

Act relating to cosmetic products and body care products, etc

Chapter I. Purpose, scope and definitions

§ 1. *Purpose*

The purpose of this Act is to help to ensure that cosmetic products, body care products and other products to which the Act applies do not represent a health risk to humans or animals.

The Act is also intended to promote consumer interests, honesty, animal welfare, ethical principles, environmental considerations, food safety and quality.

§ 2. *Substantive scope*

The Act applies to all factors pertaining to the development, manufacture, import, processing, distribution, export and placing on the market of:

- a) Cosmetic products or body care products, which means any substances or preparations intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition
- b) Cosmetic products or body care products for animals, which means any substances or preparations intended to be placed in contact with the various external parts of an animal or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition
- c) External healthcare preparations, which means any substances or preparations intended to be placed in contact with the various external parts of the human or animal body or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to preventing, alleviating or treating health problems that are not caused by disease
- d) Tattooing products, which means any substances or preparations intended for injection into the skin of humans or animals to produce permanent or long-lasting patterns, designs, lines or areas of colour on the skin, including tattoo inks and permanent make-up
- e) Skin injection products, which means any substances or preparations intended for injection into the skin of humans or animals to change the appearance of the skin in other ways than those mentioned in litra d.

The Act also applies to all factors pertaining to the manufacture by an enterprise of materials and articles that are intended to come into contact with or that may have an effect on cosmetic products, cf section 4, litra a.

The Act does not apply to substances, preparations or equipment that come within the scope of the Act of 4 December 1992 No. 132 relating to medicinal products or the Act of 12 January 1995 No. 6 relating to medical equipment. Nor does the Act apply

to food that comes within the scope of the Act of 19 December 2003 No. 124 relating to food production and food safety, etc. (Food Act).

§ 3. *Geographical scope*

The Act applies to Norwegian land territory, the territorial sea, Norwegian aircraft and vessels and installations on the Norwegian continental shelf.

The King may lay down regulations on the application of the Act in Svalbard, Jan Mayen, the Norwegian dependencies, the Economic Zone of Norway and to ships registered abroad if they call at Norwegian ports as part of a regular service. The King may lay down special provisions to take account of local circumstances.

§ 4. *Definitions*

For the purposes of this Act, the following definitions apply:

- a) Product: any cosmetic product or body care product, cosmetic product or body care product for animals, external healthcare preparations, tattooing product, or skin injection product.
- b) Enterprise: any private or public-sector business undertaking or private individual engaged in any of the activities mentioned in section 2, first paragraph, except for activities for private and non-commercial purposes.
- c) Placing on the market: possession of products with a view to sale, offering them for sale, distribution and the actual sale of products and any other form of transfer, whether or not payment is involved.

Chapter II. Prohibitions and requirements

§ 5. *Prohibition against products that represent a health risk*

It is prohibited to develop, manufacture, import, process, distribute, export or place on the market products that represent a risk to human or animal health during normal use or use that can be reasonably foreseen.

The Ministry may lay down further regulations relating to the circumstances under which products are considered to represent a risk to human or animal health.

§ 6 *Duty to obtain approval*

The Ministry may lay down regulations relating to the duty to obtain approval for and provide notification concerning specific types of products.

§ 7 *Labelling, presentation and advertising*

The labelling and presentation of products and advertisements and other marketing of such products shall be correct, give the recipient adequate information and not be misleading.

The Ministry may lay down further regulations on duties pursuant to the first paragraph, for example regulations relating to health claims and voluntary labelling schemes.

The Ministry may lay down regulations relating to the duty to provide documentation for claims used in marketing of a product and requirements for this type of documentation.

§ 8 *Manufacture, ingredients, composition and quality*

The Ministry may by regulations lay down requirements relating to the manufacture of products, their ingredients and other contents, and the quality of products and materials and articles that are intended to come into contact with or that may have an effect on products.

§ 9 *Animal testing*

The Ministry may lay down regulations prohibiting the development, manufacture, import, processing, export and placing on the market of products that have been the subject of animal testing or that contain one or more ingredients that have been tested on animals.

§ 10 *Resistance to antibiotics*

The Ministry may lay down regulations relating to a prohibition against products containing genes coding for resistance to antibiotics derived from processed genetically modified material.

§ 11 *Establishment, design and operations*

The location, design and operation of activities connected with products shall meet appropriate hygienic standards.

The Ministry may by regulations lay down further requirements relating to the establishment, location, design and operation of activities in enterprises connected with products, including requirements relating to notification, registration, approval and lapse of approval, and on health and hygiene requirements relating to personnel.

§ 12 *Duty to ensure compliance, systematic control measures*

An enterprise shall ensure compliance with relevant provisions laid down in or pursuant to this Act. The Ministry may lay down regulations prescribing which persons in an enterprise have responsibilities in this connection and on the duty to provide the supervisory authority with notification of this.

The Ministry may lay down regulations relating to the duty to establish and carry out systematic control measures.

The Ministry may lay down regulations relating to the professional qualifications of personnel.

§ 13. *Access to premises, duty to provide assistance, etc.*

An enterprise shall give the supervisory authority unimpeded access to any place or premises where activities are carried out that come within the scope of this Act, so that the said authority can make any necessary investigations. Inspectors from other countries may take part in inspections, etc., when this is necessary in order to meet Norway's international obligations.

An enterprise shall make the necessary premises, fittings, labour and equipment available free of charge for inspection activities, and otherwise provide assistance and make the necessary arrangements for such activities.

The Ministry may lay down further regulations relating to access to premises, the duty to provide assistance, sampling, etc.

§ 14. *Duty to provide notification and reports*

An enterprise shall immediately notify the supervisory authority in the event of suspicion that a product represents a risk to human or animal health.

If the supervisory authority so requires, an enterprise shall make available or submit any necessary information, samples and results of analyses free of charge. The supervisory authority may determine how the information is to be provided, including the form in which it is to be provided, the level of detail, etc.

The Ministry may lay down further regulations relating to the duty of health personnel and others to provide information and reports.

The Ministry may lay down further regulations relating to the duty to make public the results of inspection activities.

§ 15. *Documentation, etc.*

The Ministry may lay down regulations relating to documentation, including requirements to prepare documentation, the duty to obtain and keep documentation, and the duty to enclose certificates or other documentation with products that are transported or placed on the market.

Chapter III. Final provisions

§ 16 *Activities and decisions of the supervisory authority*

The supervisory authority will carry out control activities and may make any necessary decisions to prohibit the development, manufacture, import, processing, distribution, export or placing on the market of products, and on their seizure or destruction or the closure of enterprises.

The supervisory authority may order the person responsible for an enterprise to meet the actual costs of such seizure or destruction or the closure of the enterprise.

In the event of non-compliance with such orders, if it is not known who is responsible or if it is necessary to ensure that measures are implemented quickly, the supervisory authority may itself implement such measures as are mentioned in the first paragraph. These measures may be taken at the expense of the person responsible. Amounts outstanding are enforceable by execution proceedings.

The supervisory authority may, if important considerations of the public interest so require, or in the interests of meeting Norway's international obligations, lay down, amend or repeal regulations that apply for a limited period of time without a prior consultation process, and may publish such regulations according to special procedures.

The public authorities have a duty to provide necessary information to the supervisory authority on request, notwithstanding their duty of confidentiality. The police, the customs authorities, the coastguard and the municipal authorities shall on request assist the supervisory authority.

The Ministry will decide which administrative authority is to be the supervisory authority under this Act.

§ 17. *Personal data filing systems*

To ensure compliance with provisions laid down in or pursuant to this Act, the supervisory authority may establish personal data filing systems containing necessary information on the enterprises for which it is responsible.

To ensure compliance with the provisions of this Act, the supervisory authority may collect information for systems such as are mentioned in the first paragraph, including information from existing systems.

The Ministry may lay down regulations relating to further rules for such systems, including requirements on confidentiality and on the disclosure of information.

§ 18 *Taxes and fees*

The Ministry may by regulations require enterprises to pay fees to cover the costs of inspection, control and special services, such as issuing certificates and approval of products, under this Act.

The Ministry may by regulations require enterprises to pay a tax to cover any costs relating to supervision and control pursuant to this Act that are not covered by fees levied pursuant to the first paragraph.

The Ministry may lay down further regulations on the calculation, collection and payment of the said taxes and fees.

Should fees not be paid within the time stipulated, interest is to be paid according to Act of 17 December 1976 No. 100 relating to interest on overdue payments.

Fees are enforceable by execution proceedings.

§ 19. *Exemptions*

The Ministry may in special cases grant exemptions from the provisions laid down in or pursuant to this Act, provided that this is not in conflict with Norway's obligations under international law.

§ 20. *Coercive fines*

If an enterprise fails to meet the deadline for complying with orders issued pursuant to this Act, the supervisory authority may impose a coercive fine in the form of a lump-sum fine or a continuous daily fine.

A coercive fine may be imposed when the order is issued if this is necessary to ensure that the deadline is met.

An order to pay a coercive fine is enforceable by execution proceedings.

The Ministry may lay down further provisions on imposing and calculating coercive fines.

§ 21. *Penal measures*

Any person who wilfully or through negligence contravenes provisions or decisions laid down in or pursuant to this Act is liable to fines or to a term of imprisonment not exceeding one year or both. Complicity or an attempt is liable to the same penalties.

§ 22. *Entry into force and transitional provisions*

This Act enters into force on the date determined by the King.¹

The Act of 19 May 1933 No. 3 relating to the inspection of cosmetics and body care products, etc is repealed from the same date. Regulations and individual decisions laid down pursuant to the repealed Act will continue to apply until they are repealed.

¹ From 1 January 2006, pursuant to Royal Decree of 21 December 2005 No. 1642.