

Impacts of the Regulation

The purpose of the draft is to ensure the safe use of curative mud and peat for its user. Compared to the current Regulation, the draft introduces quality and safety requirements for curative mud and peat, and clarifies other provisions for the sake of legal clarity.

The implementation of the Regulation will have an impact on users of balneological procedures, service providers, and manufacturers of curative mud and peat. The impact on the target groups shall be assessed on the basis of the quality and safety requirements for curative mud and peat.

Social, economic, and environmental impacts can be expected from the implementation of the changes proposed in the draft. In order to determine the significance of the impacts, the impacts were assessed against four criteria: the magnitude of the impact, the frequency with which the impact occurs, the size of the target population affected, and the risk of adverse effects occurring.

Social impact

Target group: users of balneological procedures

Curative mud and peat are used both for rehabilitation purposes and in the provision of beauty services. Although several service providers highlight on their websites the indications and contraindications for undergoing curative mud procedures and recommend planning balneological procedures in consultation with a doctor, this service is available to everyone in spas, as well as beauty and personal services companies.

According to the Health Insurance Fund, in 2023, 1 028 people received the service 'mud therapy session for patients with rheumatoid arthritis, ankylosing spondylitis, and pronounced stiffness of joints'¹. No data are available on the number of people who received services in private medicine, spas, and at beauty and personal service providers. It is also not known how many people use balneological procedures with curative peat. However, given the upward trend in the first incidence of musculoskeletal and connective tissue diseases² and the increase in the number of medical bills over time for patients with the relevant diagnoses³, growth can also be expected in the use of mud and peat treatment services. Although the exact number of recipients of balneological procedures is not known, the service recipients are expected to represent less than 1 % of the average population (1 370 286 people) in 2023⁴ and therefore the size of the target group is small.

The implementation of quality and safety requirements for curative mud and peat will reduce the potential risk of damage to health for users of balneological services, therefore, the changes will have a positive impact on human health. By adjusting the

¹ <https://www.tervisekassa.ee/koik-teenused>.

² https://statistika.tai.ee/pxweb/et/Andmebaas/Andmebaas__02Haigestumus__01Esmashaigestumus/EH11.px/table/tableViewLayout2/.

³ <https://www.tervisekassa.ee/koik-teenused>.

⁴ https://andmed.stat.ee/et/stat/rahvastik__rahvastikunaitajad-ja-koosseis__rahvaarv-ja-rahvastiku-koosseis/RV0211/table/tableViewLayout2.

grain size of mineral particles, possible skin damage during balneological procedures is avoided. Microbiological analyses of bacteria and pathogens in curative mud and peat maintain the recommended level of (*Escherichia coli*, *Clostridium perfringens* and *Staphylococcus aureus*) and thus reduce the possibility of these microorganisms entering the body through skin injuries during the balneological procedure. These microbes can cause multiple infections of the skin, subcutaneous tissue, and muscle tissue. Determining and maintaining the recommended levels of hazardous substances (heavy metals, petroleum products, phenols, pesticides) in curative mud and peat makes it possible to prevent long-term damage to the health of all organ systems, as well as the development of chronic diseases and various ailments and pains. The negative health effects of heavy metals and other hazardous substances do not occur through direct exposure, but through long-term use, when chemicals accumulate in the body in quantities that are harmful to health. Thus, regulating the amount of hazardous substances contained in curative mud and peat helps to avoid potential long-term health problems.^{5, 6, 7}

The establishment of quality and safety requirements for curative mud and peat is unlikely to be noticed by the users of balneological procedures. Service providers whose curative mud or peat does not meet the established quality requirements may disappear from the market, but this is a positive development for the users. Upon entry into force of the amendments, the users may expect that all available balneological procedures are of uniformly good quality. The price of the service, which could limit the availability of the service, will probably not change significantly as a result of the amendments to the Regulation. Considering the above, users of curative mud and peat services do not need to adapt to the changes and the magnitude of the impact can be assessed as low. The frequency of the impact may also be considered low, since exposure to balneological services generally occurs irregularly and randomly according to the user's wishes. However, in the case of a doctor's recommendation for balneological procedures for rehabilitation purposes, the provision of the service may take the form of a regular course of treatment, in which case the frequency of the impact may be assessed as average. The risk of undesirable effects is low because, from the user's point of view, tightening the safety and quality requirements for the use of curative mud and peat reduces the risk of a number of adverse health effects and the quality of curative mud and peat can be expected to be consistent across different providers. Overall, the impact on users of balneological services can be considered negligible.

Social and economic impact

Target group: providers of balneological procedures

Providers of balneological procedures may include public and private health care facilities, spas, and beauty and personal care providers.

In 2023, health services related to curative mud were provided in eight medical institutions on the basis of the Health Insurance Fund price list: Almeda Kliinik OÜ,

⁵ https://www.terviseamet.ee/sites/default/files/content-editor/vanaveeb/Kasulikku/Keskkonnatervis/Keemilised_riskitegurid_vees_siilak.pdf.

⁶ <https://www.terviseamet.ee/sites/default/files/content-editor/vanaveeb/Keskkonnatervis/vesi/eraveevaergid.pdf>.

⁷ <https://www.eea.europa.eu/et/highlights/elis-on-vaja-teha-rohkem>.

SA Ida-Viru Keskhaigla, TÜ Kliinikum SA, SA Narva Haigla, Ida-Tallinna Keskhaigla AS, Lääne-Tallinna Keskhaigla, Adeli Eesti OÜ, and Järvamaa Haigla. Most of the services were provided by Almeda Kliinik OÜ, an institution located in Ida-Viru County, where one-third of the 10 300 mud treatment services were provided. In 2024, Neeme Family Physicians Centre was also added to the list of institutions providing mud treatment services.⁸

The number of undertakings offering balneological procedures in private health facilities is not known. Among the members of the Estonian Spa Association, mud treatment services are provided by five institutions: four in the form of mud wraps and one in the form of a mud bath, but there may actually be more service providers in spas. Providers of beauty services are not obliged to register their activities in the register of economic activities, which is why there is no information on how many such institutions exist in Estonia and how many of them engage in balneological procedures. Curative peat is used by 10–12 companies for balneological procedures.

Of all public health care institutions, of which there were 55⁹ in 2023, and of all economically active companies, of which there were 153 883¹⁰, establishments providing balneological treatments represent a small target group. Although the exact number of institutions is not known, their share of the comparable target group remains below 1 %.

Providers of balneological procedures will be obliged to carry out quality control of curative mud and peat once a year, as well as when introducing a new batch. Under the current Regulation, mud treatment service providers must carry out inspections twice a year, so the workload related to inspections does not change significantly. There were no requirements previously imposed by the Regulation on companies providing peat treatment services, so this is a new obligation for these institutions. Instead of the previously generally worded need for quality control, the amendment to the Regulation provides clarity on which quality indicators to check. Providers will be required to check the following microbiological parameters for unpackaged curative mud and peat: *Escherichia coli*, *Clostridium perfringens* and *Staphylococcus aureus*.

Performing one analysis of microbiological parameters will cost the undertaking performing the balneological procedures around 65 euros (excluding VAT)¹¹ and, as a general rule, it is a one-off cost per calendar year. The price quoted is approximate and varies depending on the laboratory performing the analysis. Additional costs must be taken into account if the service provider uses several different batches of curative mud or peat (the cost arises separately for each batch), as well as if the service provider does not comply with the temperature of curative mud and peat storage established in the Regulation, in which case additional analyses are expected.

Analysis of the microbiological parameters of curative mud and peat, and monitoring of the level of the required parameters will have a positive impact on the quality of the service. Improvements in the quality of curative mud and peat reduce the risk of

⁸ <https://www.tervisekassa.ee/koik-teenused>.

⁹ [TTO10:Health care providers by type of owner and county. PxWeb \(tai.ee\)](https://toto10.ee/Health_care_providers_by_type_of_owner_and_county.PxWeb_(tai.ee)).

¹⁰ https://andmed.stat.ee/et/stat/majandus__majandusuksused__ettevetjad/ER025/table/tableViewLayout2.

¹¹ [Microbiological research - Estonian Environmental Research Centre \(klab.ee\)](https://www.klab.ee/mikrobioloogiline-uuring-eesti-keskkonnapuudustekeskuse-koosteguts).

potential health damage and complications for the recipients of the service. Some impact can be expected on ensuring the availability of services. As the additional cost of analysing microbiological indicators from the institution's perspective is small, this aspect is unlikely to affect the availability of services. However, non-compliant products may disappear from the market if quality and safety requirements of curative mud and peat are not met. The implementation of the Regulation may therefore lead to some reduction in the availability of balneological procedures, but the impact will still be positive, as all available balneological procedures will be performed with curative mud and peat that complies with the standards.

Ordering microbiological analyses to check the quality of curative mud and peat does not change the daily work of the providers performing balneological procedures, but requires a one-time familiarisation with the requirements. For mud treatment institutions that have previously carried out quality checks under the current Regulation, the scope of the impact is small, as ordering analyses regardless of the parameters being investigated is a routine procedure. From the perspective of providers of peat treatment procedures, the requirement to conduct quality checks is new, but it is not anticipated that there will be difficulties in adapting to ordering analyses. It is possible that, from the provider's perspective, ordering analyses is a familiar procedure, so the extent of the impact is small to medium. The frequency of impact is average for providers performing balneological procedures: while respecting the recommended requirements for the preservation of curative mud and peat, the analysis of microbiological parameters is a regular but infrequent procedure. Given the improvement in the quality of balneological services related to the performance of quality control, this is a positive effect and the risk of undesirable effects is low. Overall, the impact on providers performing balneological procedures is rather negligible.

Financial impact

Target group: curative mud and peat manufacturers

There are five manufacturers of curative mud and five major manufacturers of curative peat in Estonia. Of the total number of economically active companies, i.e. 153 883¹² in 2023, the target group represents a small proportion.

Manufacturers of curative mud and peat will have the obligation to ensure that curative mud or peat offered meets the quality requirements laid down in the Regulation. The introduction of quality requirements will harmonise the market and reduce the possibility of introducing unsuitable mud or peat into the market, which will have a positive impact on market participants. On the other hand, quality control and, where necessary, interventions to achieve the quality and safety of curative mud or peat entail additional costs.

When implementing the Regulation, manufacturers must ensure that the marketed curative mud or peat meets the general quality criteria: producers of both curative mud and peat will be required to carry out checks on the amount of mineral particles and the content of water and organic substances prescribed. In the case of peat, it is also necessary to analyse the humic acid and ash content and have the von Post

¹² https://andmed.stat.ee/et/stat/majandus__majandusuksused__ettevetjad/ER025/table/tableViewLayout2.

humification class assessed. In addition to the requirement to check these general quality parameters, manufacturers of curative mud and peat will be required to determine the microbiological parameters of curative mud and peat. The relevant microbiological analysis must be conducted by the companies at least once a year for each batch extracted.

The obligation to carry out each of these analyses will impose an additional cost on businesses, which will vary depending on the price list of the laboratory from which the analysis is ordered. According to the price list of the laboratory of the Estonian Environmental Research Centre in force at the end of 2024, the cost of analysing the physical properties and chemical parameters of curative mud and peat is approximately 95 euros, with an additional 62 euros for peat (excluding the assessment of humic acid content). The cost of analysing microbiological parameters per sample is approximately 65 euros. VAT is added to these prices.

If the limit value for microbiological parameters is exceeded, the companies must take account of additional costs: in this case, it is necessary to carry out a re-analysis which, if the maximum levels are exceeded, requires an additional study on the presence of pathogenic micro-organisms, involving specialist experts. Depending on the nature and extent of the problem encountered and the necessary interventions implemented to improve the quality of curative mud or peat, as well as the price list of the laboratory used, the cost of achieving the quality of curative mud or peat suitable for the market may vary.

In addition, it is established that manufacturers of curative mud and peat must have data that goes back up to ten years regarding the content of hazardous substances in their curative mud or peat deposits. The cost of analysis of heavy metals (Pb, Cd, Sn, Zn, Hg), petroleum products (sum of C10-C40 hydrocarbons), phenols, and pesticides in curative mud and peat is approximately 1 110 euros¹³ over ten years. The companies will only incur the cost of analysis if information on dangerous substances is not available elsewhere, environmental conditions have significantly deteriorated, or if there is a justified suspicion of hazard.

In summary, the amendment to the Regulation will require manufacturers of curative mud and peat to commission analyses of quality parameters to ensure that only high quality and safe curative mud and peat reach the market. The impact of the Regulation may range from medium to high depending on the quality of the curative mud or peat extracted. Examination of the requirements introduced by the Regulation is a one-off process for the companies and is unlikely to lead to adaptation difficulties. At the same time, in a situation where the quality of the extracted curative mud or peat does not comply with the established limits and there is a need to carry out additional studies or implement interventions to improve the quality of curative mud or peat, the company will need to adapt to the changes. There may be a situation where a company abandons a batch of curative mud or peat that does not meet the requirements of the Regulation due to the costs necessary for processing curative mud or peat. The frequency of the impact on manufacturers is medium, as the analyses ordered to check compliance with the requirements for curative mud or peat are rarely carried out, but with a certain regularity: microbiological analyses are generally ordered only once a year and analysis of the content of dangerous

¹³ https://klab.ee/wp-content/uploads/2024/01/pinnaseanalyyaside_hinnad_2024.pdf.

substances, if necessary, only once every ten years. Exceeding the limits of analytical results may necessitate the assignment of additional analyses on an irregular basis; however, this is not a daily occurrence. From the point of view of the companies producing curative mud and peat, the risk of adverse effects is medium. The companies must take into account that in case of non-compliance with the result of the analyses, the curative mud or peat will require processing, which will entail costs. In addition to the costs incurred, the positive impact, manifested in market convergence and the improvement of the quality of curative mud and peat, is more important. The amendment to the Regulation reduces the possibility of bringing to the market mud and peat unsuitable for balneological treatment procedures. In conclusion, from the perspective of companies producing curative mud and peat, this has a significant impact.

Impact on governance

Target group: Health Board

The enactment of the draft will not bring about changes in the organisation of work or new tasks for state authorities. According to the Public Health Act, the Health Board exercises supervision over the current Regulation and retains the same function upon the establishment of the new draft.

Environmental impact

The collection of data on hazardous substances in curative mud and peat provides valuable information on environmental pollutants and environmental changes. However, indirect environmental impacts are broader – the information collected will enable a more precise assessment of the need for research and the planning of possible solutions and interventions to prevent the spread of hazardous substances to other natural environments, maintain the cleanliness of water and soil, and remove contaminants from the natural cycle. Preventing the spread of pollutants in the ecosystem helps prevent habitat damage, supports biodiversity, and also helps protect vegetation and aquatic fauna.