Draft Act relating to cosmetic products

Chapter I. Purpose, scope and definitions

§ 1. *Purpose*

The purpose of this Act is to ensure that cosmetic products do not represent a risk to the human or animal health and that consumer interests, animal welfare, ethical issues, environmental considerations, food safety and quality are taken into consideration in the manufacture, processing, distribution, import, export and placing on the market of such products.

§ 2. *Substantive scope*

The Act applies to all factors pertaining to the development, manufacture, import, processing, distribution, export and placing on the market of cosmetic products by an enterprise. 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.

The Act does not apply to substances, preparations or equipment that come within the scope of Act of 4 December 1992 No. 132 relating to medicinal products or Act of 12 January 1995 No. 6 relating to medical equipment.

§ 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 Ministry may lay down regulations on the application of the Act in Svalbard, in the Norwegian dependencies, in the Economic Zone of Norway and on ships registered abroad when they are in Norwegian harbours. The Ministry may lay down special provisions to take account of local circumstances.

§ 4. *Definitions*

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

a) "*Cosmetic products*": cosmetics and body care products, products used for tattoos and skin injection products
b) "*Cosmetics and body care products* ": any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to
    1. cleaning them, perfuming them, changing their appearance, correcting body odours, protecting them or keeping them in good condition, or
    2. preventing, alleviating or treating health problems that are not caused by disease

c) "*Products used for tattoos*": any substance or preparation 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.
d) "*Skin injection products*": any substance or preparation 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 c.
e) "*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.
f) "*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. The term also includes the use of products and offering them for sale in connection with the provision of goods or services, including use by hairdressers and similar businesses and for advertising purposes.

Chapter II. Prohibitions and requirements

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

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

The Ministry may lay down further regulations relating to the circumstances under which cosmetic products are considered to represent a risk pursuant to the first paragraph.

§ 6. *Prohibition against cosmetic products that represent a risk to the environment*

The Ministry may lay down regulations prohibiting the development, manufacture, import, processing, distribution, export or placing on the market of cosmetic products that may represent a risk of environmental damage or that contain one or more ingredients that may represent a risk of damage to the environment.

§ 7. *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 cosmetic products.

§ 8. *Labelling, presentation and advertising*

The labelling and presentation of cosmetic 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, including 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 cosmetic product and requirements for this type of documentation.

§ 9. *Manufacture, ingredients, composition and quality*

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

§ 10. *Animal testing*

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

§ 11. *Genetically modified organisms*

The Ministry may lay down regulations prohibiting the development, manufacture, import, processing, export, or placing on the market of cosmetic products that contain genetically modified organisms or genes from genetically modified organisms, or products that are manufactured from or using genetically modified organisms.

§ 12. *Establishment, design and operations*

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

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

§ 13. *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.

The Ministry may lay down regulations on health and hygiene requirements relating to personnel.

§ 14. *Access to premises, duty to provide assistance, sampling, etc.*

An enterprise shall give the supervisory authority unimpeded access to any 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.

An enterprise shall at the request of the supervisory authority provide the necessary samples or results of analyses free of charge.

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

§ 15. *Duty to provide information and reports*

If the supervisory authority so requires, an enterprise shall make available or submit any necessary information and samples. 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.

§ 16. *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

§ 17. *Activities and decisions of the supervisory authority*

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

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

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 measures such as are mentioned in the first paragraph. Such 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 authority, 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.

§ 18. *Registers of information*

To ensure compliance with provisions laid down in or pursuant to this Act, the supervisory authority may establish registers for any information considered necessary on the enterprises for which it is responsible.

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

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

§ 19. *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 lay down further regulations on the calculation, collection and payment of fees.

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

Fines are enforceable by execution proceedings.

§ 20. *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, including the EEA Agreement.

§ 21. *Coercive fines*

If an enterprise fails to meet the deadline for complying with orders issued pursuant to provisions laid down in or 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.

§ 22. *Penal measures*

Any person who wilfully or through gross 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.

§ 23. *Entry into force and transitional provisions*

This Act enters into force on the date determined by the Ministry. The King will decide which ministry is to be the competent authority pursuant to this Act.

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