

Order 3730/2023 amending and supplementing the Sanitary Regulatory Procedure for placing on the market the products, materials, chemicals / mixtures and equipment used in contact with drinking water, approved by Order No 275/2012 of the Minister of Health

Order 3730/2023 of 16 November 2023

Status: Acts in force

Version from: 16 November 2023

Enters into force:

16 November 2023

Order 3730/2023 amending and supplementing the Sanitary Regulatory Procedure for placing on the market the products, materials, chemicals / mixtures and equipment used in contact with drinking water, approved by Order No 275/2012 of the Minister of Health

Date of the act: 6 November 2023

Issuer: MINISTRY OF HEALTH

Considering the Approval Report of Directorate-General Public Health and Health Programmes of the Ministry of Health, registered under No AR 20098/2023;

Having regard to:

- the provisions of Article 11 of Government Ordinance No 7/2023 on the quality of water intended for human consumption;
- Government Decision No 1016/2004 on measures for the organisation and exchange of information in the field of technical standards and regulations, as well as the rules on information society services between Romania and the Member States of the European Union, as well as the European Commission, as amended and supplemented;
- Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC;

- Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008;

- Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending the Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011;

Pursuant to Article 7(4) of Government Decision No 144/2010 regarding the organisation and operation of the Ministry of Health, as amended and supplemented;

the Minister of Health issues the following order:

Article I

The Sanitary Regulatory Procedure for placing on the market of products, materials, chemicals/mixtures and equipment used in contact with drinking water, approved by Order No 275/2012 of the Minister of Health, published in Official Gazette, Part I, No 219 of 2 April 2012, as subsequently amended and supplemented, is hereby amended and supplemented as follows:

1. In Article 2, after point a), a new point a¹) shall be inserted to read as follows:

"a¹) *placing on the market of products, materials, chemicals / mixtures and equipment used in contact with drinking water* means the first making available of such a product, material, chemical substance / mixture and equipment used in contact with drinking water on the European Union market;"

2. In Article 2, points e), f) and g) shall be amended to read as follows:

"e) *the sanitary opinion* is the official document issued by the Commission for products, materials, chemicals / mixtures and equipment used in contact with drinking water, hereinafter referred to as the *Commission*, based on the product file for materials used in contact with drinking water and Technical Assessment Reference, drawn up by the experts appointed from the National Institute of Public Health structures, hereinafter referred to as *INSP*, by decision of the Director-General of the National Institute of Public Health;

f) *the notification form* is the official document issued by the Commission, based on the product file for materials used in contact with drinking water and the Technical Assessment Reference, drawn up by the experts appointed from the National Institute of Public Health structures by decision of the Director-General of the National Institute of Public Health;

"g) *the product file for materials used in contact with drinking water* is the technical documentation containing all the documents referred to in Article 6(3) for the assessment of foreseeable risks to the population and the environment;"

3. In Article 2, after point i), seven new points are inserted, i¹) to i⁷), and shall read as follows:

"i¹) *manufacturer* means any natural or legal person who manufactures a product, material, chemical substance / mixtures, equipment used in contact with drinking water, or who orders the design and manufacture thereof, or who produces goods which have not resulted from a manufacturing process and are marketed under the name or trade mark of that person;"

i²) *authorised representative* means any natural or legal person established within the European Union who has received a written mandate from a manufacturer of products, materials, chemicals/mixtures and equipment used in contact with drinking water, to act on behalf of that producer in making available products, materials, chemicals / mixtures and equipment used in contact with drinking water on the market in question;

i³) *importer* means any natural or legal person, established in the European Union, who makes available, for the first time a product, material, chemical / mixture and equipment used in contact with drinking water from a third country on the market of the European Union;

i⁴) *product used in contact with drinking water* means an article made of a material, combination of materials / type material, in its final form, which is placed / introduced on the market of the European Union;

i⁵) *material used in contact with drinking water* means a preparation from a substance or combination of substances, intended for use in manufacturing processes of products and equipment used in contact with drinking water, and placed/introduced on the European Union market;

i⁶) *substance used in contact with drinking water* means a chemical compound or a mixture of chemical compounds used in the manufacture of a material;

i⁷) *equipment used in contact with drinking water* means an assembly of parts / devices, appliances and / or mechanisms of a plant, composed of different materials and / or substances, that form a technical system, used to ensure the production and distribution of drinking water (in the process of abstraction of raw water, intake, treatment for drinking water, storage, transport, distribution of drinking water)."

4. Article 3 shall be amended to read as follows:

"Article 3.

In order to carry out the tasks relating to the sanitary regulation of the placing on the market of products, materials, chemicals / mixtures and equipment used in contact with drinking water on the territory of Romania, committees for products, materials, chemicals / mixtures and equipment used in contact with drinking water shall be established, which are specialised bodies, without legal personality, operating within the National Institute of Public Health."

5. In article 4 paragraphs 2, 3 and 4 shall be amended to read as follows:

"2. The committees shall be represented at the level of the National Centre for Monitoring of Risks in the Community Environment, the National Laboratory of Public Health in Bucharest or at the level of the regional public health centres in Cluj, Craiova, Galati, Iasi, Targu Mures and Timisoara.

3. The composition of each committee includes: the chairman of the committee, who is a doctor in hygiene, microbiology or laboratory specialty and 2-4 chemists members,

biologists / biochemists, doctors in hygiene, microbiology or laboratory specialty and/or, as the case may be, experts depending on the specifics of the documentation to be analysed. The Director-General of the National Institute of Public Health may decide, at the request of the committee, to supplement/modify its composition.

4. The technical evaluation reports shall be drawn up and signed by the designated experts from the National Institute of Public Health, respectively from the National Centre for Monitoring of Risks in the Community Environment, the National Public Health Laboratory in Bucharest or from one of the regional public health centres. The sanitary opinion / notification shall be signed by the Director-General of the National Institute of Public Health or by the Chief Doctor of the regional public health centre, as appropriate, and by the Chair of the committee."

6. In Article 5, points f) and i) shall be amended to read as follows:

"f) shall draw up the technical assessment report which shall be archived at the level of the National Institute of Public Health, respectively in the National Centre for Monitoring of Risks in the Community Environment, the National Public Health Laboratory of Bucharest or at the regional public health centres, where the sanitary opinion/notification was issued;

.....

"i) ensures the archiving of all documents, in accordance with the law."

7. Article 6 shall be amended to read as follows:

"Article 6.

1. In order to obtain the sanitary opinion / notification of introducing / placing on the market, products, materials, chemicals / mixtures and equipment used in contact with drinking water, the applicant submits the product file for materials used in contact with drinking water, in electronic form, through the Unique Electronic Contact Point platform or in printed form, at the National Institute of Public Health or in the regional public health centres, according to the county's territorial organisation, displayed on the website of the National Institute of Public Health.

2. For the product files for materials used in contact with drinking water, submitted in electronic or in printed form, in order to ensure compliance of the documents, the applicant shall submit a declaration of honour on documents forgery, in accordance with the model set out in Annex 5 to this procedure.

3. To issue the Sanitary Opinion / Notification, the product file for materials used in contact with drinking water must contain the following documents:

a) the application addressed to the National Institute of Public Health, with the applicant's letterhead, address, telephone number, Trade Register registration number, in accordance with the model set out in Annex 1 to this procedure, specifying:

i) the status of manufacturer, of manufacturer's authorised representative or products, materials, chemicals / mixtures and equipment's importer used in contact with drinking water;

ii) full name and address of the producer, if the applicant is an importer;

b) presentation sheet of the product, material, chemical / mixture or equipment used in contact with drinking water, comprising:

- i) the address where the manufacturer, importer or authorised representative is established;
- ii) the trade name of the product, material, chemical / mixture or equipment used in contact with drinking water;
- iii) the category of the product, material, chemical / mixture or equipment used in contact with drinking water;
- iv) field of use / applicability, instructions / conditions of use of products, materials, chemicals / mixtures and equipment used in contact with drinking water;
- c) quantitative and qualitative composition with CAS numbers (Chemical Abstract Service) of the material and chemical / mixture that forms part of the product or component parts of the equipment used in contact with drinking water specified by their manufacturer;
- d) Quality Certificate on Ingredient Purity Criteria, in accordance with the applicable manufacturing standards, in copy;
- e) analytical bulletins / test report with overall migration tests / specific / toxicological tests for materials / products, by type of material, within a maximum period of validity of 5 years after issuance, carried out by laboratories accredited in the field in accordance with the provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;
- f) Safety Data Sheet of the material, chemical substance/mixture used in contact with drinking water;
- g) declaration of conformity of the product, material, chemical / mixture or equipment used in contact with the drinking water, from the point of view of the effects on health;
- h) Document on proof of payment of the tariff, in accordance with Annex 4 to this Procedure.

4. The product file for materials in contact with drinking water must be presented in Romanian language or, where applicable, an authorised translation of it."

8. Article 7 (1) g) shall be amended to read as follows:

"g) Signature of the President of the Commission and of the Director-General of the National Institute of Public Health or of the Chief Physician of the Regional Centre for Public Health, as appropriate."

9. Article 8 shall be amended to read as follows:

"Article 8.1.

If The product file for materials used in contact with drinking water does not include all the documents referred to in Article 6(3), the Commission shall then request that the file be completed. The advice, following the request of the manufacturer / authorised representative of the manufacturer / importer, shall be charged in accordance with Annex 4 to this procedure and shall be provided in Romanian.

2. The deadline for completing the Product file for materials used in contact with drinking water for issuing the Sanitary Opinion / Notification is 60 days from the request of the Commission.

3. If, within the period referred to in paragraph 2, the applicant does not submit the documents requested by the Commission to complete the Product file for materials used in contact with drinking water, the file shall be filed away and the applicant shall be notified in this regard."

10. Article 9 shall be amended to read as follows:

"Article 9.

The sanitary opinion / notification shall be valid for 5 years, provided that no change is made in the qualitative and / or quantitative composition, in the field / conditions of use of the product, material, chemical / mixture or equipment concerned, the registered office of the applicant, the place of production does not change or no change or extension is made to the range of products, materials, chemicals / mixtures and equipment used in contact with drinking water."

11. Article 10 shall be amended to read as follows:

"Article 10.

Lists of Sanitary Opinions / Notifications for products, materials, chemicals / mixtures or equipment that are used in contact with drinking water shall be updated and displayed on the website of the National Institute of Public Health."

12. Article 14 shall be amended to read as follows:

"Article 14.

1. The manufacturer, the manufacturer's authorised representative or the importer has the obligation to notify the Commission in writing of any changes in the quantitative / qualitative composition or the conditions of use of the product, material, chemical substance / mixture or equipment used in contact with drinking water, the place of business of the applicant, the place of production, the change or extension of the range of products, materials, chemicals / mixtures and equipment, contained in the Product file for materials in contact with drinking water and for which the Sanitary Opinion / Notification was issued, within 30 days of the date on which they occurred.

2. The marketing and use of the product, material, chemical substance / mixture or equipment used in contact with drinking water, sanitary endorsed / notified, which has undergone changes in the quantitative / qualitative composition or conditions of use of the product, material, chemical / mixture or equipment used in contact with drinking water, place of production, change or extension of the product range, shall be subject to prior obtaining of the sanitary opinion / notification in accordance with this procedure."

13. In Article 16, paragraph 1 shall be amended to read as follows:

"Article 16.

1. Construction products may be used in contact with drinking water conditional on possession of the sanitary opinion / notification, within validity, issued in accordance with the provisions of this procedure, as well as the Declaration of Conformity, within validity, issued in accordance with the provisions of Government Decision No 668/2017

establishing the conditions for the marketing of construction products, specifying the suitability of the product for use in contact with drinking water."

14. Article 18 shall be amended to read as follows:

"Article 18.

Disinfectants used for the treatment of drinking water, which are governed by Government Decision No 617/2014 establishing the institutional framework and measures for the implementation of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, as amended, are exempted from this procedure."

15. Annex 1 is amended and replaced by Annex 1 to this Order.

16. Annex 2 is amended and replaced by Annex 2 to this Order.

17. Annex 3 is amended and replaced by Annex 3 to this Order.

18. Annex 4 is amended and replaced by Annex 4 to this Order.

19. After Annex 4, a new Annex is inserted, Annex 5, the content of which is set out in Annex 5 to this Order.

Article II

Within 6 months of the entry into force of this Order, natural or legal persons who have obtained Sanitary Opinion / Notification for products, materials, chemicals / mixtures and equipment used in contact with drinking water shall be required to submit the documents provided for in Article 6(3) of the Health Regulatory Procedure for the placing on the market of products, materials, chemicals / mixtures and equipment used in contact with drinking water, approved by Order No 275/2012 of the Minister of Health, as subsequently amended and supplemented, with a view to issuing a new Sanitary Opinion or Notification, as appropriate.

Article III.

Annexes No 1-5 form an integral part of this Order.

Article IV.

This order shall be published in the Official Gazette of Romania, Part I.

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The technical regulations contained in this Order shall comply with the notification procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015.

Minister of Health, Alexandru Rafila
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(- Annex 1 to the procedure)

To: National Institute of Public Health

Dear Madam / Dear Sir,

I, the undersigned,, request the sanitary opinion ☐ / notification ☐ for the product, material, chemical substance / mixture, equipment that comes into contact with drinking water:

1. trade name

.....
.....

2. scope of use/applicability

.....
.....

Applicant:

The applicant is - manufacturer ☐ / authorised representative ☐ / importer ☐

Full name and address (including telephone/fax):

Trade Register registration

No

NACE Code for manufacturing / marketing of products / materials / chemicals / mixtures / equipment used in contact with water intended for human consumption

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.....

Manufacturer:

Name and full address:

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.....

Name and full address of the person who prepared the Product file for materials in contact with drinking water:

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Signature and stamp of the applicant

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ANNEX 2: SANITARY OPINION - model -

(- Annex 2 to the procedure)

MINISTRY OF HEALTH

National Institute of Public Health

Commission for products, materials, chemicals / mixtures and equipment used in contact with drinking water

Applicant:

.....
.....

Address:

.....
.....

Trade Register registration

No:

SANITARY OPINION

No of

The Commission for products, materials, chemicals / mixtures and equipment used in contact with drinking water, within the National Institute of Public Health, based on Technical Assessment Reference No, decides that the following product, material, chemical substance / mixture, equipment used in contact with drinking water can be manufactured or marketed and used in Romania, according to the legal provisions in force.

☐ Product, material, chemical / mixture, equipment used in contact with drinking water:

1.1. Trade name of product, material, chemical / mixture, equipment used in contact with drinking water, construction models, types etc.:

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.....
.....
.....

1.2. Scope of use:

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.....

1.3. Materials used that come into contact with drinking water:

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.....

☐ **The manufacturer:**

2.1.Address:

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.....

2.2. Country:

.....
.....

The sanitary opinion of the product, material, chemical substance / mixture, equipment used in contact with drinking water shall be made in accordance with Order No 275/2012 of the Minister of Health approving the Sanitary Regulatory Procedure for placing on the market of products, materials, chemicals / mixtures and equipment used in contact with drinking water, pursuant to article 11 of Government Ordinance No 7/2023 on the quality of water intended for human consumption.

THE SANITARY OPINION IS VALID FOR A PERIOD OF 5 YEARS, IF NO CHANGE IS MADE IN THE QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE PRODUCT, IN THE FIELD/CONDITIONS OF USE OF THE PRODUCT(S), THE REGISTERED OFFICE OF THE APPLICANT DOES NOT CHANGE, THE PLACE OF

PRODUCTION DOES NOT CHANGE, THE PRODUCT RANGE IS NOT CHANGED OR EXPANDED. ANY CHANGES DESCRIBED ABOVE AUTOMATICALLY LEAD TO THE CANCELLATION OF THE SANITARY OPINION.

Name and surname, signature and stamp of the Director-General of the National Institute of Public Health or of the Chief Doctor of the Regional Centre for Public Health (where applicable)

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.....

Name and surname, signature of the President of the Commission

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.....

.....
.....

ANNEX 3: NOTIFICATION - model -

(- Annex 3 to the procedure)

MINISTRY OF HEALTH

National Institute of Public Health

Commission for products, materials, chemicals / mixtures and equipment used in contact with drinking water

Applicant:

.....
.....

Address:

.....
.....

Trade Register registration

No:

NOTIFICATION

No of

The Commission for products, materials, chemicals / mixtures and equipment used in contact with drinking water, within the National Institute of Public Health, based on Technical Assessment Reference No, decides that the following product, material, chemical / mixture, equipment used in contact with drinking water can be manufactured or marketed and used in Romania, according to the legal provisions in force.

|_ Product, material, chemical / mixture, equipment used in contact with drinking water:

1.1. Trade name of product, material, chemical / mixture, equipment used in contact with drinking water, construction models, types etc.:

.....
.....

1.2. Scope of use:

.....
.....

1.3. Materials used that come into contact with drinking water:

.....
.....

|_ The manufacturer:

2.1. Address:

.....
.....

2.2. Country:

.....
.....

The notification of the product, material, chemical substance / mixture, equipment used in contact with drinking water is made in accordance with Order No 275/2012 of the Minister of Health approving the Sanitary Regulatory Procedure for placing on the market of products, materials, chemicals / mixtures and equipment used in contact with drinking water, based on

article 11 of f Government Ordinance No 7/2023 on the quality of water intended for human consumption.

THE NOTIFICATION IS VALID FOR A PERIOD OF 5 YEARS, IF NO CHANGE IS MADE IN THE QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE PRODUCT, IN THE FIELD(S) OF USE OF THE PRODUCT(S), DOES NOT CHANGE THE REGISTERED OFFICE OF THE APPLICANT, DOES NOT CHANGE THE PLACE OF PRODUCTION, DOES NOT CHANGE OR EXTEND THE PRODUCT RANGE. ANY CHANGES DESCRIBED ABOVE AUTOMATICALLY LEAD TO THE CANCELLATION OF THE SANITARY OPINION.

Name and surname, signature and stamp of the Director-General of the National Institute of Public Health or of the Chief Doctor of the Regional Centre for Public Health (where applicable)

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.....

Name and surname, signature of the President of the Commission

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.....

ANNEX 4: RATES

(- Annex 4 to the procedure)

Item No	Provided service	Tariff (lei)
1.	Consultancy for the preparation of the product file used in contact with drinking water (in Romanian)	300/hour
2.	Analysis of the Product File used in contact with drinking water	700
3.	Drawing up the technical evaluation report (in Romanian)	400
4.	Drawing up the sanitary opinion / notification (in Romanian)	400
5.	Change / Modification of the sanitary opinion / notification (in Romanian)	500

ANNEX 5: DECLARATION ON HONOUR

(- Annex 5 to the procedure)

I, the undersigned,....., having Personal Identification Number, born on...../...../.....in municipality....., residing in.....,

full address....., identified with CI/BI series..... No....., issued by....., knowing the provisions of Article 326 of the Criminal Code on false declarations, I hereby declare, on my own responsibility, that the documents submitted to the product file for materials in contact with drinking water are in conformity with the original documents.

I make this statement and I support it.

Date/...../.....	Name in plane text
	Signature

Published in the Official Gazette number 1040 of 16 November 2023