

What does the law say about chemical substances and products?

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Getting acquainted with the rules on chemicals

In Denmark, the chemicals sector is regulated by the Chemical Substances and Products Act. The scope of this Act extends to all chemical substances and products manufactured, imported or sold in Denmark.

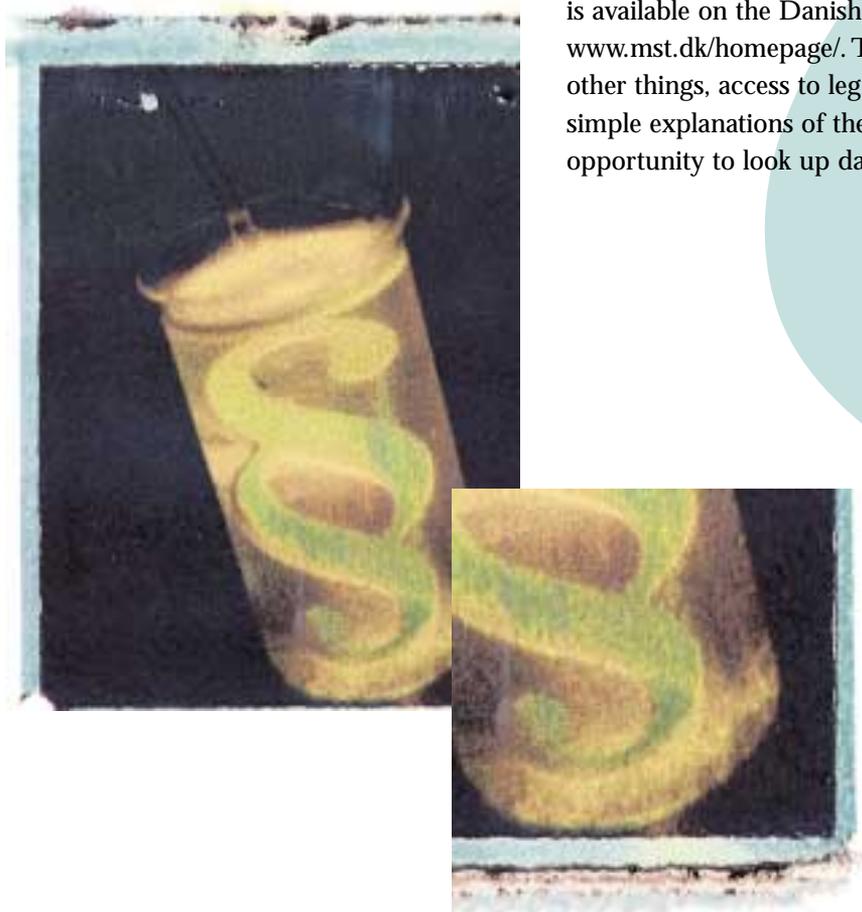
The chemicals legislation concerns chemicals in their pure form, such as acetone and hydrochloric acid, as well as products, such as detergents, paint, shampoo, jewellery, toys and refrigerators.

As an importer, manufacturer or distributor of chemical substances or products, you need to know the rules governing this area.

This pamphlet will provide you with an overview of the requirements governing, for example, classification, labelling, packaging and storage. Information is also provided on the retail sale of toxins and on the substances and products for which special rules exist.

The pamphlet addresses regulation on chemicals from the Danish Ministry of the Environment, with the exception of rules governing pesticides. If you would like to find out more about, for example, chemical substances in the working environment or in foodstuffs, we refer you to other sources.

If you would like to find out more, information is available on the Danish EPA homepage on www.mst.dk/homepage/. This provides, among other things, access to legislation and rules, simple explanations of the rules, as well as the opportunity to look up danger symbols.



Who is responsible?

If a chemical product has been manufactured in Denmark, the manufacturer is responsible for that product. If the product has been imported into Denmark, the importer is responsible.

For the import and sale of chemical substances and products, the manufacturer or importer must assess whether the substance or product is subject to special Danish rules, and whether a substance or product is classified and labelled in another EU country by a foreign manufacturer.

Importers must also be aware of whether the imported articles contain prohibited or restricted substances. For example, active ingredients in cosmetics.

It is also the responsibility of the importer to ensure the proper packaging and labelling of chemical substances and products. This also applies even if the chemical substances/products are delivered direct from abroad to the importer's Danish customers.

The manufacturer/importer is obliged to keep abreast of new legislation and to ensure that current legislation is always complied with.

As there are frequent amendments in legislation it is not enough that the rules are only addressed at the start of marketing or importation.

Every manufacturer or importer of a chemical substance or product must be in possession of documentation proving the substance or product complies with chemical legislation, including EU regulations.

This means that it is necessary to be in possession of a large amount of data on the substance or product, as well as being able to document that the substance or product has been assessed in accordance with the rules.

If the Danish EPA wishes to see that data, the manufacturer or importer is obliged to supply it.

The role of the authorities

The primary responsibility for the regulation of chemicals rests with the Danish EPA, which comes under the authority of the Danish Ministry of the Environment.

The Danish EPA Chemical Inspection Service supervises compliance with the rules laid down in the legislation on chemicals.

Other ministerial bodies also have a responsibility in the chemicals sector, including the Ministry of Employment, which regulates chemical substances in the working environment, and the Ministry of Food, Agriculture and Fisheries, which regulates chemicals in foodstuffs.

Dangerous chemical substances and products

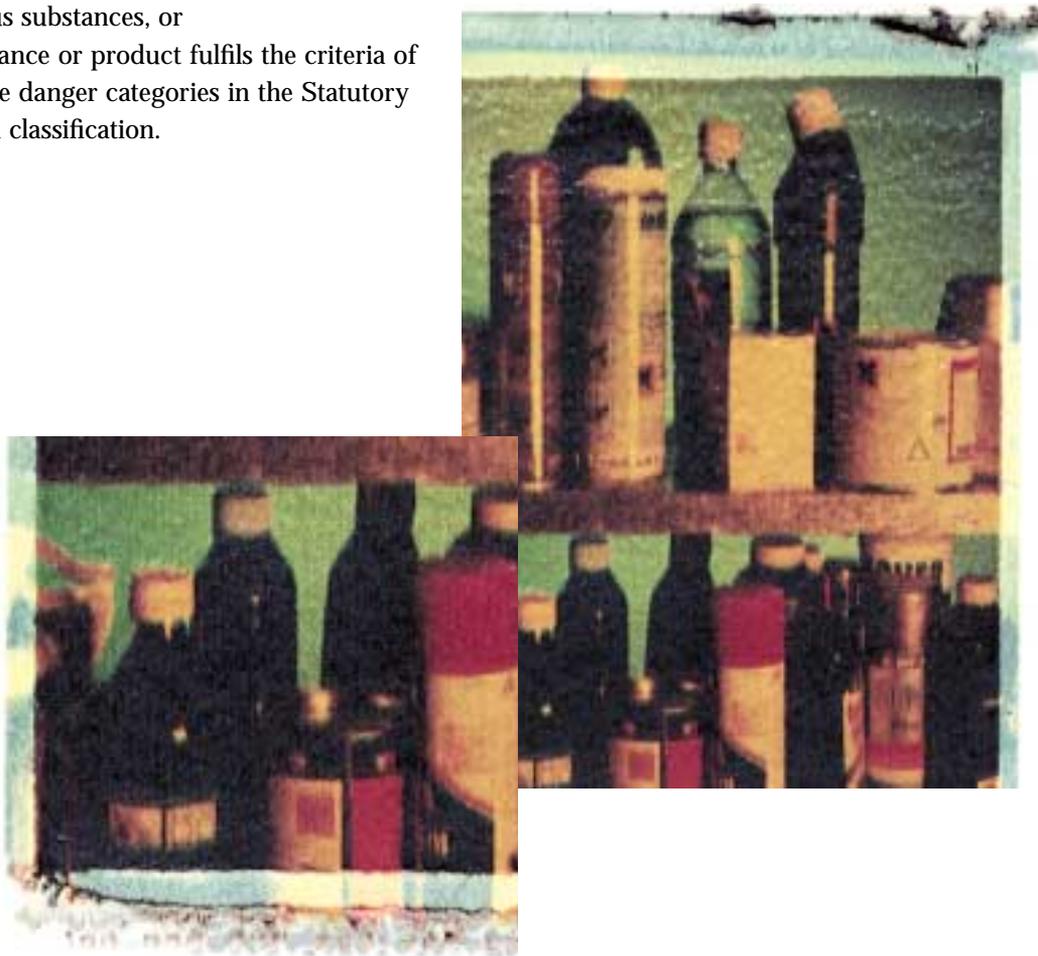
Before a chemical substance or product may be imported or distributed, the manufacturer or importer must acquire sufficient information concerning the substance or product's properties and effects in order to assess whether the substance or product must be considered as dangerous.

A chemical substance or product is defined as dangerous, if

- the substance can be found on the list of dangerous substances, or
- the substance or product fulfils the criteria of one of the danger categories in the Statutory Order on classification.

If a substance does not appear on the list of dangerous substances, the manufacturer or importer is obliged to undertake their own assessment of the substance in respect to flammability, explosiveness, health hazards and danger to the environment – possibly with the assistance of a consultant firm.

Insufficient chemical or toxicological expertise in the company does not release the manufacturer or importer from meeting these obligations.



Prohibited or restricted chemical substances and products

A number of chemical substances and products are covered by special rules. Some are prohibited, others are subject to different restrictions. Importers must be aware that goods and products not normally associated with chemical legislation might contain chemical substances subject to restrictions pursuant to chemicals legislation. Read about some of the special rules below.

Products containing lead

The general rule is that the import and distribution of products containing chemical compounds of lead are prohibited. In addition, certain products containing metallic lead are prohibited. The ban is enforced gradually for different product groups.

■ Read more in Fact Sheet no. 33, “Lead” on www.mst.dk/homepage/

Formaldehyde in chipboard

There are rules governing the amount of formaldehyde chipboard, plywood and similar woods may contain for use in furniture making, fixings, etc.

■ Read more in Fact Sheet no. 10, “Formaldehyde in Chipboard, etc”, on www.mst.dk/homepage/

Aerosol containers

There are rules governing which propellants and solvents are permitted for use in aerosol containers (spray-cans). There are also restrictions on the concentration of certain substances. These rules concern all chemical products marketed in aerosol containers, for example, spray-paint, products intended for decoration

purposes and cosmetics. Special rules apply to products in aerosol containers for industrial use.

Nitrosamines in comforters and feeding-bottle teats

For distributors of comforters and feeding-bottle teats a limit is imposed on the release of N-nitrosamines or nitrosable substances from these products. Anyone manufacturing or importing comforters or feeding bottle teats for infants must report it to the Danish EPA.

■ Read more in Fact Sheet 9, “Dummies and Baby-Bottle Teats”, on www.mst.dk/homepage/

Products containing nickel

Rules govern the content and release of nickel from a range of products designed to come in direct contact with the skin, for example, piercing jewellery. Importers and manufactures must have their products analysed using special analysis methods in order to be able to document that the products satisfy demands.

■ Read more in Fact Sheet no. 3, “Products Containing Nickel”, on www.mst.dk/homepage/

Products containing cadmium

As a general rule the manufacture, import and distribution of products containing cadmium are prohibited. However, until further notice, it is permitted to use cadmium as a colouring pigment in dental cement, artist paints and works of art. The manufacture, import and distribution of most of these products must be reported to the Danish EPA.

■ Read more in Fact Sheet no. 1, “Products containing Cadmium”, on www.mst.dk/homepage/

Ozone-depleting substances

As a general rule, the commercial use of a number of ozone-depleting substances, for example, CFC, HCFC and halons, is prohibited. Furthermore, the export and distribution of products and goods containing these substances – with a few exceptions – is also prohibited. Beside the rules of the Order itself, the import, distribution and use of ozone-depleting substances are also subject to EU regulations.

Mercury and products containing mercury

With a few exceptions, it is prohibited to sell or export mercury and products containing mercury. Some products are subject to other rules also applicable to mercury. This concerns, for example, batteries, cosmetics, medical equipment, paint, varnish and packaging. The disinfecting of walls, woods and textiles is also subject to a different rule.

■ Read more in Fact Sheet no. 12, “Mercury”, on www.mst.dk/homepage/

Batteries and accumulators

The import and sale of alkaline-manganese batteries exceeding a mercury percentage by weight of 0.0005 is prohibited. Other types of battery are subject to the rule that if they contain heavy metals, they must carry special labelling in order that they can be collected and disposed of separately. With a few exceptions the import and sale of devices containing incorporated batteries or accumulators are also only permitted if consumers can easily remove the batteries prior to the device being disposed of.



Cosmetics

A number of rules govern the manufacture or import of cosmetic products. For example, rules govern permitted and prohibited substances, labelling requirements, etc. Marketers of a cosmetic product are responsible for the product carrying an active ingredients declaration, as well as details of the company name and address, safety precautions and a number of other points of information. There are rules governing how the active ingredients and the other points of information should read.

■ Read more in Fact Sheet no. 5, “Labelling of Cosmetics”, on www.mst.dk/homepage/

Phthalates in toys for children aged 0-3 and childcare articles

It is prohibited to manufacture, import and distribute toys and childcare articles for children aged 0-3, if the products contain more than a 0.05 percentage by weight of phthalates. This ban also concerns other products that can be expected to be used as a toy by children aged 0-3, due to its construction and design.

■ Read more in Fact Sheet no. 13, “Phthalates in Toys”, on www.mst.dk/homepage/

Danger labelling

All packaging containing a chemical substance or product classified as dangerous must carry a danger label. The objective is to protect the consumer from harm.

Labelling requirements

The danger label must be directly attached to the substance or product's packaging or be printed directly onto the packaging.

The danger label must be in Danish and must – beside the danger symbol – contain a number of points of information about the product, the importer, the active ingredients as well as risk and safety precautions.

There are rules governing which format the label must take, the colour of the danger symbol, how the label is attached and the labelling of substances and products sold with an outer and inner packaging. These rules are described in greater detail in the Danish EPA guidelines on Classification etc. of Chemical Substances and Products.

In addition, a number of special labelling requirements apply regardless of whether or not a substance or product is classified as dangerous. This concerns, for example, the labelling of products containing a number of substances such as cyanoacrylates, lead, epoxy, etc.

■ Read more in Fact Sheet no. 4, "Classification, Packaging and Labelling", on www.mst.dk/homepage/.

Marketing

It is prohibited to market chemical substances and products that mislead the consumer with regard to the substance/product's use or the risk connected with the substance or product.

■ Read more in Fact Sheet no. 2: "Misleading Marketing", on www.mst.dk/homepage/



Danger class	Danger symbol	Indication of Danger
Explosive		Explosive
Oxidizing		Oxidizing
Extremely Flammable		Extremely Flammable
Highly Flammable		Highly Flammable
Flammable	No danger symbol	No indication of danger
Very Toxic		Very Toxic
Toxic		Toxic
Harmful		Harmful
Corrosive		Corrosive
Irritant		Irritant
Sensitising	 	Harmful. Irritant
Carcinogenic	 	Toxic. Harmful
Mutagenic	 	Toxic. Harmful
Toxic to reproduction	 	Toxic. Harmful
Dangerous for the environment		Dangerous for the environment

You can see and download the danger symbols on the Danish EPA homepage www.mst.dk/homepage

Requirements for packaging



Packaging for chemical substances and products must be tight. It must be possible to pour from it and empty it in such a way that precludes accidental spilling. The packaging material and fastening must not be susceptible to attack from the contents or capable of forming dangerous compounds with the contents. The packaging and fastening must be sufficiently strong so as not to come loose, and it must be capable of withstanding normal wear and tear.

If the fastening is intended for repeated use it must be designed so that it is possible to open and close the packaging several times without accidental loss of the contents. Screw caps and snap tops are typical examples of this type of fastening.

■ Read more in Fact Sheet no. 4, “Classification, Packaging and Labelling”, on www.mst.dk/homepage/

Special rules govern the packaging of a number of dangerous chemical substances and products, which are commonplace in the home, for example acetic acid, dishwasher detergents, cleaning benzene and mineral turpentine.

Child-resistant packaging

Packaging containing substances or products requiring the danger labelling “Corrosive” (e.g. dishwasher detergents) must be fitted with child-resistant fastening. The requirement for child-resistant fastenings also applies to liquid products containing oil, such as lamp oil and barbecue-lighting fluid, which are considered to represent particular danger to children, partly due to the risk of chemical lung infection.

■ Read more in Fact Sheet no. 7, “Child-resistant Fastenings”, on www.mst.dk/homepage/

Tactile warnings

Chemical substances or products requiring danger labelling with “Extremely flammable”, “Highly flammable”, “Corrosive” or “Harmful” must have tactile warnings for the benefit of the blind and visually impaired. Such tactile warnings take the form of a raised triangle.

It is the responsibility of the retailer to ensure that substances/products are fitted with child-resistant fastening and tactile warnings. This is also the case where the manufacturer has marketed the substance/product for commercial use and consequently has not fitted the packaging with child-resistant fastenings or tactile warnings.

Requirements for storage

Generally, chemical substances and products should always be stored securely and out of reach of children.

Safe storage

Substances and products labelled with the danger indication “Corrosive”, “Harmful”, and “Irritant” must always be stored securely and out of reach of children, and not together with or in the vicinity of food, animal feed, pharmaceuticals, or similar products.

This means that at retail premises, such substances and products must be stored on separate shelves and at least 1.5 metres above floor level. However, this does not apply if the packaging has child-resistant fastenings.

Note that child-resistant fastenings do not prevent children from opening the packaging; it merely delays such opening.

Chemical substances and products should generally be stored in their original packaging. If the substance/product is stored in packaging other than the original, the new packaging must be labelled with the name, indication of danger, danger symbol and R and S phrases of the substance or product in accordance with the classification and danger categories of the substance/product.

Special rules

As a distributor of substances and products which have the danger indication of “Very Toxic” and “Toxic”, it must be noted that a number of special, strict requirements exist on the storage of these substances and products.

■ Read more in Fact Sheet no. 8, “Sale and Storage of Toxic Substances and Products”, on www.mst.dk/homepage/

Substances/products classified as “Explosive” and/or “Flammable” also fall within the scope of special requirements under fire legislation. More information can be obtained by contacting the local fire authorities.



Sale of toxins

The sale of very toxic and toxic substances or products should be as restricted as possible and replaced with other, less dangerous products.

The sale of toxic chemicals, i.e. chemicals labelled “Very Toxic” and “Toxic”, is subject to special regulations.

Different rules exist governing sales with respect to whether sale is intended for commercial or private use.

The Danish EPA must be notified

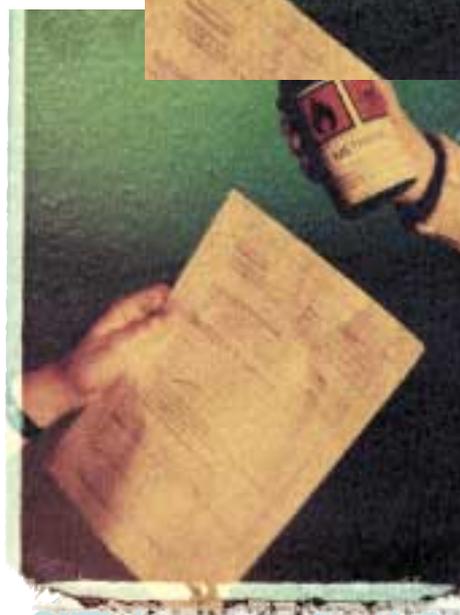
Enterprises importing and selling toxic substances and products for commercial use must report this on a special form to the Danish EPA.

Only chemists and retailers who have permission from the Danish EPA may sell very toxic or toxic substances or products to the general public. Requisitions must be endorsed by the police. Very toxic/toxic substances/products may, however, be sold without a requisition to hospitals etc. and to a number of special institutions.

Distributor responsibility

Distributors of very toxic and toxic substances and products have a number of control and bookkeeping duties. Distributors are obliged to ensure that their customers are entitled to purchase their substances or products.

■ Read more in Fact Sheet no. 8, “Sale and Storage of Toxic Substances and Products”, on www.mst.dk/homepage/



When must the Danish EPA be notified?

Notification must be given to the Danish EPA with respect to a number of chemical substances and products.

Dangerous chemical substances

If a manufacturer or importer has made his own classification of a chemical substance as dangerous, the Danish EPA must be informed of the name and classification of the substance when it is placed on the market. This responsibility also applies to the active ingredients of products. Especially strict requirements exist concerning the documentation of substances that may be carcinogenic, mutagenic, teratogenic, or toxic to human reproduction.

New chemical substances

Manufacturers and importers who import new chemical substances – i.e. substances that do not appear on the European Inventory of Existing Commercial Chemical Substances (EINECS), must report this to the Danish EPA. The manufacturer or importer must, prior to selling and importing such substances, submit a special notification form, with detailed documentation attached. Such notification will usually require the assistance of a consultant. The notification form can be obtained from the Danish EPA.

When importing from countries outside the EU, it is particularly important to be aware of whether the substances in question are ‘new’ substances.

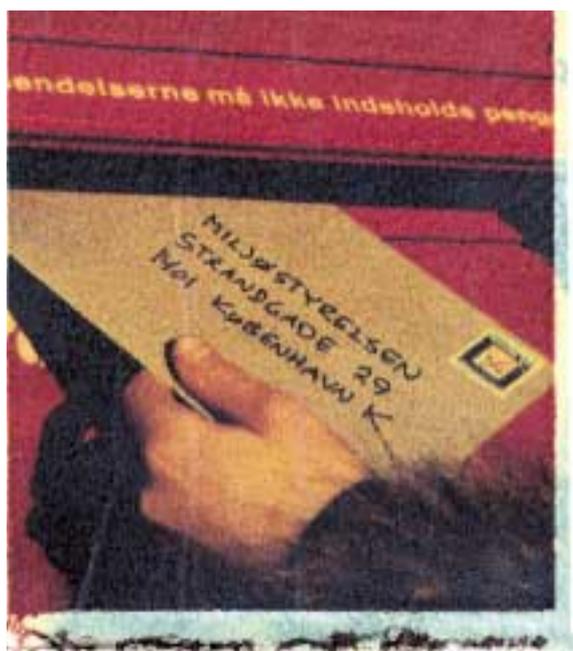
■ Read more in Fact Sheet no. 25, “Notification of New Chemical Substances”, on www.mst.dk/homepage/

Toxic chemicals for commercial use

By import and sale of toxic chemicals for commercial use, the Danish EPA must be notified by means of special toxin notification form, to be submitted on a form available from the Danish Working Environment Agency or the police. Such notification is valid for three years. The form is available on www.politi.dk
■ Read more in Fact Sheet no. 8, “Sale and Storage of Toxic Substances and Products”.

Teats for feeding bottles and comforters

Anyone manufacturing or importing teats for feeding bottles and/or comforters must notify the Danish EPA Chemical Inspection Service.
■ Read more in Fact Sheet no. 9, “Dummies and Baby-Bottle Teats”, on www.mst.dk/homepage/



Supervision and penalties

The Danish EPA Chemical Inspection Service supervises compliance with the rules laid down in the legislation on chemicals.

Areas of action

Supervision takes the form of campaigns in selected areas, toxin control, investigation of reports and likely violations and cases which the Chemical Inspection Service chooses to investigate.

In Denmark, the Chemical Inspection Service works together, for example, with the Working Environment Agency, the police and the Danish Central Customs and Tax Administration and abroad with inspectorates in the EU and the Nordic countries.

Fines and imprisonment

Violation of the Act and the majority of the Statutory Orders is punishable by fines or imprisonment for up to two years, unless more severe penalties are enforceable under other legislation.



If you want to find out more

Acts and Statutory Orders

You can find most of the Acts and Statutory Orders mentioned in this pamphlet on the homepage of the Danish EPA on www.mst.dk/homepage/

Fact Sheets on chemicals rules

The Danish EPA has published a series of Fact Sheets on most of the rules and regulations mentioned in this pamphlet. The Fact Sheets are available on the Danish EPA homepage www.mst.dk/homepage/ or at the Ministry of the Environment information centre Miljøbutikken, phone (+45) 33 95 40 00, butik@mim.dk, www.mim.dk/butik/ukindek.htm

www.mst.dk/homepage/ gives further information on chemicals regulation, substance lists, publications etc.

For further information, contact:

The Danish Environmental Protection Agency
Chemicals Division
Strandgade 29
DK-1401 Copenhagen K.
Phone (+45) 32 66 01 00
mst@mst.dk
www.mst.dk/homepage/

What does the law say about chemical substances and products?

This pamphlet gives a brief survey of legislation on chemicals under the Ministry of the Environment.

- Who is responsible when chemical substances and products are marketed?
- Which chemical substances and products are prohibited or subject to other restrictions?
- How must chemical substances and products be classified, packaged and labelled?
- How are the rules on sale and storage of chemical substances and products?
- How are the rules on retail sale of toxins?
- When must the Danish EPA be notified?
- Who supervises compliance with the regulations?

This pamphlet is aimed primarily at importers, manufacturers, and distributors of chemical substances and products.

Available at
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www.mim.dk/butik/ukindex.htm

Danish Environmental Protection Agency

Danish Ministry of the Environment