



Brussels, XXX
[...] (2023) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards methodologies for testing and accepting starting substances, compositions and constituents to be included in the European positive lists

(Text with EEA relevance)

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laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards methodologies for testing and accepting starting substances, compositions and constituents to be included in the European positive lists

(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 consumption¹, and in particular Article 11(2), point (a), thereof,

Whereas:

- (1) Testing and acceptance methodologies should be established for assessing the safe use of starting substances, compositions and constituents.
- (2) Inclusion or removal of an entry in a European positive list should be based on the identification of the starting substance, composition or organic cementitious constituent and the identification of its intended use. The physico-chemical properties of the starting substance, composition or organic cementitious constituent necessary for carrying out migration testing should be established. The starting substance, composition or organic cementitious constituent should be tested for migration.
- (3) Inclusion or removal of an entry in a European positive list should be based on the identification of species that are relevant for the acceptance methodology, or risk assessment, because they may have an impact on the safe use of a material or product, such as an impurity, the constituent of a starting substance or a degradation product. These relevant species should be determined on the basis of the information on the identification of the starting substance, composition or constituent and on the basis of its intended use as well as the results of migration testing. The toxicological properties of these relevant species should also be identified.
- (4) For proportionality and efficiency reasons, testing for physico-chemical properties and toxicological properties as well as risk assessment should be more limited if a similar assessment has already been carried out at Union level within a reasonable period of time or if the substance has a stringent classification in Part 3 of Annex VI of Regulation (EU) 1272/2008 or the applicant proposes such classification. For proportionality reasons, the testing requirements for toxicological properties should be stricter where there is a high exposure to a certain substance through migration.

¹ OJ L 435, 23.12.2020, p. 1.

- (5) In order to respect the precautionary principle and in order to cover the potential for significant exposure over a long period of time, the acceptance methodology should be based on a worst-case risk assessment of each relevant species. The risk assessment should consider migration, including release, under the worst foreseeable conditions of use. In particular, the risk assessment should consider the expected long-term exposure to materials or products in contact with water intended for human consumption and, in the case of metallic compositions, the differences in the properties, such as composition and corrosivity, of all water in the Union intended for human consumption.
- (6) Economic operators and relevant authorities should be allowed sufficient time to adapt their national methodologies to the methodologies set out in this Decision. The application of this Decision should therefore be deferred.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 22(1) of Directive (EU) 2020/2184.

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purpose of this Decision, the following definitions apply:

- (1) ‘non-intentionally added species’ means either one of the following:
 - (a) an impurity of a starting substance or of an organic cementitious constituent or composition;
 - (b) a reaction product or a degradation product of a starting substance or organic cementitious constituent that forms during the processing or use of the material;
 - (c) a reaction product or a degradation product of a starting substance or organic cementitious constituent that forms in contact with water during the use of the material.
- (2) ‘nanoform’ means a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm;
- (3) ‘particle’ means a minute piece of matter with defined physical boundaries;
- (4) ‘aggregate’ means a particle comprising strongly bound or fused particles;
- (5) ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
- (6) ‘migration’ means transfer of substances from a material into water intended for human consumption.

Article 2

Testing and acceptance of starting substances, compositions and constituents

1. The methodologies referred to in Article 11(2), point (a), of Directive (EU) 2020/2184 shall apply to the following:
 - (a) starting substance for organic materials;
 - (b) organic constituent of cementitious materials;
 - (c) composition of metallic materials;
 - (d) composition of enamels, ceramic and other inorganic materials.
2. Where a polymer is intended for use in an organic material or a cementitious material, the testing and acceptance methodologies shall be applied to the monomer, pre-polymer or polymer in accordance with the rules set out in Points iv to vii of Annex I and Points iii and iv of Annex III to Decision Commission Implementing Decision (EU) .../... [OP: please fill in the reference of C(2023)7001].

Article 3

Testing methodology

1. Starting substances, compositions and organic cementitious constituents shall be identified in accordance with the requirements set out in Annex I.
2. The intended use of starting substances, compositions, constituents, as well as materials and products shall be specified in accordance with the requirements set out in Annex II.
3. The physico-chemical properties of starting substances and organic cementitious constituents shall be determined in accordance with the requirements set out in Annex III.
4. Migration into water intended for human consumption shall be determined in accordance with the requirements set out in Annex IV.
5. The relevant species shall be identified in accordance with Section 3 of Annex IV.
6. The toxicological properties of the relevant species referred to in paragraph 5 shall be determined in accordance with the requirements set out in Annex V.

Article 4

Acceptance methodology in the European positive lists

1. Starting substances, compositions and constituents shall be accepted in accordance with Annex VI on the basis of an assessment of the risks raised by the relevant species identified for the corresponding starting substance, composition or organic cementitious constituent.
2. Starting substances and organic cementitious constituents which have a biocidal function and which are subject to Regulation (EU) No 528/2012 of the European Parliament and of the Council² shall only be accepted if they belong to product-type 6 (preservatives for products during storage) as set out in Annex V to that Regulation.

Article 5

Entry into force

This Decision 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.

Done at Brussels,

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission

² 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 (OJ L 167 27.6.2012, p. 1).