-containing motor fuel, which is commonly used in model aircrafts. However, in such cases you must ensure that the purchaser has the written consent of the guardian.
- Are there any special bans, restrictions or other special regulations that apply to the chemicals that I manufacture or sell? Is the substance that I use listed as a substance of very high concern or a substance subject to authorisation procedure in Annex XIV to the REACH Regulation? Is it included in Annex I (Prohibition Annex) or II (Restriction Annex) to the POP Regulation?
- Check also what is required under other laws. Go to page three for a list of laws.

MINISTRY OF
SOCIAL AFFAIRS AND HEALTH
Finland