ERSAR
ENTIDADE REGULADORA
DOS SERVIÇOS DE ÁGUAS E RESÍDUOS

REGULATION OF THE NATIONAL APPROVAL SYSTEM FOR PRODUCTS IN CONTACT WITH WATER INTENDED FOR HUMAN CONSUMPTION

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REGULATION OF THE NATIONAL APPROVAL SYSTEM FOR PRODUCTS IN CONTACT WITH WATER INTENDED FOR HUMAN CONSUMPTION

Preamble

ERSAR's mission, within the framework of its Statutes, approved by Law No 10/2014 of 6 March 2014 is to regulate and supervise the sectors of public water supply services, urban wastewater sanitation and urban waste management, abbreviated as water and waste services, including the exercise of the functions of competent authority for the coordination and supervision of the quality regime of water for human consumption.

In these functions as the competent authority for the quality of water intended for human consumption, governed by law, Decreto-Lei n.º 69/2023, de 21 de agosto, ERSAR has the task of drawing up a regulation establishing a national approval system for products in contact with water, whether they are substances and chemicals used for the treatment of water, or materials in the installations, from the collection, treatment, supply network, distribution network and land distribution system to the user's tap or the point of use of water intended for human consumption (*see* Article 33(1)).

As far as construction products are concerned, the content of this Regulation is based on the implementing acts adopted by the European Commission, as provided for in Article 11(2) of the Diretiva (UE) 2020/2184 do Parlamento Europeu e do Conselho, de 16 de dezembro. The adopted documents are based on Implementing Decisions 2024/365, 2024/367 and 2024/368, of 23 January 2024, published in the Official Journal of the European Union on 23 April 2024.

These Implementing Decisions were complemented by the adoption of Delegated Regulations 2024/369, 2024/370 and 2024/371 of 23 January 2024, which were also published in the Official Journal of the European Union on 23 April 2024.

These documents, drawn up and published by the European Commission, determine the implementation in all Member States of an accredited certification system for construction products in contact with water intended

for human consumption, without prejudice to compliance with other applicable legislation, in particular the Regulamento (UE) n.º 305/2011 do Parlamento Europeu e do Conselho, de 9 de março.

With regard to products used in water treatment and biocides, which were not enshrined in the rules laid down in the implementing decisions and delegated regulations referred to above, it was considered that the accredited certification system to be implemented in Portugal should not apply to this type of product, and compliance with Regulamento (CE) n.º 1907/2006 do Parlamento Europeu e do Conselho, de 18 de dezembro (Regulamento REACH), do Regulamento (UE) n.º 528/2012 do Parlamento Europeu e do Conselho, de 22 de maio (Regulamento dos Biocidas) and the respective rules of national law should be maintained, as well as compliance with the specifications laid down in the respective European standards specific to the characteristics of chemicals used in water treatment.

To this end, ERSAR considers that IRAR Recommendation 02/2006, with the necessary adaptations regarding references to legal documents, contains the appropriate procedures for the correct selection of biocides and products used in the treatment of water intended for human consumption.

This draft Regulation was drawn up within an informal Technical Commission coordinated by ERSAR and where all the stakeholders for the matters that are the subject of this regulation were in place.

It should also be noted that the Regulation will be notified to the European Commission at the draft stage, in compliance with the provisions of the Diretiva (UE) 2015/1535 do Parlamento Europeu e do Conselho, de 9 de setembro, procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Products covered by Article 34 of Decree-Law No 69/2023 of 21 August 2023, which have been approved by another Member State of the European Union pursuant to the implementing acts and delegated regulations referred to above, bearing the marking provided for in this Regulation, shall be automatically recognised in Portugal.

On this basis, in a meeting of 28 November 2024, in accordance with Articles 11(e), 12 and 24(1)(b) of its Articles of Association, the Board of Directors of the Regulatory Authority for Water and Waste Services decided to adopt the following draft Regulation of the national approval system for products in contact with water intended for human consumption and to submit it to the hearing of the Advisory Council and to the public consultation.

Chapter I
General provisions

Article 1.º
Subject

This Regulation lays down the conditions of the national approval system for products in contact with water, establishing the operating rules and the respective application regime, in accordance with Chapter VI of Decree-Law No 69/2023 of 21 August 2023.

Article 2.º
Scope of application;

1 - The provisions of this Regulation shall apply to:

a).Products made of, or incorporating, materials used in contact with water intended for human consumption from abstraction, treatment, supply network, distribution network and land distribution system to the user's tap or the point of use of water intended for human consumption;

b).....Products used for the treatment of water intended for human consumption;

c).....New installations or renovations in the case of construction products.

2 - In accordance with Article 33 of Decree-Law No 69/2023 of 21 August 2023, the territorial scope of application of the provisions of this Regulation is national.

Article 3.º

Definitions

For the purposes of this Regulation:

a) 'Accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

b) 'Migration water' means the test water that has been in contact with the test specimen under the conditions specified in Annexes I, II, III and IV to Commission Implementing Decision (EU) 2024/368 of 23 January 2024;

c) 'Water intended for human consumption':

i) All water in its original state, or after treatment, intended for drinking, cooking, food preparation, personal hygiene or other domestic purposes, whether in public or private places, irrespective of its origin and whether or not it is supplied from a distribution network, supplied from a fixed or mobile tank, in bottles or other containers, whether commercial or not, including spring water; or

ii) All water used in a food business for the manufacture, processing, preservation or marketing of products or substances intended for human consumption and for cleaning surfaces, objects and materials which may come into contact with food, except where the use of such water does not affect the wholesomeness of the food in its finished form;

d) 'Attestation' – issue of a statement based on a decision, that compliance with the specified requirements has been demonstrated.

e) ‘Enhancement of Microbial Growth (EMG)’ means the capacity of final organic or cementitious materials to increase the multiplication of microorganisms under specified conditions;

f) ‘Notifying authority’ means the authority responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 9;

g) ‘Conformity assessment’ means the process demonstrating that a product complies with minimum hygiene requirements;

h) ‘Total barrier’ means a barrier bed preventing the diffusion of any substances from the inside of the final material to its surface in contact with water intended for human consumption;

i) ‘Calibrant’ means a representative physical sample of a starting substance or an organic cementitious constituent subject to an application in accordance with this Regulation, which is used in the calibration of equipment or in a measurement procedure;

j) ‘Certification’ means a third party attestation relating to a subject of conformity assessment with the exception of accreditation;

k) ‘Cement’ – an inorganic powder-reduced material which, when mixed with water, forms a paste that sets and hardens under the effect of hydration reactions and processes and which, after hardening, retains its strength and stability even under water;

l) ‘Placing on the market’ means the first release of a product on the European Union (EU) market;

m) ‘Component’ means an identifiable part of an assembled product consisting of one or more materials;

n) ‘Maximum Tolerable Concentration at the tap (MTCtap)’: the maximum permitted concentration of a substance migrating from a specific material into water intended for human consumption;

o) ‘Constituent’ means any of the following—

i) A substance that has been intentionally used to manufacture a cementitious material;

ii) An alloying element present in a composition of metallic materials;

iii) An element or combination of elements present in a composition of enamelled, ceramic or other inorganic materials;

iv) A substance present in a mixture of substances.

p) ‘Organic cementitious constituent’ means an organic substance used in the manufacture of cementitious materials;

q) ‘Declaration of conformity’: document certifying that the product in contact with water meets the applicable minimum hygiene requirements;

r) ‘Distributor‘: a natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the EU market;

s) ‘Placing on the market" means any supply of a product for distribution, consumption or use on the market of Malta in the course of a commercial activity, whether in return for payment or free of charge;

t) ‘Reduced test’ means a test in which only part of the test procedures and methods set out in Annexes I, II, III and IV to Commission Implementing Decision (EU) 2024/368 of 23 January 2024 apply to test pieces withdrawn by the notified body during the initial or annual inspection;

u) ‘Managing body’ means the body responsible for a public or private water supply system;

v) ‘Managing body of the private supply system’: the body responsible for the operation and management of water supply systems intended for human consumption for private purposes;

w) ‘Managing body of a public supply system’ means an entity responsible for the operation and management of systems for the supply of water intended for human consumption, by means of fixed

networks or other means of water supply, within the framework of the public service remit;

x) ‘Enamel’: a vitreous material obtained by melting a mixture of inorganic substances at temperatures higher than 1200 °C, followed by vitrification;

y) ‘Unintentionally added species’ means one of the following:

i) An impurity of a starting substance, an organic cementitious constituent or a composition;

ii) A reaction or degradation product of a starting substance or an organic cementitious constituent that forms during the processing or use of the material;

iii) A reaction or degradation product of a starting substance or an organic cementitious constituent that forms in contact with water during use of the material;

z) ‘Manufacturer’ means any natural or legal person who manufactures products or has products designed or manufactured, and markets them under his name or trademark, or designs and manufactures products for his own use;

aa) ‘Formulation’: the list of substances or constituents used in the preparation of an organic material or cementitious material and their proportions;

bb) ‘Importer’: the natural or legal person established in the EU who makes products from a third country available on the EU market;

cc) ‘Authorised representative’ means any natural or legal person established within the EU who has received a written mandate from a manufacturer to act on behalf of that manufacturer in relation to specified tasks;

dd) ‘Material’ means a solid, semi-solid or liquid used in the manufacture of a product with:

i) An organic composition prepared from one or more starting substances, or

ii) A cementitious composition prepared from one or more constituents; or

iii) A metallic, enamelled, ceramic or other inorganic composition;

ee) ‘Material applied on site’ means a final material to be produced on a construction site;

ff) ‘Ceramic material’ means a non-metallic inorganic, polycrystalline or monocrystalline solid material subjected to high temperatures during manufacture;

gg) ‘Cementitious material’ means a material containing hydraulic cement in sufficient proportion to act as a main binder forming a hydrated structure that determines the performance of the material;

hh) ‘Final material’ means material subject to testing and acceptance in accordance with the testing and acceptance requirements set out in Annexes I, II, III and IV to Commission Implementing Decision (EU) 2024/368 of 23 January 2024;

ii) ‘Metallic material’ means a material which is a metal or metal alloy, used in bulk or as a metallic coating;

jj) ‘Organic material’ means a material composed primarily of carbon-based substances;

kk) ‘Migration’ means the transfer of substances from a material to water intended for human consumption, as defined in Commission Implementing Decision (EU) 2024/368 of 23 January 2024;

ll) ‘Monomer’ means a substance capable of forming covalent bonds with a sequence of additional molecules, whether similar or not, under the polymerisation reaction conditions relevant to the process in question;

mm) ‘Nanoform’ means a form of a natural or manufactured substance containing free particles or in the form of aggregate or agglomerate,

where at least 50 % of the particles in the number distribution by size have one or more external dimensions between 1 nm and 100 nm, including, by derogation, fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm. For the purposes of this definition:

i) ‘Particle’: a minute piece of matter with defined physical boundaries;

ii) ‘Aggregate’ means a particle composed of strongly bound or agglutinated particles;

iii) ‘Agglomerate’ means a collection of lightly aggregated particles or aggregates where the external surface is equal to the sum of the surfaces of the specific components;

nn) ‘Economic operator’ means any natural or legal person applying for product certification under this Regulation, which may be the manufacturer, the importer, the distributor or the authorised representative;

oo) ‘Conformity assessment body’: a body that performs conformity assessment activities, including testing, calibration, certification and inspection;

pp) ‘National accreditation body’ means a national accreditation body as defined in point (11) of Article 2 Regulamento (CE) n.º 765/2008 of;

qq) ‘Notified body’ means a conformity assessment body notified in accordance with Article 9;

rr) ‘Polymerised part’ means the part of a substance composition consisting of molecules characterised by sequences of one or more types of monomer units. Molecules such as dimers and trimers also contribute to the polymerised part. However, the term ‘polymerised part’ does not cover unreacted monomers or other unreacted reactants;

ss) ‘Polymer’: a substance consisting of molecules characterised by the sequence of one or more types of monomer units which are

distributed over a range of molecular masses, the differences between which are primarily due to differences in the number of monomer units, and which contains:

i) A simple weight majority of molecules containing at least three monomer units linked by covalence to at least one other monomer unit or to another reactant;

ii) Less than a simple weight majority of molecules of the same molecular weight;

tt) 'Pre-polymer' means a substance resulting from a polymerisation reaction, which is subjected to a new reaction to form a final polymer in a material or product;

uu) 'Product in contact with water' means an item which comes into contact with water intended for human consumption, and consists of final materials and is intended to be placed on the market with the marking provided for in Chapter IV of this Regulation;

vv) 'Assembled product': a product consisting of two or more components which are joined together, function as a unit and can be dismantled without destroying the components;

ww) 'Multi-layer product' means a product consisting of two or more layers of end-materials which are linked together and which cannot be disassembled for testing without being destroyed;

xx) 'Product used for water treatment' means biocidal products, chemicals and filter media;

yy) 'Test specimen' means a representative item of the final material used to perform the tests in accordance with the test procedures and methods set out in Annexes I, II, III and IV to Commission Implementing Decision (EU) 2024/368 of 23 January 2024;

zz) 'Minimum hygiene requirements' means the hygiene requirements laid down in Annexes I, II, III and IV to Commission Implementing Decision (EU) 2024/368 of 23 January 2024;

aaa) ‘Land distribution system’: the set of conduits, fittings and appliances installed between the devices for the use of the building and the connecting branch;

bbb) ‘Unforeseen substance’: a substance that has migrated from a product, final organic material or final cementitious material into water intended for human consumption, which has not been intentionally added during the production process of the material or product and which has not been included in the information provided with the application referred to in Article 11(5) of Directive (EU) 2020/2184;

ccc) ‘Initialising substance’ means a substance intentionally added for the production of organic materials or additives for cementitious materials;

ddd) ‘Monomer unit’ means the reactive form of the starting monomer within the polymer.

Article 4.º

Powers of ERSAR

1 - ERSAR shall be the competent authority for the coordination and enforcement of the application of this Regulation.

2 - In pursuance of the preceding paragraph, ERSAR shall be responsible for:

a) Promoting the updating of the rules of operation of the national approval system for products in contact with water intended for human consumption, where the regulatory provisions issued by the European Commission so determine;

b) Issuing general recommendations on the interpretation and application of this Regulation;

c) Monitoring the application of the products approved under this Regulation by the managing bodies of the public water supply systems for human consumption;

d) Chairing and coordinating the work of the Technical Commission.

Article 5.º

Notifying authority and notification procedure

1 - For the purposes of this Regulation, the Instituto Português da Qualidade, I.P. (IPQ) is the notifying authority responsible for the notification of conformity assessment bodies and the monitoring of notified bodies.

2 - The IPQ is responsible for notifying the European Commission and the other Member States of the bodies responsible for carrying out the conformity assessment in Portugal and for informing the national authorities, in particular ERSAR, of that notification.

3 - The IPQ shall inform the European Commission of the procedures for notifying conformity assessment bodies and of any changes thereto.

4 - To carry out the notification referred to in paragraphs 2 and 3, the IPQ uses the electronic notification tool designed and managed by the European Commission.

5 - The IPQ may only notify conformity assessment bodies which are accredited in accordance with paragraph 2 of the following Article and which satisfy the requirements set out in Article 9.

6 - A conformity assessment body may perform the activities of a notified body only if no objections are raised by the European Commission or the other Member States within two weeks of notification, and only then can it be considered as a notified body for the purposes of this Regulation.

7 - The IPQ shall notify the European Commission of any relevant changes made to the notification subsequently.

8 - The IPQ shall restrict, suspend or withdraw the notification, as appropriate, and shall immediately inform the European Commission, the other Member States and the national authorities, in particular the ERSAR, whenever it determines or is informed that a notified body no longer meets the requirements applicable to it or that it does not fulfil its obligations.

9 - In the cases referred to in the previous paragraph, or when the notified body ceases its activity, the IPQ shall take the necessary steps to ensure

that the files of that body are either processed by another notified body or kept at the disposal of the national authorities at their request.

Article 6.º

Accreditation of conformity assessment bodies

1 - The IPAC, as the national accreditation body, is responsible for assessing and monitoring conformity assessment bodies.

2 - For the purpose of notification, conformity assessment bodies must have been previously accredited by IPAC, in the modalities corresponding to the intended conformity assessment activities.

3 - For the purposes of the previous paragraph, accredited conformity assessment bodies shall comply with the requirements listed in Articles 8 to 12 and 31 of this Regulation.

Article 7.º

Requirements applicable to the notifying authority

1 - The notifying authority shall be constituted in such a way as to avoid conflicts of interest with conformity assessment bodies.

2 - The notifying authority shall be organised and operated in such a way as to safeguard the objectivity and impartiality of its activities.

3 - The notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons other than those who carried out the assessment.

4 - The notifying authority may not propose or carry out any activity that falls within the competence of conformity assessment bodies, nor provide consultancy services of a commercial or competitive nature.

5 - The notifying authority shall safeguard the confidentiality of the information it obtains.

6 - The notifying authority shall have a sufficient number of technically competent staff at its disposal for the proper performance of its tasks.

Article 8.º

Notified bodies

1 - Conformity assessment bodies wishing to be notified bodies shall be responsible for meeting the requirements of Articles 9 to 12.

2 - Notified bodies are responsible for assessing the minimum hygiene requirements for products in contact with water intended for human consumption laid down in Article 34 of Decree-Law No 69/2023 of 21 August 2023.

3 - Notified bodies are responsible for issuing a certificate for assessed products in contact with water intended for human consumption, provided they meet the minimum applicable requirements laid down in Article 34 of Decree-Law No. 69/2023 of 21 August 2023, and following the conformity assessment procedure referred to in Chapter III of this Regulation.

Article 9.º

Information requirements for notified bodies

1 - Conformity assessment bodies shall be established under Portuguese law and possess legal personality.

2 - A conformity assessment body shall be independent of the organisations of the manufacturers, importers, authorised representatives or the products it assesses.

3 - Conformity assessment bodies shall be accredited by IPAC to carry out the conformity assessment procedures set out in Article 31.

4 - Conformity assessment bodies, their management and the personnel responsible for carrying out conformity assessment tasks may not be designers, manufacturers, importers, suppliers, purchasers or users of the products to be assessed, nor authorised representatives of any of these persons, and this requirement does not prevent the use of products that are necessary for the activities of the conformity assessment body or the use of products for personal purposes.

5 - A conformity assessment body, its governing management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing or use of products which they assess or represent the persons carrying out those activities, nor shall they engage in any activity that may conflict with their independence of judgement or integrity in the performance of the conformity assessment activities for which they are notified, in particular consultancy services.

6 - Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the conformity assessment activities they perform, especially as regards persons or groups of persons with an interest in the results of those activities.

7 - In order to fulfil the assessment referred to in Article 31, a conformity assessment body shall be capable of carrying out all the conformity assessment tasks in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility, and shall have at its disposal:

a) Staff with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

b) A description of the conformity assessment procedures that ensure transparency and the ability to replicate those procedures;

c) Appropriate policies and procedures to distinguish the tasks they carry out as notified bodies from other activities;

d) Procedures for the performance of their activities taking into account the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;

e) The means necessary for the proper execution of technical and administrative tasks related to conformity assessment activities and access to all necessary equipment and facilities.

8 - The staff responsible for carrying out the conformity assessment tasks shall have:

a) Solid technical and professional training, covering all the conformity assessment activities for which the conformity assessment body has been notified;

b) Satisfactory knowledge of the requirements of the assessments they carry out and the appropriate authority to carry them out;

c) Appropriate knowledge and understanding of the minimum hygiene requirements and their rules laid down in Decisão de Execução (UE) 2024/368, da Comissão de 23 de janeiro, or any updates thereof;

d) Ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

9 - A conformity assessment body shall ensure the impartiality of its management and of the human resources responsible for carrying out the tasks associated with conformity assessment.

10 -.....The remuneration of senior management and human resources responsible for conformity assessment should not depend on the number of assessments carried out or on the results of that assessment.

11 -. .Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessments.

12 -.....The personnel of the conformity assessment bodies shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 31, except in relation to the competent authorities of the Member State in which they carry out their activities, without prejudice to the protection of property rights.

13 -.....A conformity assessment body shall participate in the relevant standardisation activities or shall ensure that its personnel responsible for carrying out the conformity assessment tasks are informed of those activities.

Article 10.º

Functional duties and information obligations of notified bodies

1 - Notified bodies shall:

a) Carry out the conformity assessment in a proportionate manner, avoiding unnecessary burdens on economic operators and in accordance with the conformity assessment procedures provided for in Article 31;

b) Carry out their activities taking into account the size, sector, structure of the undertakings in which they are carried out, the relative complexity of the technology used by the products and the mass or serial nature of the production;

c) Respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of this Regulation;

d) Refrain from issuing the certificate of conformity and oblige the manufacturer to take appropriate corrective measures if it finds that the minimum hygiene requirements have not been complied with;

e) Suspend, restrict or withdraw the certificate where, following a conformity assessment carried out following the issue of a certificate, it is established that the product no longer complies and that the manufacturer has failed to take appropriate corrective measures.

2 - The bodies notified by the IPQ shall provide the IPQ with the following information:

a) The refusal, restriction, suspension or withdrawal of certificates;

b) The circumstances affecting the scope and conditions of the notification;

c) Requests for information which they have received from the market surveillance authority on the conformity assessment activities carried out by them;

d) On request, the conformity assessment activities they have carried out as part of their notification and any other activities carried out, including cross-border and subcontracting activities.

3 - Notified bodies shall provide market surveillance authorities and other notified bodies, including those of other Member States, carrying out similar conformity assessment activities covering the same types of products, with relevant information on issues related to negative and, upon request, positive conformity assessment results.

Article 11.º

Requirements for subsidiaries and subcontractors of notified bodies

1 - Where notified bodies have recourse to a subsidiary or to the subcontracting of specific tasks in order to carry out conformity assessment, they shall ensure that the requirements laid down in Article 9 are met and shall inform the notifying authority accordingly.

2 - The responsibility for the conformity assessment tasks carried out by the subsidiaries or by subcontracting shall lie exclusively with the notified bodies, irrespective of where they are established.

3 - The performance of conformity assessment tasks by subcontracting or by subsidiaries of the notified bodies requires the agreement of the client.

4 - Notified bodies shall keep records confirming to the notifying authority the assessment made to subcontracted entities or subsidiaries, as well as the conformity assessment work carried out under Article 31.

5 - The inspection body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

Article 12.º

Request for notification

1 - Conformity assessment bodies wishing to be a notified body in Portugal and meeting the requirements of Article 9 shall submit an application for notification to the IPQ, as indicated on their website.

2 - The request for notification shall be accompanied by the following elements:

a) A description of the conformity assessment activities and procedures set out in Article 31 for which the conformity assessment body claims to be competent;

b) Accreditation certificate(s) issued by IPAC, in accordance with Article 6, attesting that the conformity assessment bodies comply with the requirements laid down in Article 9 and that their subsidiaries or subcontractors comply with the requirements laid down in Article 11.

Article 13.º

Duties of economic operators

1 - Economic operators shall be the entities responsible for the process of approval of the product in contact with water under this Regulation.

2 - In pursuance of the preceding paragraph, economic operators shall be responsible for:

a) Submitting the application for conformity assessment of the product to a notified body;

b) Immediately inform the notified body responsible for the conformity assessment of any change in the characteristics of the product or change in the production process that has an impact on the conformity of the product, failing which the certificate will be suspended, restricted or withdrawn in accordance with Article 10(1)(e).

Article 14.º

Duties of managing bodies

1 - The managing bodies shall be responsible for the selection, purchase and application of the approved product, from the collection, treatment, supply network and distribution network to the connection branch, which bears the marking provided for in Chapter IV, regardless of whether it has been allocated under this Regulation or under equivalent regulations of another Member State of the European Union.

2 - It is the responsibility of the management bodies to use products suitable for contact with water intended for human consumption, in compliance with the conditions of application and use defined by the economic operator supplying the approved product, ensuring that they do not cause changes that entail a reduction in the level of protection of human health or cause the migration of substances into water that compromise compliance with the parametric values laid down in Decree-Law No 69/2023 of 21 August 2023, as well as do not give rise, directly or indirectly, to risks to human health.

3 - Managing bodies may only use water treatment products and filter media that have been assessed on the basis of applicable European standards.

4 - Managing bodies may only use biocidal products, which are legally made available for use on the national market, in accordance with Article Decreto-Lei n.º 140/2017, de 10 de novembro, in its current wording.

5 - For the purposes of the preceding paragraph, biocidal products used for the treatment of water intended for human consumption shall be classified as biocidal products of Group 1 - Disinfectants and Product Type 5 used for the disinfection of drinking water intended for humans, in accordance with Annex V to Regulamento (UE) n.º 528/2012, de Parlamento Europeu e do Conselho, de 22 de maio.

6 - Chemicals and filter media that come into contact with water intended for human consumption shall comply with the provisions of Decreto-Lei n.º 293/2009, de 13 de outubro, and no Decreto-Lei n.º 220/2012, de 10 de outubro, in its current wording.

7 - For the purposes of paragraphs 3 to 6 of this Article, managing bodies shall request evidence from suppliers of compliance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH Regulation), Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 (Biocides Regulation) and the respective harmonised European product standards.

Article 15.º

Duties of the owners of the land distribution systems

1 - The owners of the land distribution systems shall be responsible for the selection, procurement and application of the approved product, from the connection branch to the tap or point of use of water intended for human consumption, which has the marking provided for in Chapter IV.

2 - It shall be the responsibility of the owners of the land distribution systems to:

a) Use the products appropriate for the treatment of water, where applicable, or in contact with water intended for human consumption, respecting the conditions of application and use, ensuring that these do not cause changes involving the reduction of the level of protection of human health or do not cause the migration of substances into the water that jeopardise compliance with the parametric values set out in Decree-Law No 69/2023 of 21 August 2023, as well as do not directly or indirectly cause risks to human health;

b) Inform those responsible for building water supply network projects of the obligation to select the products to be used in the building distribution systems that have the marking provided for in Chapter IV.

3 - The provisions of paragraphs 3 to 7 of the previous article also apply to building systems when a treatment is carried out there.

Article 16.º

Technical Commission

1 - ERSAR shall be assisted by a Technical Commission as part of the operation of the national approval system for products in contact with water intended for human consumption.

2 - This Technical Commission shall issue an opinion on:

a) Proposals for amendments to this Regulation;

b) The operating conditions of the national approval system for products in contact with water intended for human consumption;

c) The recommendations to be published by ERSAR concerning products used in contact with water intended for human consumption from the perspective of protecting human health.

3 - The Technical Commission is also responsible for issuing an opinion at the request of ERSAR on any other matter within the scope of the national approval system for products in contact with water intended for human consumption.

4 - The Technical Committee for the national approval system for products in contact with water intended for human consumption shall consist of:

a) Four representatives of the ERSAR, one of whom shall be the chairperson and another registry;

b) A representative of the Regulatory Authority for Water and Waste Services of the Azores;

c) A representative of the Regional Directorate for Environment and Climate Action of the Autonomous Region of Madeira;

d) A representative of the Competition Authority.

e) A representative of the Directorate-General for Consumer Affairs;

f) A representative of the Directorate-General for Economic Activities;

g) A representative of IAPMEI;

h) A representative of the Instituto Português da Qualidade, I.P.;

i) A representative of the Portuguese Institute for Accreditation (Instituto Português da Acreditação);

j) A representative of the Agência Portuguesa do Ambiente (Portuguese Environmental Agency);

k) Two representatives of the notified bodies;

l) A representative of the laboratories;

m) Two to three representatives of laboratories specialising in the evaluation of products in contact with water intended for human consumption;

n) Five to ten representatives of the industry associations.

5 - The entities represented in accordance with points k) (a) to (n) of the preceding paragraph shall be appointed by order of the Board of Directors of ERSAR, according to criteria of representativeness of the sector and proven experience in the matter.

6 - The members of the Technical Commission of the national approval system shall be appointed by the head of the entities they represent.

7 - The term of office of the members of the Technical Committee of the national approval system shall be four years, renewable for equal periods, without prejudice to the possibility of being replaced at any time by the entities appointing them.

8 - The position of member of the Technical Commission of the national approval system for products in contact with water intended for human consumption shall not be remunerated, without prejudice to the payment of expenses by the entity represented to its representative, when this takes place.

9 - The Technical Committee may include experts, designated by its chairman, in accordance with the designation procedure laid down in the rules of procedure for the operation of the Technical Committee.

10 -. The regulation referred to in the previous paragraph shall be drawn up and approved by the Technical Commission itself within 60 days after the date of the first meeting and shall be published on the ERSAR website within 10 days after its approval.

Chapter II

Capítulo IIInitialising substances, compositions and constituents

Article 1.º
European positive lists

1 - Products that may be used in contact with water intended for human consumption shall consist of the starting substances, compositions or constituents on the European positive lists.

2 - Four European positive lists are defined:

a) The European positive list of starting substances for organic materials and groups of starting substances for organic materials, as indicated respectively in Tables 1 and 2 of Annex I to Decisão de Execução (UE) 2024/367, da Comissão de 23 de janeiro, or their updates;

b) The European positive list of compositions of metallic materials and groups of compositions for metallic materials, as set out respectively in Tables 1 and 2 of Annex II to Commission Implementing Decision (EU) 2024/367 of 23 January 2024, or their updates;

c) The European positive list of organic constituents of cementitious materials and groups of organic constituents for cementitious materials, as indicated respectively in Tables 2 and 3 of Annex III to

Commission Implementing Decision (EU) 2024/367 of 23 January 2023 or its updates;

d) the European positive list of compositions of enamels, ceramics and other inorganic materials as set out in Table 1 of Annex IV to Commission Implementing Decision (EU) 2024/367 of 23 January 2024 or its updates.

Article 2.º

Inclusion of a starting substance, composition or constituents in the positive lists

The procedure for the inclusion of a starting substance, composition or constituents in the positive lists shall follow the procedures set out in Articles 2, 3 and 7 of Regulamento Delegado (UE) 2024/369, da Comissão de 23 de janeiro, or updates thereto.

Article 3.º

Verification of the conformity of applications

The compliance check of applications for inclusion of a starting substance, composition or constituents in the positive lists shall be carried out in accordance with the provisions of Article 4 of Commission Delegated Regulation (EU) 2024/369 of 23 January 2024 or any updates thereto.

Article 4.º

Consultation of interested parties

Within four weeks of the publication of an application on its website, as provided for in Article 5 of Commission Delegated Regulation (EU) 2024/369 of 23 January 2024, or its updates, ECHA shall invite interested parties to submit scientific information.

Article 5.º

Consultation of the applicant and opinion

Opinions issued by the ECHA Risk Assessment Committee on the risks to human health arising from the uses of the starting substance, composition or organic cementitious constituent subject to the application and consultation with the applicant shall be carried out in accordance with the provisions of Articles 6 and 8 of Commission Delegated Regulation (EU) 2024/369 of 23 January or their updates.

Article 6.º

Acceptance methodologies in European positive lists

1 - The inclusion of starting substances, compositions and constituents on the European positive lists, supported by an assessment of the risks raised by the identified relevant chemical species, is conditional on compliance with the requirements in Annex VI to Decisão de Execução (UE) 2024/365, da Comissão de 23 de janeiro, or its updates.

2 - Starting substances and organic cementitious constituents which have a biocidal function and are subject to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 may only be accepted if they are of product-type 6 (preservatives for products during storage) listed in Annex V to that Regulation.

Article 7.º

Testing methodologies and acceptance criteria for starting substances, compositions and constituents

1 - The testing methodologies referred to in Article 34(2) of Decree-Law No 69/2023 of 21 August 2023 shall apply to:

a) Initialising substances for organic materials;

b) Organic constituents of cementitious materials;

c) Compositions of metallic materials;

d) Compositions of enamels, ceramics and other inorganic materials.

2 - For situations where a polymer is used in an organic or cementitious material, the testing methodologies and acceptance criteria shall be applied to the monomer, pre-polymer or polymer in accordance with the rules set out in points (v) to (viii) of Annex I and points (iii) to (iv) of Annex III to Commission Implementing Decision (EU) 2024/367 of 23 January 2024, or any updates thereof.

3 - The identification of starting substances, compositions and organic cementitious constituents shall be carried out in accordance with the requirements set out in Annex I to Commission Implementing Decision (EU) 2024/365 of 23 January 2024 or its updates.

4 - The intended use of starting substances, compositions and constituents, as well as materials and products, shall be specified in accordance with the requirements set out in Annex II to Commission Implementing Decision (EU) 2024/365 of 23 January 2024, or any updates thereto.

5 - The determination of the physicochemical properties of the relevant chemical species shall be carried out in accordance with the requirements set out in Annex III to Commission Implementing Decision (EU) 2024/365 of 23 January 2024, or any updates thereto.

6 - The determination of migration into water intended for human consumption shall be carried out in accordance with the requirements set out in Annex IV to Commission Implementing Decision (EU) 2024/365 of 23 January 2024 or any updates thereto.

7 - The identification of the relevant chemical species shall be carried out in accordance with Section 3 of Annex IV to Commission Implementing Decision (EU) 2024/365 of 23 January 2024 or its updates.

8 - The determination of the toxicological properties of the relevant chemical species referred to in paragraph 7 shall be carried out in accordance with the requirements set out in Annex V to Commission Implementing Decision (EU) 2024/365 of 23 January 2024, or any updates thereto.

Article 8.º

Publication of information

ECHA publishes the information set out in Article 9 of Commission Delegated Regulation (EU) 2024/369 of 23 January 2024 or its updates.

Article 9.º

Confidentiality

The information sent to ECHA is not confidential, with the exception of:

a) Information concerning the identification of an applicant, where there is a designated representative;

b) Information on the manufacturing process of a starting substance, composition or cementitious organic constituent or on the manufacturing process in which it is used;

c) Information on possible links between operators in the same supply chain;

d) Information received from another EU body, office or agency or from a Member State that has been considered confidential by the body that provided it to ECHA;

e) Information on an impurity, unless that impurity is a relevant chemical species.

Article 10.º

Change of communication transmitter or applicant

1 - The performance of the communication transmitter function pursuant to Article 18 may be transferred by mutual agreement between a current and a future transmitter before the submission of the application.

2 - The function of applicant may be transferred by mutual agreement between an existing applicant and a future applicant until the applicant has received the draft opinion in accordance with Article 21.

3 - The notice of intent referred to in Article 18 shall be submitted to ECHA jointly by the current and future transmitters or applicants.

Article 11.º

Withdrawal of an Application

The withdrawal of an application for inclusion pursuant to Article 18 shall comply with the requirements of Article 12 of Commission Delegated Regulation (EU) 2024/369 of 23 January 2024 or any updates thereto.

Article 12.º

Additional obligations of the applicant

1 - The applicant shall cooperate with ECHA, in particular by submitting the complete study reports supporting their applications, as well as by responding to the questions of this Agency without undue delay.

2 - The applicant shall, within two months of the publication of the opinion of the Committee for Risk Assessment to include, maintain or amend an entry in one of the European positive lists, provide the European Commission with a calibrant of its starting substance or its cementitious organic constituent or a representative sample of the accepted composition of metallic, enamelled, ceramic or other inorganic materials.

3 - Following a decision by the European Commission to include an entry in one of the European positive lists, the applicant shall keep available all information required to comply with its obligations under this Regulation for at least 20 years after the date on which the authorisation was withdrawn or expired.

4 - The applicant shall submit the information referred to in paragraph 1 or make it available without delay upon request to any competent authority of the Member State in which it is established or to ECHA.

5 - In the event that an applicant ceases its activity or transfers part or all of its operations to a third party, the party entrusted with the liquidation of the applicant’s undertaking, or assuming responsibility for the operations

in question, shall be bound by the obligations laid down in paragraphs 1 and 2 in place of the applicant.

Chapter III

Capítulo IIIProducts that come into contact with water intended for human consumption

Article 1.º
General requirement

1 - The assessment of products in contact with water intended for human consumption shall apply to all types of products specified in the Annexes to the Implementing Acts and Delegated Regulations referenced in this Regulation, and shall comply with the technical specifications defined therein, without prejudice to compliance with other legal requirements and other specific technical rules applicable to the product.

2 - Construction products in contact with water intended for human consumption, and the substances which constitute them or are used in their manufacturing process, shall be evaluated with the aim of determining possible adverse health effects, in accordance with the requirements specified in the Annexes to the implementing acts and delegated regulations referred to in this Regulation.

Article 2.º
Assessment of the effects on water quality

The products shall be subjected to the tests set out in the Annexes to the implementing acts and delegated regulations referred to in this Regulation for organoleptic evaluation of water, increase of microbial growth (EMG) and/or migration of chemicals into water.

Article 3.º

Assessment of the conformity of products in contact with water intended for human consumption

1 - For products classified in risk groups 1 or 2 in accordance with the respective update(s) Decisão de Execução (UE) 2024/368, da Comissão de 23 de janeiro, or, in the case of a metal composition, in product groups A or B in Table 2 'Product groups for metal compositions' of Annex II of the respective update(s), Decisão de Execução (UE) 2024/365, da Comissão de 23 de janeiro, the following conformity assessment procedures shall apply:

a) Module B set out in Annex II to Decisão n.º 768/2008/CE, implemented by a notified body, with the following specifications:

i) Conformity assessment including an examination of a test specimen (production type);

ii) The performance by or on behalf of the notified body of all the relevant tests referred to in Commission Implementing Decision (EU) 2024/368 of 23 January 2024 or their updates;

iii) The collection of test specimens by the notified body at the time of the inspection of the production site in accordance with paragraph 1(b)(ii) or (iii) of this Article, unless production of the products has not yet started.

b) Module D set out in Annex II to Decision No 768/2008/EC with the following specifications:

i) . .The assessment of the quality system by the notified body that carried out the conformity assessment procedure referred to in paragraph 1(a) of this Article;

ii) An initial inspection of the production site by the notified body to assess the quality system and remove test pieces for type examination;

iii) The performance of an annual inspection of the place of production to assess the quality system and take test pieces for

the re-evaluation of the type examination provided for in subsection (1)(a) of this section or for a reduced test pursuant to sub-paragraph (iv);

iv) The notified body or another entity on its behalf may carry out annual reduced tests, without prejudice to the manufacturer carrying out tests as part of its quality system.

2 - For products classified in risk groups 3 or 4 pursuant to Commission Implementing Decision (EU) 2024/368 of 23 January 2024 or its updates or, in the case of a metal composition, in product groups C or D of Table 2 ‘Product groups for metal compositions’ of Annex II to Commission Implementing Decision (EU) 2024/365 of 23 January 2024 or its updates, the following conformity assessment procedures shall apply:

a) Module B (EU type-examination) set out in Annex II to Decision No 768/2008/EC, performed by a notified body, with the following specifications:

i) The conformity assessment shall include a type examination of a test specimen (production type).

ii) The performance by or on behalf of the notified body of all the relevant tests referred to in Commission Implementing Decision (EU) 2024/368 of 23 January 2024 or their updates;

iii) The test pieces shall be provided by the manufacturer, importer or authorised representative to the notified body for type examination.

b) Module C (conformity to type based on internal production control) set out in Annex II to Decision No 768/2008/EC.

3 - Where the conformity assessment procedures referred to in paragraphs 1 and 2 demonstrate that the product complies with the minimum hygiene requirements, the notified body shall issue a certificate to the manufacturer, importer or authorised representative for both of the conformity assessment procedures referred to in points (a) and (b) of paragraph 1 and point (a) of paragraph 2 of this Article.

4 - The certificate shall be valid for five years and shall contain the following information:

a) Identification of the manufacturer;

b) Address of the manufacturer,

c) Conclusions of the conformity assessment;

d) Other conditions applicable to the certificate;

e) Data necessary for the identification of the approved type.

5 - The notified body may withdraw the certificates as part of the annual inspections carried out in accordance with paragraph 1(b)(iii) of this Article.

6 - For the products referred to in paragraph 2 of this Article, the manufacturer shall ensure and declare that the product is in conformity with the type described in the EU-type examination certificate and satisfies the requirements laid down in this Regulation.

7 - The conformity assessment procedure applicable to an assembled product shall be determined by the component with the highest risk group classification (RG1 is the highest risk group, RG4 is the lowest risk group) pursuant to Implementing Decision (EU) 2024/368 or, in the case of metal compositions, by the product group with the highest classification set out in Table 2 ‘Product groups for metal compositions’ of Annex II to Implementing Decision (EU) 2024/365.

8 - The conformity assessment procedure applicable to the manufacturing of a component of an assembled product shall be determined by the risk group of that component in accordance with Implementing Decision (EU) 2024/368 or, in the case of metal compositions, by the product group of the component set out in Table 2 ‘Product groups for metal compositions’ of Annex II to Implementing Decision (EU) 2024/365.

9 - Manufacturers or their authorised representatives shall draw up an EU declaration of conformity where the conformity of their products has

been demonstrated by the conformity assessment procedures described in paragraphs 1 and 2 of this Article.

10 - The declaration of conformity referred to in the previous paragraph binds the manufacturer to the responsibility for the compliance of the product with the minimum hygiene requirements.

11 - The declaration of conformity, relating to the products or materials covered by this Decree-Law that are placed or made available on the national market, must follow the model set out in the Annex to Commission Delegated Regulation (EU) 2024/370 of 23 January 2024, be continuously updated and drafted in Portuguese.

12 - The declaration of conformity, relating to products or materials covered by this Decree-Law which are placed or made available on other EU markets, shall comply with the model set out in the Annex to Commission Delegated Regulation (EU) 2024/370 of 23 January 2024, be continuously updated and be in the language of the country of destination of the marketing.

Chapter IV

Capítulo IV Marking of products coming into contact with water intended for human consumption

Article 1.º
Symbol

1 - The marking of products which come into contact with water intended for human consumption provided for in Article 11(11) of Directive (EU) 2020/2184 shall be carried out with the symbol set out in the Annex to Regulamento Delegado (UE) 2024/371, da Comissão de 23 de janeiro.

2 - The symbol must be indelible and must be placed visibly on one or more surfaces of the product, on all accompanying technical and administrative documents and on its packaging.

3 - In situations where the symbol with the minimum dimensions cannot be placed on the product, it must be on the packaging and in the documentation accompanying the product.

Article 2.º

Marking characteristics

1 - The symbol referred to in Article 32 shall be at least 5 mm high.

2 - The marking shall also include on the packaging and documentation the information text ‘Suitable for drinking water’.

3 - The information text referred to in paragraph 2 shall be clearly visible and placed below the symbol in capital letters in Helvetica bold type, the minimum font size being 5 mm.

4 - The information text referred to in paragraph 2 is written in the official languages of the country in which the product is placed on the market.

5 - The colour and presentation of the marking shall be such that the symbol stands out clearly.

6 - Another marking may be placed on the product, the documentation and the packaging, provided that it does not impair the visibility, readability and meaning of the specific marking of products that come into contact with water intended for human consumption.

7 - All elements of the marking shall be located next to the other labelling on the product, on the documentation and on the packaging.

Chapter V

Final and transitional provisions

Article 3.º
Gap-filling

In all matters not specifically provided for in this Regulation, the provisions of the legislation in force shall apply.

Article 4.º
Monitoring of the application of the Regulation

1 - The monitoring of compliance with this regulation shall be carried out in accordance with the provisions of Article 41 of Decree-Law No 69/2023 of 21 August 2023.

2 - The supervision of the building networks of non-priority installations is the responsibility of the entities responsible for approving the projects of these networks.

Article 5.º
Sanctioning regime

Failure to comply with the provisions laid down in this Regulation shall be subject to the system of penalties laid down in Decree-Law No 69/2023 of 21 August 2023.

Article 6.º
Obligation of secrecy

All entities involved in the application of this Regulation, in particular representatives of ERSAR, the Technical Commission, notified bodies, and laboratories shall be bound by the obligation of professional secrecy with regard to facts and documents of which they have knowledge in the context of their tasks and may not disclose or use information obtained other than in the strict performance of their tasks.

Article 7.º

Technical and scientific documentation

1 - All documentation required under this Regulation shall be drawn up and made available in Portuguese, without prejudice to the authorisation of the use of English, in particular for technical and scientific documentation.

2 - With regard to the European standards referred to in this Decree-Law, the latest edition and subsequent errata, amendments, revisions, integrations or consolidations of those standards shall apply as they are published by the European Committee for Standardisation (CEN) and/or the Portuguese Quality Institute (Instituto Português da Qualidade, I.P.), as the national standardisation body.

Article 8.º

One-stop-shop and computer records

1 - All communications and notifications provided for in this Regulation, as well as the sending of documents, requests or information, shall be carried out by electronic means through the electronic single point of contact for services.

2 - When, for reasons of unavailability of electronic platforms, it is not possible to comply with the provisions of the preceding paragraph, the transmission of the information in question may be carried out by other means provided for by law.

3 - Entities shall be required to keep records of product approvals under this Regulation in computerised form for a minimum period of 5 years.

Article 9.º

Successive assessment

Three years after the date of entry into force of this Regulation, ERSAR, with the collaboration of the Technical Commission, shall assess the need to review the national approval system for products in contact with water intended for human consumption, in the light of the objectives initially set

and the changes that have occurred in the meantime, in particular as regards technical and scientific developments in products in contact with water, the evolution of product certification methodologies and the workload carried out by ERSAR.

Article 10.º

Legal references

References to legal acts, whether national or EU, shall be construed as references to legal acts in force on the date on which this Regulation takes effect or to those which replace them.

Article 11.º

Effective date

1 - As of 31 December 2026, only products approved in accordance with the provisions of this regulation may be used.

2 - Without prejudice to the previous paragraph, substances, compositions and constituents which, in accordance with national provisions, have been approved by a competent authority of a Member State during the period from 13 July 2021 to 31 December 2026 may be used until 31 December 2032 in the manufacture of materials or products coming into contact with water intended for human consumption, provided that they comply with the parametric value of 5 µg/l set for lead at the point of use by the consumer set out in Part B of Annex I to Directive (EU) 2020/2184.

3 - Without prejudice to paragraph 2 of this Article, in the case of products for which compliance with national hygiene requirements for products in contact with water intended for human consumption has been established and for which the certificate of conformity is still valid on 31 December 2026, this Regulation shall apply from 31 December 2032.