Registration, Notification Review and Amendment of Registration of Filter Materials and Chemicals Used for Drinking Water Treatment in Direct Contact with Water in Drinking Water and Domestic Hot Water Supply

1. Name and subject of the case

Government Decree 5/2023. (I.12) *on the quality requirements for drinking water and the inspection procedure* (hereinafter referred to as "Government Decree"), the distributor (hereinafter referred to as the "notifier") shall notify the National Centre for Public Health and Pharmacy (hereinafter referred to as the "NCPHP") of all filtering substances and drinking water treatment chemicals (hereinafter referred to as the "filtering substances/drinking water treatment chemicals") that are in direct contact with water in the supply of drinking water and domestic hot water, in accordance with the requirements set out in Annex 5, point 3, prior to their first domestic distribution.

On the basis of the notification, the NCPHP examines the compliance with the minimum hygiene requirements for filtering substances/drinking water treatment chemicals **on the basis of its preliminary opinion**, taking into account Article 10 (1) and (4) of the Government Decree.

In order to ensure the clear identification and official verification of the filtering substances/drinking water treatment chemicals, the composition, the basic materials and excipients of the filtering substances/drinking water treatment chemicals and their manufacturer must be provided during the procedure, and it is not possible to keep this information confidential.

In view of the above, the registration is preceded by an expert opinion procedure, which is carried out by the NCPHP Department of Public Health Laboratories in a separate procedure, the fee for which is set as a service based on the Department's price offer.

The NCPHP will acknowledge the receipt of the application within 60 days of receiving the application, which fully complies with the requirements set out in point 3 of Annex 5 of the Government Decree, and will determine the conditions of use.

The notifier and, in the case of redistribution, the redistributor also have an obligation to provide information to consumers on the public health conditions of use when the filtering substances/drinking water treatment chemicals are placed on the market or redistributed.

According to Act LXXXVIII of 2012. *on the Market Surveillance of Products*, the first distributor in Hungary is obliged to provide consumers and other end-users with instructions for use and handling of the chemicals/water treatment filter materials in Hungarian, as well as safety warnings, which must include information on water treatment. The instructions for use and handling must be clear and easy to understand. The notification number shall be indicated next to the name of the filtering substances/drinking water treatment chemicals when it is placed on the market.

The package of the filtering substances/drinking water treatment chemicals shall bear a clearly visible, legible and indelible mark indicating that the filtering substances/drinking water treatment chemicals comply with the requirements of the Decree. The specifications for the marking to be used shall be published by the Chief Medical Officer on their website and, if necessary, amended on the basis of standards uniformly applied in the European Union. The marking shall be accompanied by the registration number.

The existence of registration of the filtering substances/drinking water treatment chemicals, the conditions of use and compliance with the obligation to provide information are checked by the Public Health Agency and the NCPHP.

The notifier may request a public health review of the registered filtering substances/drinking water treatment chemicals every five years at the NCPHP. The content requirements for the review application are set out in Annex 5, point 4 of the Government Decree.

A preliminary opinion from the NCPHP Department of Public Health Laboratories must also be obtained before requesting a review.

The review may be initiated if less than 5 years have elapsed since the first notification and the filtering substances/drinking water treatment chemicals remains unchanged (in particular with regard to its composition, the quality, type, manufacturer of the basic and auxiliary materials used in its manufacture) and the manufacturing conditions of the filtering substances/drinking water treatment chemicals remain unchanged.

Failure to report changes in conditions and data existing at the time of registration, if the filtering substances/drinking water treatment chemicals no longer meet the minimum hygiene requirements set, and failure to carry out the mandatory review will result in removal from the register. Items removed from the register will be published by the NCPHP on its website, together with the reasons for removal.

The register can be modified in case of a change in the data in the notification that does not require an assessment, or in the case of the addition of a new type to the registered product family, if the substances used in the filtering substances/drinking water treatment chemicals in contact with drinking water or domestic hot water and their manufacturer are the same.

The NNGYK maintains a record of the issued notifications, which is published on its website (https://www.nnk.gov.hu/) on a monthly basis, free of charge, and is accessible and searchable by anyone without any restrictions.

A family of products can be registered if it is proven that the manufacturer, the quality and the water contact materials of the members of the family are fully identical (material, exact composition, quality and 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 electronic address, telephone number and opening hours of the managing authority

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

3. Title, number of applicable legislation

Government Decree 5/2023. (I.12) *on the quality requirements for drinking water and the inspection procedure*.

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 guide

4.1 Who can apply and how

The application for registration may be submitted by the distributor or the manufacturer of the filtering substances/drinking water treatment chemicals, or, in the case of a natural person or legal entity, by its representative. The application must be submitted in writing, certified by a stamp in the manner specified in point 9.

A positive prior opinion from the NCPHP Department of Public Health Laboratories must be obtained before submitting an application for registration and review.

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 entity (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 commercial name of the filter material/drinking water treatment chemical, list of product family types
d) Names, tax numbers and locations of domestic distributors
e) Name of the manufacturing company, location, manufacturing sites
f) Area of use of the filtering substances/drinking water treatment chemicals (in details)
g) In case of a product family, the list of filtering substances/drinking water treatment chemicals included in the product family (name or types)

4.3 Documents to accompany the application when filing

a) Instructions for use in Hungarian, or an instruction manual or a machine manual containing 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.

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

a) Manufacturer's declaration of unchanged manufacturing conditions of the filter material/sewage treatment chemical,

b) A declaration that the filtering substances/drinking water treatment chemicals are unchanged (in particular, its composition, the quality of the raw and auxiliary materials used in its manufacture, its construction, type and manufacturer),

c) Proof of payment of the administrative service fee,

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

e) The number of a prior public health assessment carried out by the NCPHP.

4.5 Documents to be submitted when changing registration

a) The application for the modification of the permit must be signed in the company's official manner (it should include the product name, manufacturer, distributor, types, application area, and the subject of the requested modification),

b) In the event of a change in the licensee's data, the document proving it,

c) In case of a change in the product name or type name, a declaration that the product, type structure, components in contact with drinking water, materials, their manufacturers, and manufacturing technology are identical to those of the types listed in the previous permit, a new product list, and an updated user manual in accordance with the new product list.

d) Document proving the payment of the administrative service fee.

4.6 Forms required by law or recommended by the licensing authority

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4.7 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: referred to as "GPAP").

The authority will check the completeness and adequacy of the documentation once it has been received. If the application is incomplete or incorrectly submitted, the authority will request the applicant to submit a single notification during the procedure.

Types of deficiencies and consequences of failure to complete the application:

- failure to attach a confirmation of the payment of the administrative service fee will result in a deficiency report pursuant to Section 44 of the GPAP, which will include 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.

- if the documents required for the procedure are not submitted or are incomplete, a notice of deficiency shall be issued pursuant to Section 44 of the GPAP, setting a reasonable time limit, taking into account the procedural time limit. Failure to submit a supplementary statement 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 reasonable time limit may

be set for the submission of evidence. Failure to complete the application within the time limit shall result in the rejection of the application.

If the clarification of the situation requires it, 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 processed in the absence of such a statement, then 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 whether to accept or reject the authorisation on the basis of the data and documents required by law and submitted and examined during the procedure, and on the basis of the preliminary opinion issued by the NCPHP Department of Public Health Laboratories.

4.8 Other authorities, institutions involved

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5. Deadline for administrative action

According to Section 39 of the GPAP, 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.

According 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.

Pursuant to Section 50 (2) of the GPAP, The administrative time limit shall be twenty-four hours in the case of automated decision-making; eight days for summary proceedings and sixty days for full hearings.

Pursuant to Article 14/B (9) of Act XI of 1991. *on Health Authorities and Administrative Activities*, no summary procedure is available in cases of notification of substances and products in direct contact with water and the authorisation of technologies and products for water safety in the supply of drinking water, bathing water and hot water for domestic use. Thus, the authorisation is always carried out in a full procedure.

Article 49 (1) of the GPAP states that he proceedings shall be stayed where so requested by the client, provided it is not excluded by law, or if requested jointly by the clients where two or more clients are involved. Moreover, Article 49 (2) of the GPAP claims that the proceedings shall be continued at the request of either of the clients. After a period of six-month stay, proceedings which are opened upon request only shall be terminated. Where proceedings are terminated the authority shall so inform those parties to whom the resolution would be delivered.

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

6. Administrative service fee rate, method of payment

The administrative service fee pursuant to Annex IV.8. of Annex 1 of EüM Decree 1/2009. (I.30.) *on the Ministry of Public Health and Veterinary Services on the fees payable for certain administrative procedures and administrative services of the State Public Health and Veterinary Service* (hereinafter: fee) shall be paid upon the initiation of the procedure. The fee for the administrative service is HUF 129,600 per product. Proof of payment is required at the time of filing the application.

The fee for the public health review of the registered filtering substances/drinking water treatment chemicals, according to Annex 1, IV.13. of the EüM Decree 1/2009. (I.30.) – hereinafter: EüM Decree, is to be paid at the time of initiation of the procedure. The administrative service fee is HUF 64,800 per product. Proof of payment is required at the time of application.

In the case of a product family, if it is proven that the manufacturer, quality and water contact materials of the members of the product family are fully identical (material, exact composition, quality, manufacturer), the notification procedure costs HUF 129,600 and the review fee HUF 64,800. A list of the filtering substances/drinking water treatment chemicals in the product family (name or types) must always be provided when applying for registration.

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

In case of an amendment to the registration, the fee according to Annex 1, IV.11. of the EüM Decree (HUF 64 800 per product) is to be paid.

The fee may be paid by the initiating party to the account of the NCPHP 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 reference.

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

The fee is tax-free, and the NCPHP will send an official invoice to the client once the amount has been received.

Pursuant 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.

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

According 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

According to 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 contests the decision of the authority may bring an administrative action for damages within 30 days of the date of the decision, by lodging a statement of claim. The statement of claim must be addressed to the competent territorial court, 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 irregularities which do not have a material impact on the merits of the case, and, if necessary, order the authority to conduct new proceedings. In the absence of an infringement, the Tribunal shall dismiss the action.

The submission of the application does 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.

The possibility of appealing against the decision is excluded by Section 116 (4) of the GPAP. 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 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: products in direct contact with water for the supply of drinking water, domestic hot water and swimming pool and bathing water that are subject to notification

Budapest, 2025 January