Registration of Substances and Products in Direct Contact with Water in Bathing Water Supply and Authorisation of Technologies for Bathing Water Safety, Registration, Review of Authorisation, Amendment of Registration and Authorisation

1. Name of the case and the matter of the subject

According to Article 16. § (1) of Government Decree 510/2023. (XI. 20.) *on the Establishment and Operation of Public Baths* (hereinafter referred to as "Government Decree 510/2023."), prior to the first national distribution**, the distributor is required to report to the** National Centre for Public Health and Pharmacy (hereinafter referred to as "NCPHP") on the **substances in direct contact with water and the products** listed in Annex 8, point 1, sub-point 1.1. Based on Article 17 § (1) of Government Decree 510/2023., **the technologies** listed in Annex 8, point 1, sub-point 1.3, **to be used in the water supply of bathing establishments must be licensed** by the NCPHP.

The list of the product groups that are not obligatory to be registered is contained in Annex 8, point 1 and sub point 1.2 of Government Decree 510/2023.

Chemicals used in bathing water treatment, whose quality requirements are covered by a valid national standard and whose product quality complies with it, **do not need to be reported** to the NCPHP. However, the **marking of the standard must appear on the product labelling.**

During the registration and licensing procedure, the NCPHP examines, **on the basis of its prior expert opinion**, whether the substances, products, and water treatment procedures that come into contact with bathing water do not endanger human health or the quality of bathing water.

In regards to the above, the registration and the issuance of the license is preceded by an expert opinion procedure, which is conducted by the NCPHP Department of Public Health Laboratories in a separate procedure, the fee for which is specified as a service based on the Department's price offer.

In order to ensure the clear identification of the product/technology and its control by the authorities, the raw materials, types/commercial names of the bathing water and their manufacturers must be provided during the procedure, and it is not in any way possible to keep this information confidential.

The decision on registration and the bathing water safety permit shall be issued by the NCPHP within 60 days of receipt of the application, which fully complies with the requirements of Annex 8, point 3 of Government Decree 510/2023., and shall specify the conditions of use, on the basis of the previously issued expert opinion.

The notifier/authoriser and, in the case of further distribution, the resellers are also obliged to provide information on the public health conditions of use of the registered substance, product or technology with a bathing water safety permit when marketing or reselling substances or products in direct contact with water in the water supply of bathing water establishments.

The NCPHP and the public health authority verify the application, the validity of the bathing water safety permit, the adherence to the permit's conditions, and the requirement to submit information.

The applicant must apply to the NCPHP every five years for a public health review of registered substances, products and authorized technologies, unless the NCPHP specifies a shorter period

of one, two or three years for registration or authorisation due to an increased risk to public health. The requirements of the content for the review application are set out in Annex 8, point 3 of Government Decree 510/2023.

It is imperative to have a preliminary expert opinion from the NCPHP Department of Public Health Laboratories before requesting a review.

If the product or technology is unchanged (especially in terms of its composition, the quality of the raw materials and auxiliary materials used in its manufacture, type and manufacturer), and the manufacturing conditions are unchanged, the review may be started if less than five years have passed since the first notification or authorization was issued.

Failure to apply for an adjustment to the data expiry date of the register due to changes in the conditions, proven non-compliance, and failure to carry out the mandatory review will result in removal from the register. Items deleted from the register will be published by the NCPHP on its website, together with the reasons for the deletion.

The NCPHP will withdraw the authorisation if

→the license holder fails to notify a change in the conditions existing at the time of granting the license, or

→a license cannot be granted on the basis of the outcome of the review.

In the event that the bathing water used, the contact materials or types, and their manufacturer remain the same, the registration or authorization may be amended. This also applies to the addition of a new type to the registered and authorized product family. Any changes to the data included in the registration or authorization do not require an assessment.

Every month, the NCPHP updates and publishes a list of notifications and bathing water safety permits issued on its website (https://www.nnk.gov.hu/), which is open to the public and can be searched without any restrictions.

It is possible to register and authorise a family of products if it can be demonstrated that the manufacturer, quality, operation, construction and materials in contact with bathing water of the members of the family are fully identical (material, exact composition, quality, manufacturer).

The national jurisdiction of the NCPHP is established in Article 3 of Government Decree 333/2023. (VII. 20.) on the National Centre for Public Health and Pharmacy.

2. Name, postal and e-mail address, telephone number and opening hours of the managing authority

National Centre for Public Health and Pharmacy
1097 Budapest, Albert Flórián út 2-6.
Address for correspondence: National Centre for Public Health and Pharmacy, Department of Public Health
National Institute of Public Health and Pharmacy,
Budapest, 1437 Budapest, PO Box 839.
Telephone: 06 1/476-1220
E-mail: kozegeszseg@nngyk.gov.hu
Office Gate: NNKKOZEG, KRID ID: 369732197
Customer reception by prior arrangement by telephone.

3. Title, number of applicable legislation

Government Decree 510/2023. (XI. 20.) *on the establishment and operation of public baths.*

Act No XI of 1991 *on Health Authorities and Administration.*

Act CL of 2016 *on the General Public Administration Procedures.*

Government Decree 333/2023 (20 July) *on the National Centre for Public Health and Pharmacy.*

Decree No 1/2009 (I. 30.) *on the fees payable for certain administrative procedures and administrative services of the National Public Help and Medical Officer Service*

Act I of 2017 on the *Code of Administrative Court Procedure.*

Act CLXXXIV of 2010 *on the designation, seat and jurisdiction of courts*.

Act CIII of 2023 on the *Digital State and on the Provisions for Supplying Digital Services*

4. Administrative guidance

1 Who can submit an application and how

The distributor or manufacturer of the product or technology, or, in the case of a natural person or legal entity, by its representative, may submit an application for registration or for a bathing water safety authorisation. The application must be submitted in writing, certified by a stamp in the manner specified in point 9.

Prior to submitting an application for registration, authorisation and review, a prior positive opinion must be obtained from the NCPHP Department of Public Health Laboratories.

4.2 Information to be included in the application

The application must include the following information:

a) The applicant's
   aa) name,
   ab) registered office and place of business, tax number,
   ac) document certifying the establishment of the legal person (company registration, company registration number, court registration number or, in the case of a service provider not subject to court or official registration, the founding document), the name and contact details of its representative, the nature and content of the representation;
b) Authorisation for delivery or other authorisation, if relevant
c) The marketing name of the product or technology
d) The names, tax numbers and locations of the domestic distributors
e) Name of the manufacturing company, place of establishment, manufacturing sites
f) The area of the use of the product or technology (in details)
g) In case of a product family, list of products in the family (name or types)

4.3 Documents to be attached to the application at the time of the submission

(a) Instructions for use in Hungarian, or an instruction manual or machine manual, which includes the conditions of use from a public health point of view.

b) Document proving payment of the administrative service fee,

c) The number of the public health assessment previously prepared by the NCPHP Department of Public Health Laboratories,

d) Product list,

e) In the case of a bathing water treatment process, a description and data required to assess the effectiveness of the treatment and its effects on public health and bathing water safety.

4.4 Documents to be attached to the application at the time of review

a) Manufacturer's declaration of unchanged manufacturing conditions of the product or technology,

b) A declaration that the product or technology is unchanged (in particular, its composition, the quality of the raw materials and auxiliary materials used in its manufacture, its construction, type and manufacturer),

c) Document proving the payment of an administrative service fee,

d) Instructions for use in Hungarian, or operating instructions or a user manual for machinery containing the conditions of use from the point of view of public health,

e) The number of the public health assessment previously prepared by the NCPHP Department of Public Health Laboratories

4.5 Documents to be submitted when modifying registration

a) Application for modification of the notification, bathing water safety authorisation, signed by the company (indicate the name of the product, technology, manufacturer, distributor, types, field of application, subject of the requested modification),

(b) A statement that the bathing water contact materials used in the new types and their manufacturer and production technology are the same as those used in the previous notification,

(c) A list of the bathing water contact parts, materials, type and manufacturer of the new types,

d) The new product list,

e) The instructions for use corrected in accordance with the new product list,

f) Document proving payment of the administrative service fee.

4.6 Documents to be submitted when there is a change in the applicant's details

a) The application for the modification of the notification or bathing water safety authorisation, signed by the company (including the name of the product, technology, manufacturer, distributor, types, field of application, subject of the requested modification),

(b) Document confirming the change in the details of the notifier,

(c) Document proving the payment of the administrative service fee.

4.7 Forms required by law or recommended by the authorising authority

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4.8 Description of the administrative process

The administrative process is based on the provisions of Act CL of 2016. *on the General Public Administration Procedures* (hereinafter: GPAP).

Upon receiving the documentation, the authority will examine its completeness and adequacy. If the application has been submitted incompletely or inadequately, the authority will request the applicant to submit a deficiency report once during the procedure.

Types of deficiencies and the consequences of not filling them:

→Failure to attach a certificate of payment of the administrative service fee is subject to a deficiency report pursuant to Section 44 of the GPAP, which includes a request for payment

(typically within 8 days of receipt of the order). Failure to pay within the specified time limit will result in the termination of the procedure pursuant to Section 47 (1) d) of the GPAP. The product may not be placed on the market or marketed without a notification/authorisation.

→In the event of failure to submit the documents required for the procedure or their incompleteness, a request for the submission of a deficiency shall be issued pursuant to Section 44 of the GPAP, with a reasonable deadline set taking into account the procedural deadline. Failure to complete the submission of a deficiency report within the specified time limit may result in the termination of the procedure with regard to Section 47 (1) b) of the GPAP. The product may not be placed on the market or marketed without a notification/authorisation.

→If further information is required to clarify the facts, the authority shall conduct an evidentiary procedure with regard to Section 62 (1) of the GPAP, during which a deficiency may be remedied by granting a reasonable time limit, which shall be determined taking into account the procedural time limit. Failure to complete the application within the time limit shall result in the rejection of the application.

If the clarification of the facts makes it necessary, the authority may request the customer to make a statement pursuant to Section 63 of the GPAP. If the customer does not make a statement and the application cannot be judged in the absence of such a statement, the procedure is terminated pursuant to Section 47 (1) b) of the GPAP. The product may not be placed on the market or marketed without a notification/authorisation.

The authority decides on the acceptance or rejection of the notification on the basis of the data and documents required by law and submitted and examined during the procedure, as well as on the basis of the preliminary opinion issued by the NCPHP Department of Public Health Laboratories

4.9 Other involved authorities, institutions

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5.0 Deadline for administrative procedures

According to Article 39 of the GPAP, the applications are assessed by the automated decision-making process, in a summary proceeding or full hearing. The use of summary proceedings in certain specific cases may be prohibited by law.

Pursuant to Section 50 (1) of the GPAP, unless otherwise provided by an act, the administrative time limit shall begin on the date of the opening of proceedings.

Under Section 50 (2) of the GPAP, the administrative time limit shall be:
a) twenty-four hours in the case of automated decision-making;
b) eight days for summary proceedings;
c) sixty days for full hearings.

Pursuant to Article 14/B (9) of Act XI of 1991. *on Health Authorities and Administrative Activities*, there is no place for summary proceedings in official matters related to the notification of products, water treatment chemicals, and filter materials subject to public health registration that come into contact with drinking water and hot water, the authorization of products and equipment for water treatment that can be marketed under drinking water safety permits, the notification of substances and products subject to notification that come into direct contact with bathing water, and the authorization of bathing water treatment procedures subject to bathing water safety permits. Thus, registration and bathing water safety authorisation are always carried out in a full procedure.

Pursuant to Section 49 (1) of the GPAP, the client may request the suspension of the procedure. The proceedings shall be continued pursuant to Section 49 (2) of the GPAP at the request of the client. After a six-month suspension, the procedure, which may only be continued upon request, shall be terminated. The authority shall notify the persons to whom it would notify the decision of the termination.

According to Section 50 (5) of the GPAP, the administrative time limit shall not include:
a) the duration of suspension, stay of proceedings; and
b) the duration of default or delay of the client.

6. Administrative service fee amount, method of payment

The administrative service fee for registration or licensing pursuant to Annex IV.8. of Annex 1 of EüM Decree 1/2009. (I.30.) *on the fees payable for certain administrative procedures and administrative services of the National Public Help and Medical Officer Service* (hereinafter referred to as the "fee") shall be paid at the time of initiation of the procedure. The Administrative Service Fee is HUF 129,600 per product. Proof of payment of the fee is required at the time of filing the application.

The fee for the public health review of the registered product and authorised technology according to Annex 1, point IV.13. of EüM Decree 1/2009. (I.30.) -hereinafter referred to as EüM Decree - the must be paid at the time of initiation of the procedure. The administrative service fee is HUF 64,800 per product. Proof of payment of the fee is required at the time of application.

In the case of a product family, if it is proven that the manufacturer, quality and bathing water contact materials of the members of the product family are fully identical (material, exact composition, quality, manufacturer), the registration procedure costs HUF 129,600 and the review fee HUF 64,800. The list of the products or technologies belonging to the product family (name or type) must be provided in each case for the notification or authorisation procedure.

In the case of a change due to a change in the data of the applicant or the licensee, the fee (HUF 21,600) according to Annex 1, No IV.12. of the EüM Decree shall be paid.

In the case of registration and amendment of the bathing water safety permit, the fee according to Annex 1, No. IV.11. of the EüM Decree (HUF 64,800/product) shall be paid.

The fee may be paid by the initiating party to the NCPHP account by bank transfer, cash transfer order, domestic postal order or to the NCPHP's cashier's office.

If the fee is paid by bank transfer, the fee can be paid to the NCPHP's account number 10032000-00290438-00000000 at the Hungarian State Treasury. The name of the company and the material/product must be indicated in the communication.

The document proving payment of the fee – in order to speed up the process- must be sent to the NCPHP as part of the application or, in the case of an ongoing procedure, with reference to the case number and the person responsible for the case.

The fee is tax-free and the NCPHP will send an official invoice to the client upon receipt of the amount.

According to Section 47 (1) (d) of the GPAP, the authority shall terminate its proceeding if the client fails to comply with the obligation of advancing procedural costs

7. Rights and obligations of the customer

According to Section 5 (1) of the GPAP, clients shall have the right to make statements and comments at any time during the proceedings.

Section 6 of the GPAP states that all parties to the proceedings are required to act in good faith, and to cooperate with the other parties. No one shall be permitted to engage in conduct aimed to mislead the authority, nor to unduly delay the decision-making process or the enforcement procedure. The good faith of clients and other persons participating in the proceedings shall be presumed. The burden of proof for bad faith lies with the authority.

According to Article 33 (1) GPAP, *the client shall be allowed access to the documents of the proceedings any time during the proceedings and also after the conclusion thereof*.

Pursuant to Section 64 (1) of the GPAP, if not precluded by law, the client's statement shall be admissible as a substitute for any unavailable evidence, if obtaining such evidence is impossible. This is not excluded by sector-specific legislation in this type of case.

Under Section 65 (1) of the GPAP, the authority, where considered necessary in ascertaining the relevant facts of the case, and it cannot be obtained pursuant to Act CIII of *2023 on the Digital State and on the Provisions for Supplying Digital Services* - except where Subsection (2) of Section 36 applies - may request the client to present some document or other instrument.

8. Legal remedies

A customer who objects to the decision of a public authority may bring an administrative action for damages within 30 days of the date of the publication of the decision, by lodging a statement of claim. The statement of claim must be addressed to the competent territorial court, and handed in to the NCPHP. A party acting through a legal representative and an economic operator may submit the application only by electronic means.

The final decision shall, at the request of the client, be altered, annulled or set aside by the Tribunal in the event of a finding of infringement, except for procedural violations that do not have a significant impact on the outcome of the case, and, if necessary, order the authority to conduct new proceedings. In the absence of an infringement, the court or tribunal shall dismiss the action.

The lodging of an application shall not have suspensory effect on the validity of the decision.

The tribunal hears administrative cases out of court, but at the request of one of the parties it will hold a hearing. The applicant client may request a hearing in the application. Failure to do so shall not give rise to a request for justification. The court proceedings are subject to the payment of a fee, which is set by the court.

Section 116 (4) of the GPAP excludes the possibility of appealing against the decision. The possibility of judicial review is provided for in Section 114(1) of the GPAP. The place and time for filing an application for legal remedy is provided for in Section 39(1) of Act I of 2017 on the *Code of Administrative Court Procedure*.

The amount of the *fee* is determined by Section 45/A (1) of Act XCIII of 1990. on Duties (hereinafter: Act on Duties.). The right to record the fee is provided for in Section 62(1) (h) of the Act on Duties.

9. Information on acts that can be carried out electronically

The application and its annexes, as well as the documents to be submitted in the course of the completion of the application, must be submitted in accordance with the provisions of Act CIII of 2023 on the *Digital State and on the Provisions for Supplying Digital Services* (hereinafter: Digital Act), so **in the case of a business entity with its registered office in Hungary, it must be submitted via a company gateway to the NCPHP's office gateway.**

Customers pursuant to Section 8 (21) of the Digital Act shall perform their administrative acts electronically before the digital service provider in the digital space in accordance with the Digital Act, and make their statements electronically.

According to § 29 of the Digital Act:

"Article 29 (1) The user shall choose the method of electronic communication with the digital service provider using the contact details specified in the information published by the digital service provider.

(2) When making statements addressed to the user, the organisation providing the digital service shall, if the law does not specify the method of contact, contact the user via the user's official contact details."

Furthermore, pursuant to Section 20 of the Digital Act, the customer shall make the declarations, procedural acts and other obligations required for electronic administration by electronic means in accordance with the information published by the organisation providing the digital service.

According to Paragraph (1) of Article 26 of the Digital Act: "*Unless otherwise provided by law, a user of a business organisation shall, within eight days of its registration, if the registration is not required by law for the operation of the business organisation, register its contact details for electronic communication (hereinafter referred to as "official contact details") in the register of dispositions as official contact details, which may be*

a) registered electronic delivery service address, or

b) ePosta contact details"

From 1 January 2018, it will be mandatory for business organisations to communicate electronically with the state, and the state will provide a **Company Gateway service** for business organisations to do so.

Business organisations acting as customers and the legal representatives of customers are obliged to contact the bodies obliged to provide electronic administration **through the company gateway as the official contact point**.

If the notifying company does not have a registered office in Hungary, it must designate a representative for service of documents (a business organization or a natural person with a Hungarian address) and attach the representative for service of documents to the NCPHP at the time of notification. All other forms of communication to the NCPHP are determined by the fact that the representative or agent for service of process to be designated by the Client is a business organisation or natural person.

a) For **business organisations**: they are obliged to communicate electronically in the manner specified by the Digital Act through **the company gateway.**

b) **Natural persons:** they are not obliged to communicate electronically, this is only an option under the aforementioned Act, but if they do not choose the specified electronic channel (client gateway - electronic document meeting the formal requirements), in which case it is recommended to perform the procedural act on paper, and paper documents are suitable for producing legal effects.

Business organisations acting as clients are obliged to contact the NCPHP **via the contact details for the Office Gate provided in point 2 of this information notice**.

If a natural person has a client account, he/she can submit the application and its annexes, as well as the documents to be submitted in the case of a deficiency, via https://epapir.gov.hu/:

→ Addressee: National Centre for Public Health and Pharmacy, Department of Public Health
→ Subject group: request
→ Type of case: notifiable products and technologies in direct contact with water in the supply of hot water for drinking and domestic use and in the supply of swimming pool and bathing water

Budapest, January 2025.