Message 001

Communication from the Commission - TRIS/(2025) 0300

Directive (EU) 2015/1535

Notification: 2025/0064/EE

Notification of a draft text from a Member State

Notification – Notification – Notification – Notification – Γνωστοποίηση – Notificación - Teavitamine - Ilmoitus - Obavijest - Bejelentés - Notifica - Pranešimas - Pazinojums -Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo -Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20250300.EN

- 1. MSG 001 IND 2025 0064 EE EN 03-02-2025 EE NOTIF
- 2. Estonia
- 3A. Majandus- ja Kommunikatsiooniministeerium, aadress Suur-Ameerika 1, 10122 Tallinn Ettevõtluse ja tööstuse osakond, karl.stern@mkm.ee
- 3B. Sotsiaalministeerium, Rahvatervishoiu osakond, info@sm.ee
- 4. 2025/0064/EE S00S HEALTH, MEDICAL EQUIPMENT
- 5. Draft Regulation 'Requirements for natural mud and peat used in balneological procedures'
- 6. Natural curative mud and peat for use in balneological procedures

7.

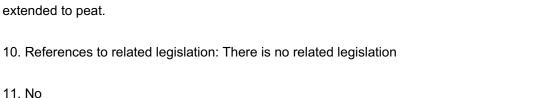
8. The draft Regulation lays down safety requirements for natural sea mud, lake mud, and peat used in

balneological procedures, and for their handling and labelling, in order to protect the recipients of the balneological procedure from poor quality services and related health risks (skin damage, infections, poisoning, etc.). In order to assess the safety and quality of curative mud and peat, limit values and criteria are established on the basis of which the manufacturer of curative mud or peat or the provider of a balneological procedure can assess the suitability of curative mud and peat for use in balneological procedures.

9. Curative mud and peat have been used in balneological procedures in Estonia for nearly 200 years. In Estonia, such procedures are mostly offered by spas and healthcare institutions, as well as beauty and personal care providers. In order to protect the recipients of the procedure from poor quality service and the accompanying health hazards, requirements for the handling of curative mud and peat are provided. This is because mud that is extracted and used in procedures can be contaminated with heavy metals and other hazardous chemicals or pathogenic microbes during formation and handling. Microbes may enter the body through skin injuries (including microscopic ones) and cause various conditions, such as wound infections, eye infections, as well as purulent skin and soft tissue infections, tissue necrosis, etc. Most heavy metals are harmful, carcinogenic, or toxic to the body even in very small quantities, damaging the central nervous system, liver, kidneys, skin, bones, and teeth. Although adverse effects do not occur immediately, chemicals in quantities harmful to the health may accumulate in the body as a result of repeated procedures.

There are currently requirements for the marketing, storage, and use of curative mud, but no requirements for the criteria necessary to ensure its safety, such as the permitted content of hazardous chemicals and microbes. So far, therefore, there has been no legal basis to declare curative mud contaminated and to require its disposal.

In addition to curative mud, curative peat is also used in balneological procedures, which is why similar requirements to those for curative mud are imposed on curative peat. The peat used in the procedures has so far been imported to Estonia from elsewhere in Europe, not extracted from Estonian deposits. In order for peat extracted in Estonia to be used safely in balneological procedures, the requirements must also be extended to peat.



12.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu