EUROPEAN
COMMISSION

Brussels, 23.1.2024
C(2024) 240 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 23.1.2024

supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down the procedure regarding inclusion in or removal from the European positive lists of starting substances, compositions and constituents

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Directive (EU) No 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption includes minimum hygiene requirements for materials that come into contact with water intended for human consumption.

This Commission Delegated Regulation establishes the procedure to amend the European Positive Lists of substances, compositions or constituents established under Article 11(2)(b) of Directive (EU) 2020/2184.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In the context of the development of this Regulation, the Commission carried out targeted consultations with stakeholders in the water sector and consulted Member States experts in meetings of the expert group on the implementation of the Drinking Water Directive. The Commission also discussed this Regulation with Member States experts in meetings of the aforementioned expert group's subgroup on substances in contact with drinking water. The last Drinking Water Expert Group meeting took place on 16 June 2023, where stakeholders were invited to provide comments on this draft act. In accordance with the Better Regulation rules, the draft delegated act was published on the Have Your Say portal for a four-week feedback period between 16 October 2023 and 13 November 2023. Comments were made on this draft delegated act, mainly in relation to the additional protection needed for certain data submitted in the context of applications and the clarification/corrections to be made in the text. Based on careful examination of the feedback received, changes and clarifications were introduced in the text.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

According to Article 11(5) of Directive (EU) 2020/2184, the Commission is to determine the conformity assessment procedure applicable to products covered by that Article. That procedure is to be used to demonstrate that those products fulfil the requirements set out in Directive (EU) 2020/2184.

The procedure will start with a notification of intention to the European Chemicals Agency (ECHA) (Article 2). Articles 3 to 6 set out information and time requirements to be respected by applicants, requirements for the consultation of interested parties and for opinions of the Committee for Risk Assessment (RAC) on applications. Articles 7 to 10 lay down rules on the management of information from applications submitted to ECHA. The application of this Regulation will be delayed by 2 years after its entry into force in order to align it with the date of application of the drinking water contact materials package, with the exception of the provisions on "notification of intention" to allow ECHA to assess the number of applications in advance (Article 14).

COMMISSION DELEGATED REGULATION (EU) …/...

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption[1], and in particular Article 11(5) thereof,

Whereas:

(1) Directive (EU) 2020/2184 provides for the establishment of European positive lists of starting substances, compositions, or constituents for each type of materials, namely organic, metallic, cementitious, enamels, ceramic or other inorganic materials, which are authorised for use in the manufacture of materials or products that come into contact with water intended for human consumption. Applications for inclusion or removal and for the purpose of the review of starting substances, compositions or constituents from those lists are to be submitted to the European Chemicals Agency (ECHA). The Commission is to establish the procedure for such applications.

(2) Potential applicants should be encouraged to group their efforts and avoid unnecessary animal testing by preparing a single application for the same starting substance, composition or constituent. In addition, in order to allow for advance planning of the processing of applications and for these applications to be processed efficiently and in a timely manner, potential applicants must notify their intention to ECHA within 12 months before submitting the application.

(3) Persons not established in the Union should be allowed to apply for inclusion in or removal from the European positive lists of a starting substance, composition or constituent provided that they appoint a representative established in the Union for that purpose.

(4) In order to protect human health, it should be possible for the Commission to initiate a procedure by requesting the Committee for Risk Assessment of ECHA to prepare an opinion on the inclusion or removal of a starting substance, composition or constituent in the European positive lists.

(5) An application should contain all necessary information to assess the application in accordance with the testing and acceptance methodologies established in Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]*.

[1] OJ L 435, 23.12.2020, p. 1.

(6) In the case of a polymer with a high molecular weight which is used as an additive in an organic material and is not obtained from microbial fermentation, the application should be on the monomer, since the monomer is expected to be more reactive and thus more relevant for human health. Furthermore, assessing each and every polymer manufactured from such monomer would not be proportionate. In the case of a pre-polymer for some silicones or for coatings, the assessment is more efficiently and proportionally addressed at the level of the pre-polymer. In the case of an admixture for cementitious material, the application should be for the polymer since the polymer may be composed of multiple monomers whose interaction can only be assessed if the application is for the polymer.

(7) In order to protect confidential information, an applicant other than a relevant authority should be allowed to appoint a representative that can be named instead of that economic operator in any public communication.

(8) The accordance check should ensure that only applications that are complete and of sufficient quality are reviewed by the Committee for Risk Assessment of ECHA. The accordance check should also exclude applications which are outside the scope of Article 11 of Directive (EU) 2020/2184. Sacrificial anodes, membranes and ions exchange resins are water treatment chemicals and/or filter media and are covered by Article 12, therefore they are excluded of the scope of Article 11. The implementation of the accordance check should also allow for grouping of applications that have passed the accordance check in order to ensure an efficient evaluation of a potentially high number of applications at the same time.

(9) To facilitate the verification of compliance with the conditions for use and migration limits established in the European positive lists, applications should contain information on the relevant analytical methods for the measurement of migration of relevant chemical species into drinking water. That information should make it possible to verify the identity of and to quantify substances that migrate into water intended for human consumption when a starting substance, composition or constituent that is listed in the European positive list is used in the manufacture of materials or products that come into contact with such water. The calibration of the analytical methods and the associated measuring equipment might require physical testing of migration that could be conducted only if the applicant provides a calibrant of the corresponding starting substance or organic cementitious constituent or a sample of the composition. Therefore, an applicant shall provide the Commission with a calibrant of its starting substance or organic cementitious constituent or a representative sample of the accepted composition of metallic materials, enamels, ceramic or other inorganic materials upon a positive opinion by the Committee for Risk Assessment of ECHA.

(10) In order to give sufficient time to ECHA but also to economic operators and relevant authorities to prepare, the application of this act will start from 31 December 2026. However, Article 2 should apply as from 31 December 2025.

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Definition

For the purpose of this Regulation, the following definition shall apply:

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

CHAPTER II

NOTIFICATION OF INTENTION

Article 2

Notification of intention

1. A potential applicant shall submit to ECHA a notification of its intention to submit within a determined period of time an application for the inclusion of a starting substance, composition or constituent in the European positive lists. Unless the potential applicant is a competent relevant authority for an application justified by urgency, this notification shall be made within 12 months prior to the submission of the application.

2. ECHA shall acknowledge receipt of the notification of the intention.

CHAPTER III

APPLICATION PROCEDURE

Article 3

Application

1. ECHA shall acknowledge receipt of the application submitted for the inclusion or removal of a starting substance, composition or constituent in the European positive lists to the applicant without undue delay.

2. The Commission may also initiate the application procedure by requesting ECHA to issue an opinion on the inclusion or removal of a starting substance, composition or constituent in the European positive lists.

3. Applicants not established in the Union shall appoint a representative established in the Union.

Applicants established in the Union, other than a relevant authority, may also appoint a representative.

4. In the case of a polymer intended as a starting substance or as organic cementitious constituent in the manufacture of cementitious materials other than admixtures, the application shall be made for any of the following:

   (a) the monomer in the case of a polymer not used as an additive;

(b) the monomer or other reactant in the case of a polymer without a polymerised part below 1000 Da which is used as an additive and is not obtained from microbial fermentation;

(c) the pre-polymer, in the case of organopolysiloxanes used in the manufacture of silicones, rubbers, lubricants and surface treatment for fillers or in the case of coatings;

(d) the polymer in all other cases.

5. In the case of a polymer intended for use as organic cementitious constituent in the manufacture of admixtures, the application shall cover all the monomers included in that polymer.

6. An application from a relevant authority may cover several starting substances, compositions, organic cementitious constituents, nanoforms or entries.

An application from a person other than a relevant authority shall cover only one starting substance, composition, organic cementitious constituent or nanoform.

7. The application shall contain the information listed in the Annex.

8. Where an application concerning an existing entry in one of the European positive lists is made after the first review referred to in Article 11(4), fourth subparagraph of Directive (EU) 2020/2184 is completed, the following shall apply:

(a) by way of derogation from points (c) and (d) of the Annex, the information may be limited to a reference to the existing entry;

(b) by way of derogation from points (e) to (i) of the Annex, in relation to already submitted information which complies with Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]*, the applicant is only required to submit any new or updated information.

9. In the case of an application by a relevant authority that concerns the review of an existing entry on a European positive list and that is justified by a concern for human health, the following shall apply:

(a) by way of derogation from points (c) and (d) of the Annex, the information may be limited to a reference to the existing entry;

(b) by way of derogation from points (e) to (i) of the Annex, the applicant is only required to address the concern for human health and submit any available information relevant to that concern.

10. The information referred to in point (h) of the Annex shall be submitted in the form of a robust study summary.

The information referred to in point (e) of the Annex, shall be submitted in the form of a study summary.

The information referred to in point (f) of the Annex shall be submitted in the form of a full study report complying with reporting requirements established by the corresponding EN standard or the standard determined by ECHA in accordance with Section 1, point 1.2 of Annex IV to Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]*.

Article 4

Accordance check

1. ECHA shall assess whether the application from an applicant complies with the following:

   (a) it provides the information which is necessary and sufficient to be in accordance with Article 3(7);

   (b) it falls within the scope of Article 11(5) of Directive 2020/2184 and complies with Article 3(3) to (6).

2. Where the application does not fulfil the criterion of Article 4(1), point (a), ECHA shall notify the reasons to the applicant. The applicant shall bring its application into accordance within six months of the date of receipt of the reasons from ECHA.

   Where the application does not fulfil the criterion of Article 4(1), point (b), ECHA shall notify this conclusion to the applicant. The applicant shall provide its comment within one month of the date of receipt of the reasons from ECHA.

3. Where the application does not comply with the requirements set out in Article 4(1), the procedure shall be terminated and ECHA shall notify it to the applicant.

4. ECHA shall inform the applicant of the accordance of its application without undue delay, indicating the date of completion of the accordance check.

5. Passing the accordance check is without prejudice to the opinion of the Committee for Risk Assessment in accordance with Article 6.

6. Where an application for review of an existing entry limited to the indication of the adoption of a harmonised classification and labelling under Section 3 of Annex VI to Regulation (EC) 1272/2008 or the inclusion of a substance in the Candidate List established under Article 59 of Regulation (EC) 1907/2006 ECHA may address that application directly to the Commission upon completion of the accordance check. In such case, Articles 5 and 6 of this Regulation shall not apply.

7. Where an application under Article 3(9) for which no updated information is available, ECHA may address that application directly to the Commission upon completion of the accordance check. In such case, Article 6 shall not apply.

8. Where applications to which Annex VI, Section 1, point 3 of Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]* may apply, ECHA may address the corresponding parts of that application directly to the Committee for Risk Assessment. In such case, Article 5 shall not apply.

9. Where an application is submitted to ECHA to review an entry from one of the positive lists referred to in Article 1 of Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)237]*, that entry shall remain valid after its expiry date until the Commission decides on the application to review that entry provided that the application is submitted to ECHA no later than 18 months prior to the expiry date.

Article 5

Consultation of interested parties

Within four weeks of the publication of an application on ECHA's website, ECHA shall invite interested parties to submit scientific information.

Article 6

Consultation of the applicant and opinion

1. The Committee for Risk Assessment shall provide an opinion on the risks to human health arising from the uses of the starting substance, composition or organic cementitious constituent covered by the application for on the basis of Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]*.

   The Committee for Risk Assessment shall prepare a draft opinion taking into account any information submitted by interested parties within 10 months from the publication of the application or within 13 months from that publication in the case of a joint opinion in accordance with the below.

   The draft opinion may be a joint draft opinion covering several applications in the following cases:

   (a) where they cover the same starting substance, composition or organic cementitious constituent;

   (b) where they cover the same non-intentionally added species;

   (c) where they are based on similar toxicological information;

   (d) where they raise similar considerations, in particular in case of absence of adverse effect identified;

   (e) in any other duly justified case.

2. ECHA shall send the draft opinion of the Committee for Risk Assessment to the applicant without undue delay. ECHA shall at the same time inform the applicant of the right to comment within 30 days.

3. The Committee for Risk Assessment shall finalise its opinion taking into account the comments from the applicant on the draft opinion, if any.

4. ECHA shall forward the opinion of the Committee for Risk Assessment to the applicant and the Commission without undue delay.

5. The Commission shall without undue delay, taking into account the opinion of the Committee for Risk Assessment, decide on the application in accordance with Article 11(4) of the Directive.

CHAPTER IV

TREATMENT OF INFORMATION

Article 7

Submission of information

Any information shall be submitted to ECHA using the format and the submission tools made available for free by ECHA as well as the International Uniform Chemical Information Database for notifications of intention and applications.

Article 8

Access to information by the Committee for Risk Assessment

1. For the purpose of preparing its opinion under this Regulation, the Committee for Risk Assessment may, if it considers necessary, refer to any relevant information submitted to ECHA, the Commission, other Union bodies and agencies or Member States for the purpose of other Regulations or Directives, taking into account in particular the latest scientific and technological developments. Union bodies and agencies as well as Member States in possession of the requested information shall provide it to ECHA upon request informing it of any valid confidentiality claims with regard to the information at the same time.

2. The information referred in paragraph 1, may not be used to substitute missing standard testing or information required by Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]* in the application.

Article 9

Publication

ECHA shall publish the following without delay:

(a) the notifications of intention;

(b) the date of submission of an application;

(c) the applications which passed the accordance check;

(d) the opinions of the Committee for Risk Assessment;

(e) a notice of withdrawal of an application for a duration of 30 days;

(f) the date of termination of any application process;

(g) following the decision of the Commission on an application, a description of the analytical method described by the applicant in its application for each relevant chemical species as identified under Section 3 of Annex IV of Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2024)239]*.

Article 10

Confidentiality

1. Information submitted to ECHA shall be considered as non-confidential and may be made publicly available.

2. By way of derogation to paragraph 1, the following shall be considered confidential and may not be made publicly available:

(a) information concerning the identification of an applicant in case of a designated representative;

(b) information on the manufacturing process of a starting substance, composition or organic cementitious constituent or the manufacturing process into which it is involved;

(c) information on any link between any operators in the same supply chain;

(d) information received from another Union body, agency or a Member State, for which confidentiality has been granted by the body which has provided this information to ECHA;

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

CHAPTER V

FINAL PROVISIONS

Article 11

Change of notifier or applicant

1. The role of a notifier under Article 2 may be taken over by mutual agreement between an existing and a prospective notifier prior to the submission of the application.

2. The role of an applicant may be taken over by mutual agreement between an existing and a prospective applicant until the draft opinion is received by the applicant pursuant to Article 6(2).

3. A notification referred to in paragraphs 1 or 2 shall be submitted jointly to ECHA by the prospective and the existing notifiers or applicants.

Article 12

Withdrawal of application

In case of withdrawal of an application before the draft opinion has been received by the applicant, the withdrawal shall be notified to ECHA. The withdrawal shall take effect 60 days after the publication of the notice of withdrawal referred to in Article 9, point (e), unless a change of applicant in accordance with Article 11(3) is notified prior to the expiration of that time limit.

Article 13

Additional obligations of the applicant

1. The applicant shall cooperate with ECHA. Upon request from ECHA, the applicant shall provide a full study report for any study covered in the application. It shall also answer questions from ECHA without undue delay.

2. Within 2 months from the publication of an opinion of the Committee for Risk Assessment to include, maintain or amend an entry in one of the European positive lists, the applicant shall provide the Commission with a calibrant of its starting substance or organic cementitious constituent or a representative sample of the

accepted composition of metallic materials, enamels, ceramic or other inorganic materials .

3. After a decision of the Commission to include an entry in one of the European positive lists, the applicant shall keep available all the information it required to carry out its duties under this Regulation for a period of at least 20 years from the date on which the authorisation was removed or expired.

The applicant shall submit the information referred to in the first subparagraph or make it available without delay upon request to any relevant authority of the country in which he is established or to ECHA.

Where an applicant ceases activity, or transfers part or all of its operations to a third party, the party responsible for liquidating the applicant's undertaking or assuming responsibility for the operations concerned shall be bound by the obligations set out in paragraphs 1 and 2 in place of the applicant.

Article 14

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 31 December 2026.

However, Article 2 shall apply from 31 December 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23.1.2024

For the Commission
The President
Ursula VON DER LEYEN