

Brussels, 12 March 2024 (OR. en)

7631/24

ENV 285 SAN 151 DELACT 51

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	11 March 2024
То:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 1459 final
Subject:	COMMISSION DELEGATED DECISION of 11.3.2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down a methodology to measure microplastics in water intended for human consumption

Delegations will find attached document C(2024) 1459 final.

Encl.: C(2024) 1459 final

7631/24 am TREE.1.A



Brussels, 11.3.2024 C(2024) 1459 final

COMMISSION DELEGATED DECISION

of 11.3.2024

supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down a methodology to measure microplastics in water intended for human consumption

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 13(6) of 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 empowers the Commission to adopt delegated acts to establish a methodology to measure microplastics with a view to including them on the watch list referred to in Article 13(8) once the conditions set out under that paragraph are fulfilled.

In accordance with point (c) of Article 13(2), Member States have to monitor the substances and compounds included in the watch list.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In the context of the development of this Decision, the Commission carried out targeted consultations of stakeholders in the water sector and consulted Member State experts in meetings of the expert group on the implementation of the Drinking Water Directive. The Drinking Water Expert Group consultation took place from 30 October 2023 to 8 December 2023, where stakeholders were invited to provide written comments on this draft act.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

In accordance with Article 13(6) of Directive (EU) 2020/2184, the Commission is to determine the methodology to be used by Member States to measure microplastics in water intended for human consumption.

Relevant definitions are in the Annex of this Decision. Article 2 indicates that this Decision is addressed to Member States; it will therefore enter into force on the date of the notification to Member States. The methodology is established in the annex of this Decision.

COMMISSION DELEGATED DECISION

of 11.3.2024

supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down a methodology to measure microplastics in water intended for human consumption

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive (UE) 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 13(6) thereof,

Whereas:

- (1) It is widely acknowledged that the release of plastics into the environment and its fragmentation results in an ubiquitous presence of tiny fragments of polymers, which are insoluble in water, degrade very slowly and can be easily ingested by living organisms.
- (2) Those small plastic particles, commonly referred to as microplastics, are not only widespread in the environment, but also have been found in food and water intended for human consumption and have a potential to be ingested by humans. The potential impacts of ingested microplastics on the human health have raised concerns, however the current data on this question provides limited conclusive scientific evidence on the adverse effects of microplastics on human health, due to substantial limitations of the available information on the biological effects of, and exposure to, microplastics.
- (3) Microplastics are very heterogeneous, as they have widely variable dimensions, compositions and shape, can be composed of one or more different polymers, can contain additives and their physicochemical characteristics are influenced by their degradation history. This diversity makes the detection, identification and quantification of microplastics very complex.
- (4) As regards exposure to microplastics, it is necessary to understand better the occurrence of microplastics throughout the supply chain for water intended for human consumption, by means of quality-assured methods and harmonized reporting criteria, and to determine the concentration, shape, size and composition of the microplastics.

.

OJ L 435, 23.12.2020, p. 1, ELI: http://data.europa.eu/eli/dir/2020/2184/oj.

- (5) Article 13(6) of Directive (EU) 2020/2184 empowers the Commission to adopt a methodology to measure microplastics with a view to including them on the watch list referred to in Article 13(8) of that Directive, once the conditions set out in that provision are met. In accordance with Article 13(8), fifth subparagraph, of Directive (EU) 2020/2184, Member States are to monitor substances, which have been placed on the watch list.
- (6) The Commission reviewed published studies that reported measurement of microplastics in drinking water with the objectives to identify: (1) the methods used to separate and collect microplastics from drinking water samples; (2) the analytical techniques used to identify and quantify microplastics in the collected samples; (3) the capabilities and limitations of the analytical techniques used, and (4) the quantities, size, composition and shape of microplastics found in the collected samples, with a view to determine the most appropriate analytical technique.
- (7) The analytical techniques reported belonged to two distinct categories: (1) Infra-Red (IR) or Raman optical micro-spectroscopy methods, which can identify the type of polymer in individual particles and additionally provide information on its size and shape, and (2) Thermo-analytical methods, which can identify the polymers contained in a sample and quantify the total mass of each polymer type. In the case of IR or Raman optical micro-spectroscopy methods, identification of polymer compositions requires a comparison of particle spectra with a library of spectra from known polymers. The lowest detectable particle size which still allows polymer identification, depends on the methods (IR or Raman) and the instrument used. In the case of thermoanalytical methods, identification of polymer compositions requires a comparison of their thermal decomposition products with a library of mass spectra of pyrolysis products from known polymers. Quantification of identified polymers requires a calibration for each polymer. Thermo-analytical methods alone are unable to provide information on particle numbers, size or shape. Thermo-analytical methods have no intrinsic lower detection limit for particle size, but are limited by the minimum mass detection levels.
- (8) Reported levels of microplastics in drinking water ranged from 0,0001 to 440 particles per litre, but data from European studies are primarily in the lower concentration range. These low levels are more reliably detectable by IR or Raman optical microspectroscopy methods than by thermo-analytical methods.
- (9) Identification of polymers by the techniques listed in recital (7) requires comparison with spectral libraries of known polymers. Microplastics may be composed of a very wide range of polymers, copolymers and additives; spectral libraries cannot be guaranteed to contain all possible variants. Thus, a pragmatic approach to monitoring should be to analyse and record the presence of a smaller group of specific polymers, which are known to be commonly present in the environment and water intended for human consumption. In addition, where the analysis method positively identifies particulates of other synthetic polymers materials, they shall be recorded as well.
- (10) The Commission, after consulting with Member States, appointed experts in the field to supplement the information gathered from published studies and steer the development of the most appropriate methodology to measure the range of microplastics concentrations most likely to be expected in European drinking water.

- (11) The samples should be representative of the supply system of water intended for human consumption and, where possible, they should be collected according to standardized procedures.
- (12) In view of the limitations and difficulties in collecting data on microplastics in water intended for human consumption across the broad range of polymer types, forms and concentrations, and taking into account that monitoring of microplastics is a novel exercise and that there is an administrative and financial burden associated with the sampling, analysis and documenting of data, the methodology for measuring microplastics should be proportional, appropriate and cost-efficient.
- (13) Therefore, the methodology should allow for flexibility in the use of a variety of sampling equipment, instruments and data analysis/treatment techniques, provided that these meet certain requirements for collecting and identifying microplastic particles and fibres within a specific size range.
- (14) In view of the complex and multifaceted nature of the information obtained from the analysis of microplastics in water intended for human consumption (microplastic concentration, composition, size and shape), a pragmatic approach should be taken to reduce the level of complexity of the data, by classifying microplastics on the basis of predefined size bins, shape categories and composition categories,

HAS ADOPTED THIS DECISION:

Article 1

The methodology to measure microplastics in water intended for human consumption, as set out in the Annex, is hereby adopted.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11.3.2024

For the Commission Virginijus SINKEVIČIUS Member of the Commission