Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

CHAPTER III

EUROPEAN FOOD SAFETY AUTHORITY

SECTION 3

OPERATION

Article 29

Scientific opinions

1 The Authority shall issue a scientific opinion:

a at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;

b on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2 Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3 Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4 Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5 Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

[[F1]6 In order to apply this Article, the Commission after consulting the Authority shall adopt:

a delegated acts in accordance with Article 57a in order to supplement this Regulation by establishing the procedure to be applied by the Authority to the requests for a scientific opinion;

b implementing acts laying down the guidelines governing the scientific evaluation of substances, products or processes which are subject, under Union legislation, to a

system of prior authorisation or entry on a positive list, in particular where Union legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2).**]**

7 The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 30

Diverging scientific opinions

1 The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2 Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3 Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

4 Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 31

Scientific and technical assistance

1 The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

2 Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.

Article 32

Scientific studies

1 Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2 The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 33

Collection of data

1 The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

a food consumption and the exposure of individuals to risks related to the consumption of food;

b incidence and prevalence of biological risk;

c contaminants in food and feed;

d residues.

2 For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3 The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4 The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5 Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

a for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;

b the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.

6 The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 34

Identification of emerging risks

1 The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

2 Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.

3 The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4 The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 35

Rapid alert system

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.

Article 36

Networking of organisations operating in the fields within the Authority's mission

1 The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2 The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

[[F2]3 **[**[F1]The Commission is empowered to adopt delegated acts in accordance with Article 57a in order to supplement this Regulation by establishing the criteria for the inclusion of an institute on the list of competent organisations designated by the Member States, the

arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.**]**

Other implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the regulatory procedure referred to in Article 58(2).**]**

4 Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 178/2002 of the European Parliament and of the Council, SECTION 3.