



REGULATION OF THE MINISTER

No.

Requirements for natural mud and peat used in balneological procedures

This Regulation is adopted on the basis of section 17(2) of the Public Health Act and section 5(4) of the Product Conformity Act.

§ 1 Scope of application

This Regulation establishes requirements for natural sea mud and lake mud used in balneological procedures (hereinafter together: *curative mud*) and peat, as well as their handling and labelling.

§ 2 Scope

Manufacturers of curative mud and peat, as well as legal entities and self-employed persons offering balneological procedures, must comply with the requirements laid down in the Regulation.

§ 3 Definitions

The terms in this regulation are defined as follows:

- 1) 'balneological procedure' – the external use of curative mud and peat on the human body surface for the purpose of improving one's well-being;
- 2) 'manufacturer of curative mud or peat' – manufacturer within the meaning of section 4(1) (9) of the Product Conformity Act;
- 3) 'sea mud, lake mud, and peat' – mineral resources registered as extracted in Estonia for the purposes of the regulation of the minister responsible for the area, established on the basis of section 19(3), section 20(3), and section 22(3) of the Earth's Crust Act;
- 4) 'making available on the market' – making available within the meaning of section 4(1)(11) of the Product Conformity Act.

§ 4 Requirements for the quality of curative mud and peat

(1) Curative mud and peat used in balneological procedures shall not contain mineral particles with a grain size greater than 1.0 mm. Mineral particles with smaller grain sizes may constitute up to 3 % in sea mud and up to 2 % in lake mud and peat.

(2) The physical properties and chemical parameters of curative mud and peat for use in balneological procedures shall be as follows:

- 1) sea mud must have a water content of 65–85 % and an organic matter content in dry matter of more than 5 %;

- 2) lake mud must have a water content of 90–95 % and an organic matter content in dry matter of more than 35 %;
- 3) the water content in peat must be more than 85 %, the organic matter content in dry matter more than 90 %, the humic acid content in dry matter at least 20 %, the humification class of von Post at least H7 and the ash content must not be more than 12 %.

§ 5 Microbiological quality indicators

The content of bacterial indicators and pathogens in curative mud and peat used in balneological procedures shall not exceed the following limits:

- 1) *Escherichia coli* no more than 10 bacteria per wet weight gram of curative mud or peat, expressed in MPN (most probable number) or CFU (colony-forming unit);
- 2) *Clostridium perfringens* up to 100 CFU per gram of wet weight of curative mud or peat;
- 3) *Staphylococcus aureus* must not be present in one gram or millilitre of curative mud or peat.

§ 6 Storage of curative mud and peat

(1) Curative mud and peat must be stored at a temperature between +4 °C and +15 °C. Higher temperatures are permitted only immediately before the procedure.

(2) A quantity of curative mud and peat greater than one tonne shall be stored in a dedicated mud storage tank or reservoir.

§ 7 Labelling of curative mud and peat

(1) The labelling of curative mud and peat made available on the market shall include the following information:

- 1) the manufacturer's name or trade mark, postal address and email address;
- 2) the quantity;
- 3) the instructions for use and safety information;
- 4) the conditions of storage;
- 5) the date until which the packaged product retains its original properties and effects under appropriate storage conditions, or an indication of the period of time after opening for which the product is fit for use and safe;
- 6) the batch or serial number, or the place and time of extraction, which enables identification of the product;
- 7) the prohibition established in section 8(2) of the Regulation.

(2) The information referred to in subsection 1 may be provided on the label of the packaging of the curative mud or peat or in a document accompanying the curative mud or peat.

§ 8 Use of curative mud and peat

(1) The provider of the balneological procedure must have the following information on the curative mud and peat:

- 1) the place of extraction;
- 2) the manufacturer;
- 3) the quantity;
- 4) the time of arrival;
- 5) the time of commissioning.

(2) Repeated use and regeneration of curative mud and peat shall not be permitted.

§ 9. Verification of microbiological parameters and hazardous substances

(1) The manufacturer of curative mud or peat and the provider of the balneological procedure must check the microbiological parameters of unpackaged curative mud and peat in a mud tank or container at least once a year.

(2) If the limit value for microbiological parameters of curative mud or peat is exceeded or if there is a justified suspicion of danger, a re-analysis must be carried out. If the limit value established by the repeat analysis is exceeded, an additional test for the presence of pathogenic micro-organisms must be carried out.

(3) The results of the safety inspection of microbiological parameters shall be stored in a format that allows for written reproduction for five years.

(4) When introducing a new batch of curative mud or peat, the provider of the balneological procedure must ensure its microbiological safety.

(5) The manufacturer of curative mud or peat must have data on the concentration of hazardous substances in the curative mud or peat deposit. The data on the content of hazardous substances in curative mud and peat must not be more than ten years old.

(6) The content of heavy metals (Pb, Cd, Sn, Zn, Hg), petroleum products (hydrocarbons C10–C40, sum), phenols and pesticides (hereinafter *hazardous substances*) shall be determined in curative mud and peat. The assessment of the content of hazardous substances in curative mud or peat shall be based on the regulation of the minister responsible for the area established on the basis of section 83 of the Water Act, which establishes the limit values for the content of hazardous substances in soil.

(7) In the event of a significant deterioration in environmental conditions or reasonable suspicion of danger, the manufacturer of curative mud or peat must check the content of hazardous substances in the curative mud or peat.

(8) If the curative mud or peat does not comply with the requirements established for microbiological indicators and the content of hazardous substances, the reasons for the non-compliance of the curative mud or peat shall be ascertained and the necessary measures shall be taken to eliminate the non-compliance. If necessary, curative mud or peat shall be withdrawn from the market and the Health Board shall be notified thereof.

§ 10. Entry into force of the Regulation

This Regulation shall enter into force on 1 September 2025.

(signed digitally)
Riina Sikkut
Minister for Health

(signed digitally)
Maarjo Mändmaa
Secretary General