

Regulations no. 1044 of 13 October 1989 concerning the prohibition against new tobacco and nicotine products

Statutory authority: Laid down by Royal Decree in pursuance of section 4, first paragraph (e), cf. section 15, of Act no. 79 of 11 June 1976 relating to Product Control.

Section 1. *Object*

The object of these regulations is to limit the damage to health caused by use of tobacco and nicotine products.

Section 2. *Prohibition*

It is prohibited to produce, bring to Norway, sell or hand over to others new types of tobacco and nicotine-containing products. The same applies to tobacco and nicotine-containing products which are intended to be used in other ways than those normally practised in Norway.

Section 3. *Definitions*

In these regulations, the term "new types" of tobacco and nicotine-containing products means all products containing tobacco or nicotine, with the exception of the products which, by tradition, are or have been sold in Norway (cigarettes, cigars, cigarillos, smoking tobacco, chewing tobacco and snuff).

In these regulations, the expression "intended to be used in other ways" means intake of tobacco and nicotine-containing products to the human body in ways other than the form of smoking, taking snuff and chewing used today.

Section 4. *Relationship to other Acts*

Exempt from the prohibition in section 2 are tobacco and nicotine-containing products that are to be used for smoking cessation purposes and are classified as medicines, cf. Act no. 132 of 4 December 1992 relating to medicines etc.

Section 5. *Supervisory authority*

The Ministry bears overall responsibility for the enforcement of these regulations. The Directorate for Health supervises compliance with the rules in these regulations.

Section 6. *The obligation to submit information*

At the instruction of the Ministry or the Directorate each and every person is under obligation to submit the information necessary for the Ministry and the Directorate to carry out their tasks pursuant to these regulations.

The Ministry and the Directorate may instruct manufacturers, importers or dealers to submit representative samples of the product or implement the investigations necessary in order to evaluate the product's properties and effects. The manufacturer or importer bears the costs of such investigations.

The Ministry and the Directorate may themselves instigate such investigations. When such is found to be reasonable, the costs may be charged to the manufacturer or importer. The costs are a basis for execution of distraint.

Section 7. *Access to buildings etc*

The Ministry and the Directorate have free access to buildings, conveyances, warehouses, installations, areas etc. where products governed by these regulations are to be found.

The Ministry and the Directorate may also carry out sampling and control of such products.

Section 8. *Dispensation*

The Directorate may grant dispensation from the prohibition in section 2 if the manufacturer or importer can document that a new product or its manner of use is significantly less harmful to health than products already on the market.

A manufacturer and importer of a product has the right to apply for dispensation. Applications for dispensation are submitted to the Directorate. The application shall contain the information necessary to evaluate the properties and effects of the product.

The dispensation may be made subject to conditions when this is found to be necessary in order to prevent and limit possible damages to health.

The Directorate may revoke a dispensation if

- a) new information on or evaluations of the product, its manner of use or effects make this desirable, or
- b) the party who has been granted the dispensation contravenes the conditions laid down for the dispensation.

Section 9. *Appeal*

Decisions by the Directorate pursuant to these regulations are individual decisions and may be appealed to the Ministry pursuant to Chapter VI of the Public Administration Act.

Section 10. *Coercive fines*

In the case of contravention of conditions, orders or prohibitions laid down in or pursuant to these regulations, the Ministry may impose a coercive fine. The coercive fine is a basis for execution of distraint.

Section 11. *The obligation of secrecy*

Anyone whose duty it is to enforce these regulations shall observe secrecy concerning operation or business matters which, from the point of view of competition, it is important to keep secret out of consideration for the enterprise or enterprises to which such information refers. The obligation of secrecy applies with the limitations resulting

from the tasks of the person concerned pursuant to the provisions of the legislation and the regulations issued pursuant thereto.

Section 12. *Penal liability*

Any person who wilfully or negligently contravenes the provisions laid down in these regulations, or who contravenes the conditions laid down pursuant to section 8, shall be liable to penalty in the form of fines or imprisonment for up to 3 months, or both. Complicity is punishable in the same manner.

Section 13. *Geographical area of application*

The provisions laid down in or pursuant to these regulations apply in Norway, included Svalbard and Jan Mayen, on board Norwegian ships and aircraft located in areas not under the supreme jurisdiction of any state and on facilities and installations on the Norwegian continental shelf.

Section 14. *Amendments to the regulations*

The Ministry may supplement and amend these regulations.

Section 15. *Entry into force*

These regulations enter into force immediately.