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 1

## MISSION AND TASKS

#### Article 22

# Mission of the Authority

- 1 A European Food Safety Authority, hereinafter referred to as the 'Authority', is hereby established.
- 2 The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.
- 3 The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.
- 4 The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.
- 5 The mission of the Authority shall also include the provision of:
  - a scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;
  - b scientific opinions on other matters relating to animal health and welfare and plant health:
  - c scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.
- The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.
- The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

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, CHAPTER III. (See end of Document for details)

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

- 8 The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.
- 9 The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

#### Article 23

# Tasks of the Authority

The tasks of the Authority shall be the following:

- (a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;
- (b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;
- (c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;
- (d) to commission scientific studies necessary for the accomplishment of its mission;
- (e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;
- (f) to undertake action to identify and characterise emerging risks, in the fields within its mission;
- (g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;
- (h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;
- (i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;
- (j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;
- (k) to express independently its own conclusions and orientations on matters within its mission;
- (1) to undertake any other task assigned to it by the Commission within its mission.

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, CHAPTER III. (See end of Document for details)

#### **SECTION 2**

## **ORGANISATION**

#### Article 24

## **Bodies of the Authority**

The Authority shall comprise:

- (a) a Management Board;
- (b) an Executive Director and his staff;
- (c) an Advisory Forum;
- (d) a Scientific Committee and Scientific Panels.

### Article 25

## **Management Board**

1 The Management Board shall be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing consumers and other interests in the food chain.

The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

- 2 Members' term of office shall be four years, and may be renewed once. However, for the first mandate, this period shall be six years for half of the members.
- 3 The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.
- 4 The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.
- 5 The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

- The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.
- 7 The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

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, CHAPTER III. (See end of Document for details)

8 Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

- [F19] The financial rules applicable to the Authority shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(1)</sup> unless such departure is specifically required for the Authority's operation and the Commission has given its prior consent.]
- 10 The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

#### **Textual Amendments**

**F1** Substituted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.

## Article 26

## **Executive Director**

- The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the *Official Journal of the European Communities* and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.
- 2 The Executive Director shall be the legal representative of the Authority and shall be responsible for:
  - a the day-to-day administration of the Authority;
  - b drawing up a proposal for the Authority's work programmes in consultation with the Commission;
  - c implementing the work programmes and the decisions adopted by the Management Board;
  - d ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;
  - e ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

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, CHAPTER III. (See end of Document for details)

- [FIf the preparation of the Authority's draft statement of estimates of revenue and expenditure, and the execution of its budget;]
  - g all staff matters;
  - h developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.
- [F13] Each year, the Executive Director shall submit to the Management Board for approval:
  - a a draft general report covering all the activities of the Authority in the previous year;
  - b draft programmes of work.

The Executive Director shall, following adoption by the Management Board, forward the programmes of work to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

The Executive Director shall, following adoption by the Management Board and by 15 June, forward the Authority's general report to the European Parliament, the Council, the Commission, the Court of Auditors, the European Economic and Social Committee and the Committee of the Regions, and shall have it published.

The Executive Director shall forward annually to the budgetary authority all information relevant to the outcome of the evaluation procedures.]

<sup>F2</sup> 4																

## **Textual Amendments**

- F1 Substituted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.
- **F2** Deleted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.

#### Article 27

## **Advisory Forum**

- 1 The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.
- 2 Members of the Advisory Forum may not be members of the Management Board.
- 3 The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.

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, CHAPTER III. (See end of Document for details)

- 4 The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:
  - a avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;
  - b in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;
  - c in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);
  - d where the Authority or a Member State identifies an emerging risk.
- The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the invitation of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.
- 6 The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.
- Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.

Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

#### Article 28

## Scientific Committee and Scientific Panels

- 1 The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.
- The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.

Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.

- 3 The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.
- The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:
  - a the Panel on food additives, flavourings, processing aids and materials in contact with food;

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, CHAPTER III. (See end of Document for details)

- b the Panel on additives and products or substances used in animal feed;
- [F3c the Panel on plant protection products and their residues;]
  - d the Panel on genetically modified organisms;
  - e the Panel on dietetic products, nutrition and allergies;
  - f the Panel on biological hazards;
  - g the Panel on contaminants in the food chain;
  - h the Panel on animal health and welfare[F3;]
- [F4i the Panel on plant health.]

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 58(2).

- The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities*, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.
- 6 The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.
- 7 The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.
- 8 The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.
- 9 The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

These procedures shall relate in particular to:

- a the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;
- b the number of members in each Scientific Panel;
- the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;
- d the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;
- the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;
- f the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;
- g the possibility of organising public hearings.

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, CHAPTER III. (See end of Document for details)

#### **Textual Amendments**

- **F3** Substituted by Commission Regulation (EC) No 575/2006 of 7 April 2006 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority.
- **F4** Inserted by Commission Regulation (EC) No 575/2006 of 7 April 2006 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the 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.
- 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.
- 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.
- 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.
- The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:
  - a the procedure to be applied by the Authority to the requests referred to it;
  - b the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

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, CHAPTER III. (See end of Document for details)

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

#### 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.
- 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.
- 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.
- 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

- 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.
- 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.

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, CHAPTER III. (See end of Document for details)

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.
- 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.
- 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.
- 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

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, CHAPTER III. (See end of Document for details)

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.
- 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

- 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.
- 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.
- The 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 procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.
- 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.

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, CHAPTER III. (See end of Document for details)

#### **SECTION 4**

# INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION

#### Article 37

## **Independence**

1 The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2 The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

#### Article 38

# **Transparency**

- 1 The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:
  - a agendas and minutes of the Scientific Committee and the Scientific Panels;
  - b the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;
  - c without prejudice to Articles 39 and 41, the information on which its opinions are based;
  - d the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;
  - e the results of its scientific studies;
  - f the annual report of its activities;
  - g requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

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, CHAPTER III. (See end of Document for details)

- The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.
- 3 The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

#### Article 39

## **Confidentiality**

- 1 By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.
- Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.
- 3 The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.
- 4 The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

## Article 40

## **Communications from the Authority**

- 1 The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.
- 2 The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.
- 3 The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

4 The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

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, CHAPTER III. (See end of Document for details)

# I<sup>F1</sup>Article 41

#### Access to documents

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding access to European Parliament, Council and Commission documents (2) shall apply to documents held by the Authority.
- The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 within six months after the entry into force of Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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<sup>(3)</sup>.
- Decisions taken by the Authority pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the EC Treaty respectively.]

#### **Textual Amendments**

**F1** Substituted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.

#### Article 42

# Consumers, producers and other interested parties

The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

## **SECTION 5**

#### FINANCIAL PROVISIONS

## Article 43

# Adoption of the Authority's budget

1 The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.

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, CHAPTER III. (See end of Document for details)

- The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.
- [F13] The Executive Director shall draw up, in good time before the date referred to in paragraph 5, a draft statement of estimates of the Authority's revenue and expenditure for the following financial year and shall forward it to the Management Board, together with the establishment plan.
- 4 Revenue and expenditure shall be in balance.
- Each year the Management Board, on the basis of a draft statement of estimates of revenue and expenditure, shall produce a statement of estimates of revenue and expenditure of the Authority for the following financial year. This statement of estimates, which shall include a draft establishment plan together with the provisional work programmes, shall be forwarded by 31 March at the latest by the Management Board to the Commission and to the countries with which the Community has concluded agreements in accordance with Article 49.
- The statement of estimates shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the budgetary authority) together with the preliminary draft general budget of the European Union.
- [F57] On the basis of the statement of estimates, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.
- 8 The budgetary authority shall authorise the appropriations for the subsidy to the Authority.

The budgetary authority shall adopt the establishment plan for the Authority.

- 9 The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.
- The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of the budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.]

## **Textual Amendments**

- F1 Substituted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.
- F5 Inserted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.

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, CHAPTER III. (See end of Document for details)

# I<sup>F1</sup>Article 44

# Implementation of the Authority's budget

- 1 The Executive Director shall implement the Authority's budget.
- By 1 March at the latest following each financial year, the Authority's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the general Financial Regulation.
- 3 By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Authority's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded to the European Parliament and the Council.
- 4 On receipt of the Court of Auditors' observations on the Authority's provisional accounts under Article 129 of the general Financial Regulation, the Executive Director shall draw up the Authority's final accounts under his own responsibility and submit them to the Management Board for an opinion.
- 5 The Management Board shall deliver an opinion on the Authority's final accounts.
- The Executive Director shall, by 1 July at the latest following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.
- 7 The final accounts shall be published.
- The Executive Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.
- 9 The Executive Director shall submit to the European Parliament, at the latter's request, all information necessary for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the general Financial Regulation.
- The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.]

## **Textual Amendments**

F1 Substituted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.

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, CHAPTER III. (See end of Document for details)

#### Article 45

## Fees received by the Authority

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.

#### **SECTION 6**

#### **GENERAL PROVISIONS**

#### Article 46

# Legal personality and privileges

- 1 The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.
- 2 The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

## Article 47

## Liability

- The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.
- In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.
- 3 The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.

## Article 48

## **Staff**

1 The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.

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, CHAPTER III. (See end of Document for details)

2 In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

#### Article 49

## Participation of third countries

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.

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, CHAPTER III. (See end of Document for details)

- (1) [FIOJ L 357, 31.12.2002, p. 72; corrigendum in OJ L 2, 7.1.2003, p. 39.]
- (2) [F1OJ L 145, 31.5.2001, p. 43.]
- (**3**) [F1OJ L 245, 29.9.2003, p. 4.]

#### **Textual Amendments**

**F1** Substituted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 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.

## **Status:**

Point in time view as at 28/04/2006.

# **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, CHAPTER III.