

I. COSMETICS

I1 The Public Health Act

Passed on 14 June 1995,

(RT* I 1995, 57, 978),

entered into force 21 July 1995,

amended by the following Acts:

25.02.99 entered into force 01.01.00 - RT I 1999, 30, 415;

23.04.97 entered into force 26.05.97 - RT I 1997, 37, 569;

26.07.96 entered into force 26.07.96 - RT I 1996, 49, 953;

19.12.95 entered into force 01.04.96 - RT I 1996, 3, 56.†

Chapter 1

General Provisions

§ 1. Purpose of Act

The purpose of this Act is to protect human health, prevent disease and promote health, which is to be achieved through the performance of duties by the state, local governments, legal persons in public law, legal persons in private law and natural persons, and through national and local measures.

§ 2. Definitions used in this Act

In this Act, the following definitions are used:

- 1) "public health" means the science and art of disease prevention, extending life expectancy, promoting and improving mental and physical health through the organised efforts of society;
- 2) "health" means a state of physical, mental and social well-being of a person, not only the absence of disability or disease;
- 3) "health protection" means activities aimed at ensuring a physical and social environment which is safe for human health and at preventing health disorders and disease associated with the physical and social environment;
- 4) "health promotion" means the creation of behaviour and lifestyles which value and enhance health, and the purposeful development of a physical and social environment which is conducive to health;
- 5) "disease prevention" means activities aimed at early detection of disease in persons and measures to prevent illness;
- 6) "health education" means the purposeful dissemination of information and formation of people's habits for the preservation and improvement of health;
- 7) "physical and social environment" means the aggregate of natural, artificial and social environmental factors with which people come into contact and which affects or may affect human health.

§ 3. Primary objectives of health protection, disease prevention and health promotion

The primary objectives of health protection, disease prevention and health promotion are:

- 1) to value the health of individuals, families and the public;
- 2) to develop, legislate and implement measures for the healthy development of children, prevention and reduction of infectious, non-infectious, occupational and other diseases, to reduce incidents of premature death and disability, improve the quality of life and extend the duration of working life;
- 3) to study the physical and social environment and assess the risk factors thereof, and monitor and predict the state of human health depending on the state of the physical and social environment;
- 4) to inform the public of the deterioration or danger of deterioration of the physical and social environment;
- 5) to reduce disparities in the state of health in different regions of the country and different groups of people;
- 6) to develop and enact health protection legislation and state supervision over compliance therewith.

§ 4. Basic requirements for protection of physical and social environment and health

The basic requirements for protection of the physical and social environment and health are:

- 1) no person shall endanger the health of other persons by his or her direct action or by harming the physical and social environment;
- 2) the development and spread of infection and other health hazards shall be prevented in the manufacture, preparation, transport, preservation and sale of foodstuffs intended for sale;
- 3) drinking water consumed by the public shall be safe for health;
- 4) consumer goods, in particular products for children, shall be produced from such materials and in such a way that ordinary use is safe for human health;
- 5) the safety of the preparation and intended use of chemical products shall be established in advance, and the permission of a state health protection supervisory official is required for preparation and sale of chemical products;

(23.04.97 entered into force 26.05.97 - RT I 1997, 37, 569)

- 6) the same requirements shall apply to goods produced in and imported to Estonia;
- 7) buildings, structures and means of transport shall be designed and built such that their intended use promotes the maintenance of health and considers the needs of persons with physical disabilities;

8) study and working conditions shall be harmless to health; in areas of activity where health hazards may be present, persons shall undergo a medical examination prior to commencing studies or work and regular medical examinations thereafter.

§ 5. Means of disease prevention

Means of disease prevention are:

- 1) preventive medical examinations for children in order to ensure the healthy development of children and early detection of disease;
- 2) implementation of measures for prevention of the spread of infectious diseases and vaccination for prevention of infectious diseases;
- 3) initial and regular medical examinations of the health of persons working in jobs which are hazardous to health, for prevention and early detection of health disorders and occupational diseases which may develop due to working conditions;
- 4) monitoring of risk factors for prevention of chronic non-communicable diseases, and development and implementation of such disease prevention programmes;
- 5) development of programmes for early detection of diseases and study of risk groups.

§ 6. Means of health promotion

Means of health promotion are:

- 1) health education as part of educational programmes;
- 2) dissemination of health information and promotion of healthy lifestyles;
- 3) development of health promotion services;
- 4) influencing of lifestyles and reduction of behavioural risks;
- 5) development of a health-enhancing physical and social environment.

Chapter 2

Duties of State, Local Governments, Legal Persons in Public Law, Legal Persons in Private Law and Natural Persons

§ 7. Duties of Government of the Republic

(1) The duties of the Government of the Republic are to:

- 1) oversee national health protection and health promotion policy;
- 2) establish the procedure for state health protection supervision and ensure supervision;
- 3) approve national programmes for prevention of health disorders and diseases, for health promotion and creation of a physical and social environment safe for health.

(2) The Government of the Republic shall enact health protection legislation on:

- 1) selection of construction sites, and on building, occupying and using buildings, structures and means of transport;
- 2) manufacture, import, transport, preservation and sale or distribution of mineral water and drinking water, and manufacture, import and use of materials which come into contact therewith;
(25.02.99 entered into force 01.01.00 - RT I 1999, 30, 415)
- 3) manufacture, import and use of synthetic materials and products made therefrom, machinery, equipment and tools which may be hazardous to health;
- 4) manufacture, import, transport, storage, use and rendering harmless of substances or equipment containing radionuclides and toxic or strong substances and biological products, except medicinal products;
- 5) preparation, import and sale of products for children, chemical products, cosmetics, consumer products which come into direct contact with persons, household effects and building materials;
- 6) prevention of the spread, at the state border and within the state, of infectious diseases designated as extremely dangerous in international agreements (quarantine diseases);
- 7) provision of consumer services to the public.

§ 8. Duties of Ministry of Social Affairs

(1) In addition to the duties prescribed in the Health Care Administration Act (RT I* 1994, 10, 133; 1995, 57, 978; 1997, 86, 1462; 1999, 18, 305; 23, 351), the duties of the Ministry of Social Affairs are to:

- 1) plan and implement plans for health protection, disease prevention and health promotion;
- 2) draft health protection, disease prevention and health promotion laws and other legislation;
- 3) concord draft legislation relating to health protection, disease prevention and health promotion prepared by other ministries;
- 4) propose to the Government of the Republic to establish an emergency situation in the state or in part of the state to eliminate an infectious disease, intoxication or radiation damage;

5) co-ordinate the activities of other ministries, agencies and inspectorates in the area of health protection and health promotion;

6) plan and organise implementation of national programmes, projects and other measures for creation of a physical and social environment

which is safe for health, prevention of health disorders and disease, and health promotion;

7) organise health education and activities aimed at creating healthy lifestyles and health appreciation, and, in co-operation with the Ministry of Education, to organise health education in educational institutions;

(26.07.96 entered into force 26.07.96 - RT I 1996, 49, 953)

8) co-ordinate research relating to health protection, disease prevention and health promotion;

9) co-ordinate state supervision over health protection through the Health Protection Inspectorate.

(26.07.96 entered into force 26.07.96 - RT I 1996, 49, 953)

(2) The Minister of Social Affairs shall establish health protection legislation on:

1) introduction and use of technologies, machinery, equipment and tools which may be hazardous to health;

2) organisation of workplaces and prevention of occupational diseases and intoxication;

3) prevention of the spread of infectious and parasitic diseases;

4) preparation of daily schedules and study timetables in educational institutions;

5) food service in child care institutions, educational institutions, medical institutions and social welfare institutions;

6) transport, burial and reburial of the deceased.

§ 9. Duties of county governors

The duties of county governors are to:

1) ensure implementation of health protection, disease prevention and health promotion measures in the territory of the county;

2) develop and organise implementation of programmes aimed at creation of a physical and social environment which is safe for health, prevention of health disorders and disease in the county;

3) co-ordinate co-operation between agencies dealing with health protection and health promotion and rural municipality medical officers and city medical officers

(26.07.96 entered into force 26.07.96 - RT I 1996, 49, 953)

§ 10. Duties of local governments

The duties of the local governments are to:

1) organise implementation of health protection legislation and monitor observance thereof in the territory of the local government;

2) organise activities aimed at prevention of disease and health promotion among the population in the territory of the local government.

§ 11. Duties of rural municipality medical officers and city medical officers

(1) In addition to the duties prescribed in the Health Care Administration Act, rural municipality medical officers and city medical officers shall monitor observance of health protection legislation in territories, buildings and structures in state, municipal or private ownership which are administered by or in the ownership of legal persons in public law, legal persons in private law or natural persons under their jurisdiction and, upon violation of legislation, shall make proposals to the management of enterprises, agencies or organisations or to natural persons for the elimination of violations.

(2) In the implementation of this Act, rural municipality medical officers and city medical officers have the rights of state health protection supervisory officials specified in clause 16 (1) 1) of this Act. Rural municipality medical officers and city medical officers shall notify state health protection supervisory agencies of violations of health protection legislation.

(3) It is the duty of rural municipality medical officers and city medical officers to make proposals to local governments or other competent bodies on improving the state of the physical and social environment and on health promotion in the rural municipality or city.

(4) The duties of rural municipality medical officers and city medical officers include co-operation with county health protection offices.

§ 12. Duties of legal persons in public law, legal persons in private law and natural persons

(1) Prior to commencing manufacture of a product, legal persons in public law, legal persons in private law and natural persons shall ensure inspection of manufacturing conditions and the safety of the product or, in the absence of methods to determine hazards, develop such methods; in the absence of normative documents concerning the product prepare and concord normative documents with a state health protection supervisory agency in the following areas of production:

1) manufacture of materials which come into contact with raw material for food, food, mineral water and drinking water;

(25.02.99 entered into force 01.01.00 - RT I 1999, 30, 415)

2) preparation of synthetic materials and products containing synthetic materials, toxic or strong substances and biological products, except medicinal products and products prepared using biotechnology;

(23.04.97 entered into force 26.05.97 - RT I 1997, 37, 569)

3) manufacture of products for children, consumer chemicals, cosmetics, consumer products which come into direct contact with persons and household effects;

4) manufacture of products which emit or cause radiation, noise or vibration which are potentially harmful to health.

(2) The list of categories of substances and goods specified in subsection (1) of this section and the procedure for inspection and ensurance of safety of manufacturing conditions, products and services connected therewith shall be established by the Government of the Republic.

(3) Legal persons in public law, legal persons in private law and natural persons shall obtain approval for the plans of enterprises which handle products or provide services specified in subsection (1) of this section and the plans of child care institutions, medical institutions, care institutions and means of transport with state health protection supervisory agencies.

(4) Legal persons in public law, legal persons in private law and natural persons shall ensure regular laboratory testing of raw materials, working conditions, products and waste of manufacturing processes in areas of activity and pursuant to the procedures prescribed by the Government of the Republic.

(5) Legal persons in public law, legal persons in private law and natural persons shall promptly notify state health protection supervisory agencies and local governments of accidents and situations which may harm human health or the physical and social environment.

(6) Legal persons in public law, legal persons in private law and natural persons shall not by word, print or other means disseminate ideas, opinions, beliefs or other information which could be hazardous to human health and the physical and social environment.

(7) Legal persons in public law, legal persons in private law and natural persons shall, pursuant to the procedure prescribed by the Minister of Social Affairs, ensure:

1) laboratory testing of water used by the public, for recreational swimming or sport, in the administration of bodies of water and beaches;

2) disinfection or eradication of insect or rodent vermin if favourable conditions develop for the spread of infections;

(8) Legal persons in public law, legal persons in private law and natural persons shall, pursuant to the procedure established by the Government of the Republic, present documents certifying the safety of imported goods and products. [23.04.1997]

§ 13. Institutions performing health protection, disease prevention and health promotion duties

(1) Health care institutions shall perform the primary objectives of health protection, disease prevention and health promotion according to their main areas of activity.

(2) Other institutions and organisations perform health protection, disease prevention and health promotion duties in the cases provided by law, their statutes or articles of association.

(3) The safety of objects in the physical and social environment may be assessed by agencies and specialists licensed by the Ministry of Social Affairs.

§ 14. Availability of information relating to state of human health and physical and social environment

Agencies dealing with health protection, disease prevention and health promotion shall ensure the availability of information intended for public use on human health and the physical and social environment.

Chapter 3

State Supervision over Health Protection

§ 15. Supervisory authorities

(1) State supervision over health protection with regard to implementation of the requirements prescribed by this Act and legislation established on the basis thereof shall be exercised by the Health Protection Inspectorate and its local offices within the area of government of the Ministry of Social Affairs.

(26.06.96 entered into force 26.07.96 - RT I 1996, 49, 953)

(2) Officials licensed for supervision of state health protection perform state supervision over health protection pursuant to the procedure and conditions established by the Government of the Republic.

(3) In the performance of his or her duties, a state health protection supervisory official is a representative of state authority and his or her lawful requirements and precepts for elimination of offences are mandatory for all officials and persons.

§ 16. Rights and obligations of supervisory officials

(1) Upon presentation of identification, supervisory officials have the right:

1) regardless of the form of ownership, to inspect without hindrance the territory, buildings, structures, manufacturing processes, products, means of transport and documentation of sites under inspection and to demand explanations in order to resolve health protection issues;

2) to take samples of materials and products without charge and samples of objects for the duration of the inspection from sites under inspection in order to monitor health protection, monitor health protection and assess the safety of an inspected site;

3) to require legal persons in public law, legal persons in private law and natural persons to restrict, suspend or terminate activities which are or may be a hazard to human health upon possession, use and disposal of assets; to issue precepts for elimination of violations of health protection legislation and impose deadlines for the performance thereof; and monitor the performance of such precepts.

(2) In the case of a spread of infectious disease or intoxication, or danger of such spread, supervisory officials may:

1) hospitalize persons suffering from an infectious disease who are a danger to themselves or others, and require potentially infected persons to undergo medical examinations;

2) require employers to temporarily suspend from work employees who have not undergone a mandatory medical examination on a timely basis, persons suffering from an infectious disease, carriers of germs and persons who due to the nature of their work may infect others;

(3) Health protection supervisory officials are required to:

1) exercise their rights to terminate violations of health protection legislation and if necessary, inform the media;

2) maintain medical and business secrets and information regarding the private lives of persons that they become aware of in the performance of health protection supervision duties.

§ 17. Contestation of precepts or other acts of state health protection supervisory agencies or officials

(1) If a legal person in public law, legal person in private law or natural person does not agree with a precept or other act of a state health protection supervisory agency or official, such person has a right to file a complaint with the Director General of the Health Protection Inspectorate within ten calendar days after the date of becoming aware of the precept or other act.

(26.06.96 entered into force 26.07.96 - RT I 1996, 49, 953)

(2) Filing of a complaint does not relieve persons of the duty to comply with a precept of a state health protection supervisory agency or official.

(3) The Director General of the Health Protection Inspectorate shall review a complaint within one month after the date of receipt of the complaint.

(26.06.96 entered into force 26.07.96 - RT I 1996, 49, 953)

(4) Upon reviewing a complaint, the Director General of the Health Protection Inspectorate shall make one of the following decisions: to uphold, amend or repeal the precept or other act.

(26.06.96 entered into force 26.07.96 - RT I 1996, 49, 953)

(5) Decisions are communicated to complainants and issued against a signature or sent by certified mail. Upon opposition, a decision may be contested in an administrative court.

§ 18. Appeal to court

(1) Regardless of an earlier filing of a complaint specified in § 17 of this Act, legal persons in public law, legal persons in private law and natural persons have a right to appeal a precept or other act of a state health protection supervisory agency or official to an administrative court.

(2) Filing of an appeal does not relieve persons of the duty to comply with a precept of a state health protection supervisory agency or official until a court declares it unlawful in part or in full.

§ 19. Liability for violation of health protection legislation

(1) Legal persons in public law, legal persons in private law and natural persons are liable for violations of this Act and other health protection legislation.

(2) Natural persons bear disciplinary, civil, administrative or criminal liability for violation of this Act and other health protection legislation pursuant to the procedure prescribed by law.

(3) For violation of this Act and other health protection legislation, legal persons shall bear the following administrative liability:

- 1) a fine of up to 10 000 kroons shall be imposed for failure to obtain approval for the required supporting documentation with a state health protection supervisory agency prior to commencing manufacture or other activity;
 - 2) a fine of up to 100 000 kroons shall be imposed for occupying or using a building, structure or means of transport for purposes other than those for which it is designed without the approval of a state health protection supervisory official;
 - 3) a fine of up to 150 000 kroons shall be imposed for preparation or sale of chemical products without the approval of a state health protection supervisory official;
 - 4) a fine of up to 100 000 kroons shall be imposed for violation of other requirements of health protection legislation in a manner which endangers human health or the physical and social environment;
 - 5) a fine of up to 250 000 kroons shall be imposed for failure to comply with a precept which has been communicated to a legal person if failure to comply therewith causes damage to human health or illness in a person;
- (4) The Director General of the Health Protection Inspectorate, his or her deputy, the chief doctor of the Estonian Sanitary Quarantine Office, the chief doctors of health protection offices and administrative court judges have the right to review and impose punishment in matters concerning offences specified in subsection (3) of this section.
- (5) In matters concerning offences specified in subsection (3) of this section, the Director General of the Health Protection Inspectorate, his or her deputy, the chief doctor of the Estonian Sanitary Quarantine Office and the chief doctors of health protection offices have the right to impose fines of up to 10 000 kroons; greater fines may be imposed only by administrative court judges.
- (6) The procedure for matters concerning administrative offences by legal persons specified in subsection (3) of this section, including the imposition of punishment, contestation thereof and execution of orders concerning administrative punishment which have entered into force are effected pursuant to the procedure provided for in the Code of Administrative Offences (RT 1992, 29, 396; I 1997, 66–68, 1109; 73, 1201; 81, 1361 and 1362; 86, 1459 and 1461; 87, 1466 and 1467; 93, 1561, 1563, 1564 and 1565; 1998, 2, 42; 17, 265; 23, 321; 30, 410; 34, 484; 36/37, 552 and 552; 38, 562; 51, 756 and 759; 52/52, 771; 60, 951 and 952; 64/65, 1004; 86/87, 1409; 98/99, 1574; 103, 1695; 108/109, 1783; 1999, 4, 53; 10, 149 and 156; 16, 267, 271, 272, and 276; 23, 350; 29, 398 and 404; 30, 415) taking into consideration to the rules of the Code of Enforcement Procedure (RT I 1993, 49, 693; RT I 1997, 43/44, 723; 1998, 41/42, 625; 51, 756; 61, 981; 103, 1695; 1999, 18, 302; 27, 380) and the Code of Administrative Procedure (RT I 1993, 50, 694; 1994, 16, 290; 28, 425; 1995, 29, 358 and 359; 1996, 37, 739; 1997, I, 16, 260; 30, 472).
- (7) Officials specified in subsection 205 (3) of the Code of Administrative Offences have the right to prepare reports on administrative offences by legal persons specified in subsection (3) of this section. A report shall indicate the date and place of preparation of the report; the name and address of the agency in whose name the report is prepared; the official title, given name and surname of the person who prepared the report; the name and address of the violating legal person; the given name and surname and official title of a competent representative of the legal person; the place, time and description of the offence; a reference to a clause of subsection (3) of this section which provides for liability for such offence; an explanation provided by the representative of the offender; and other information as required. The report shall be signed by the person who prepares the report and the representative of the offender. If the representative of the offender refuses to sign the report, a corresponding entry shall be made therein by the person who prepares the report. Written notations of the representative of the offender concerning the report and refusal to sign the report shall be appended to the report.
- (8) If a natural person acting as an employee of a legal person or with the authorisation of a legal person commits an offence specified in subsection (3) of this section, liability for such offence may be simultaneously applied to the natural person pursuant to the Code of Administrative Offences and the legal person pursuant to subsection (3) of this section.

§ 20. Compensation for damage due to violation of Public Health Act

Legal persons in public law, legal persons in private law and natural persons who violate this Act or health protection legislation are required to compensate for damage and bear expenses relating to elimination of damage if the violation causes harm to human health or damage to the physical and social environment or to another legal person or natural person pursuant to the procedure prescribed by law.

Chapter 4

Final Provisions

§ 21. Financing

- (1) The activities of state health protection supervisory agencies are financed from the state budget.
 - (2) National programmes relating to health protection, disease prevention and health promotion are financed from the state budget.
 - (3) Local programmes relating to health protection, disease prevention and health promotion may be financed in part or in full from the state budget.
 - (4) Programmes relating to disease prevention and health promotion may be financed in part or in full from the health insurance budget.
 - (5) State health protection agencies provide health protection services for a fee pursuant to the procedure and fee schedule established by the Ministry of Social Affairs.
 - (6) Legal persons in public law, legal persons in private law and natural persons shall bear the expenses relating to performance of functions and duties assigned by this Act.
- [§ 22 omitted]‡

* RT = Riigi Teataja = State Gazette

† Any amendment to the Act contained herein is noted with the date of passage, date of entry into force and Riigi Teataja citation. If a whole or a part of a section has been amended, reference to the amending Act appears in brackets immediately after the amended whole or part.

‡ The omitted section amends other legislation.

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12 The Regulation of the Government of Estonia No. 228 of November 26, 1997

Kosmeetikavahendite valmistamise, terviseohutuse tagamise ja importimise korra kinnitamine Vabariigi Valitsuse 26. novembri 1997. a. määrus nr. 228

Rahvatervise seaduse (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569) paragrahvi 7 lõike 2 punkti 5 ja paragrahvi 12 lõike 2 alusel Vabariigi Valitsus määrab:

Kinnitada Kosmeetikavahendite valmistamise, terviseohutuse tagamise ja importimise kord (juurde lisatud).

Peaminister Mart SIIMANN

Sotsiaalminister Tiiu ARO

Riigisekretär Uno VEERING

Kinnitatud

Vabariigi Valitsuse 26. novembri 1997. a. määrusega nr. 228

Kosmeetikavahendite valmistamise, terviseohutuse tagamise ja importimise kord

1. Üldnõuded kosmeetikavahenditele

1.1. Kosmeetikavahend ei tohi põhjustada üldisi tervisehäireid ega kutsuda esile ärritusnähte kasutamiskohal, kui teda tarvitatakse kasutamishendi kohaselt. Kosmeetikavahendite põhirühmade loetelu on toodud käesoleva korra lisa 1.

1.2. Kosmeetikavahendid võivad sisaldada aineid või teatud otstarbeks valmistatud segusid (edaspidi valmistis), mis vastavad järgmistele nõuetele:

1) ei kuulu keelatud ainete loetelusse (käesoleva korra lisa 2);

2) on lubatud kasutada ainult käesoleva korra lisades 3, 4, 5 ja 6 märgitud kogustes ja tingimustel;

3) kosmeetikavahendit pakendist väljasuruvad gaasid peavad olema bioloogiliselt lagundatavad vähemalt 30% ulatuses, nad ei tohi kahandada osoonikihti ja kuuluda Osoonikihti kahandavate ainete nimekirja (RTL 1997, 91, 534).