Authorisation of Products in Direct Contact with Water for The Supply of Drinking Water and Domestic Hot Water, Renewal of Authorisation and Modification of Authorisation

1. Name of the case, subject

According to Article 12 (1) of Government Decree 5/2023. (I.12.) *on the quality requirements for drinking water and the inspection procedure* (hereinafter referred to as "Government Decree"), the products listed in Annex 5, point 2 shall be authorised by the National Centre for Public Health and Pharmacy (hereinafter referred to as "NCPHP") for the safety of drinking water prior to their first domestic marketing, upon application by the person placing them on the market (hereinafter: referred to as "the authorisation holder"), by laying down conditions of use, taking into account the method of use and the substances used, in order to prevent or reduce the health risk to the consumer.

As long as there is no valid European product standard introduced as a Hungarian standard for the testing and assessment of products in direct contact with water in the supply of drinking water and domestic hot water, the products listed in Annex 5, Section 1, subsections 1.3-1.5 of Government Decree shall be subject to a drinking water safety approval procedure in accordance with Section 2, subsections 2.4-2.6 of Annex 5, Section 1, subsections 1.3-1.5.

During the licensing procedure, the NCPHP shall, **on the basis of its prior expert opinion**, assess compliance with the minimum hygiene requirements for materials in contact with drinking water and hot water for domestic use, taking into account Article 10(1), (2) and (4). The public health conditions of use required by the drinking water safety authorisation to ensure safe use of the product without risk to health shall be provided to users by the licensee in the instructions for use of the product.

In order to ensure clear identification and official control of the product/technology, the raw materials in contact with water and their manufacturer must be provided during the procedure, and it is not feasible to keep this information confidential.

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

The licence is issued by the NCPHP within 60 days of receipt of an application that fully complies with the requirements set out in point 3 of Annex 5 of the Government Decree, and specifies the conditions of use, on the basis of a prior expert opinion.

The licensee and, in the case of onward distribution, the onward distributor also have an obligation to provide information to consumers on the public health conditions of use when marketing or onward distributing products that come into contact with drinking water and domestic hot water.

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, as well as safety warnings in Hungarian, which must also include information on water purification, for products that come into contact with drinking water and domestic hot water. The instructions for use and handling must be clear and easy to understand. The marketing authorisation number shall be indicated next to the name of the product.

The packaging of products intended to come into contact with hot water intended for human consumption shall bear a clearly legible, indelible and visible mark indicating that the product conforms to the requirements of this Regulation. The national official veterinarian shall publish on his website the requirements concerning the marking to be applied, amending them if necessary on the basis of the uniform standards applied in the European Union. The marking shall be accompanied by the authorisation number.

The existence of a drinking water safety authorisation, the conditions of use and compliance with the information requirements for products intended to come into contact with drinking water and domestic hot water are checked by the public health body and the NCPHP.

The drinking water safety permit is valid for five years. The holder may apply for renewal of a drinking water safety authorisation before the expiry of the authorisation. The content of the renewal application and the list of documents to be submitted are set out in point 4 of Annex 5 of the Government Decree.

A preliminary opinion from the NCPHP Department of Public Health Laboratories must also be obtained before applying for renewal.

Renewal may be initiated provided that not more than 5 years have elapsed since the authorisation was granted and the product is unchanged (in particular as regards its composition, the quality, type and manufacturer of the raw materials and excipients used in its manufacture) and the conditions under which it was manufactured.

A drinking water safety authorisation will be withdrawn if the authorisation holder fails to notify a change in the conditions that existed at the time of authorisation or if the product no longer meets the minimum hygiene requirements that were assessed during the authorisation procedure.

The authorisation may be modified on request due to a change in the data included in the permit which does not require an evaluation or to add a new type to the authorised product family if the final materials in contact with drinking water or domestic hot water and their manufacturer are the same.

In the case of community applications, the use of small installations for the after-treatment of mains water or water dispensers must be notified to the district office responsible for public health (hereinafter referred to as "the district office"). The conditions for the territorial specificity of the application shall be determined by the district office. In the case of use of the product for community purposes, the public health conditions of use ensuring safe use of the product without endangering health shall be indicated on the place of use by the manager of the building where the product is used or, failing this, by the owner of the building.

The NCPHP keeps a register of licences issued, 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 restriction.

A family of products may be authorised if it is demonstrated that the manufacturer, quality, function, construction and water contact materials of the members of the family are fully compatible (material, exact composition, quality, and manufacturer).

The national competence 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 út 2-6.
Address for correspondence: National Centre for Public Health and Pharmacy, Department of Public Health
Budapest, 1437 Budapest, PO Box 839.
Telephone: 06 1/476-1220
E-mail: kozegeszseg@nngyk.gov.hu
Offical Gateway: NNKKOZEG, KRID ID: 369732197
Client reception by prior appointment by telephone.

3. Title and 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 submit an application and how

The application may be submitted by the distributor or the manufacturer of the product, or, in the case of a natural or legal person, 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 the application and renewal requests are submitted.

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 instrument of incorporation), 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 product, product family, list of types of the product, product family

d) The name, tax number and place of business of the domestic distributor
e) Name of the manufacturing company, place of establishment, manufacturing sites
f) Area of use of the product (in details)
g) In case of a product family, list of products belonging to the family (name or types)

4.3 Documents to accompany the application at the time of authorisation

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) Reference number of the public health assessment previously carried out by the NCPHP.

4.4 Documents to be attached to the application when renewing the licence

a) A declaration by the manufacturer that the conditions of manufacture of the product remain unchanged,

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

c) Document proving the payment of an 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 reference number of a prior public health assessment carried out by the NCPHP.

4.5 Documents to be submitted when amending a permit

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 *General Public Administration Procedures* (hereinafter: 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 in the course of 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*, 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, 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 (2) 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 of the fee is required at the time of filing the application.

The fee for the renewal of the drinking water safety permit, as set out in Annex 1, point IV. 13. of EüM Decree 1/2009. (I.30.) - hereinafter: EüM Decree must be paid at the time of the 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 filing the application.

In the case of a family of products, if it is proven that the manufacturer, quality, construction, operation and water contact materials of the members of the family are fully identical (material, exact composition, quality, manufacturer), the fee for the authorisation procedure is HUF 129 600 and the renewal fee is HUF 64 800. A list of the products belonging to the product family (name or type) must always be provided for the authorisation procedure.

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

In the case of a change to the drinking water safety permit, the fee (HUF 64 800 per product) according to Annex 1, IV.11. of EüM Decree is to be paid.

The fee may be paid by the party initiating the procedure by transfer to the account of the NCPHP, by cash transfer order, by 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 notification.

The document proving payment of the fee 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.

Pursuant to Section 47 (1) (d) of the GPAP, if the client fails to comply with the obligation to advance the costs of proceedings, the authority shall terminate the proceedings.

7. Rights and obligations of the customer

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

According to Section 6 of the GPAP, 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.

Section 33 (1) of the GPAP states that 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.

Pursuant 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: 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.