►B REGULATION (EC)No 178/2002OF 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

(IO L 31, 1.2.2002, lch. 1)

Arna leasú le:

		Iris Oifigiúil		
		Uimh	Leathanach	Dáta
►M1	Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 (*)	L 245	4	29.9.2003
►M2	Commission Regulation (EC) No 575/2006 of 7 April 2006 (*)	L 100	3	8.4.2006
►M3	Commission Regulation (EC) No 202/2008 of 4 March 2008 (*)	L 60	17	5.3.2008
►M4	Rialachán (CE) Uimh. 596/2009 ó Pharlaimint na hEorpa agus ón gComhairle an 18 Meitheamh 2009	L 188	14	18.7.2009
►M5	Rialachán (AE) Uimh. 652/2014 ó Pharlaimint na hEorpa agus ón gComhairle an 15 Bealtaine 2014	L 189	1	27.6.2014
►M6	Commission Regulation (EU) 2017/228 of 9 February 2017 (*)	L 35	10	10.2.2017
►M7	Rialachán (AE) 2017/745 ó pharlaimint na hEorpa agus ón gComhairle an 5 Aibreán 2017	L 117	1	5.5.2017
►M8	Rialachán (AE) 2019/1243 ó Pharlaimint na hEorpa agus ón gComhairle an 20 Meitheamh 2019	L 198	241	25.7.2019
►M9	Rialachán (AE) 2019/1381 ó Pharlaimint na hEorpa agus ón gComhairle an 20 Meitheamh 2019	L 231	1	6.9.2019

(*) Níor foilsíodh an gníomh seo i nGaeilge.

▼B

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 I

SCOPE AND DEFINITIONS

Article 1

Aim and scope

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

It establishes the European Food Safety Authority.

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Article 2

Definition of 'food'

For the purposes of this Regulation, 'food' (or'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

(a) feed;

▼B

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directives 65/65/EEC ([1]) and 92/73/EEC ([2]);

(e) cosmetics within the meaning of Council Directive 76/768/EEC ([3]);

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC ([4]);

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;

(h) residues and contaminants;

▼M7

(i) feistí leighis de réir bhrí Rialachán (AE) 2017/745 ó Pharlaimint na hEorpa agus ón gComhairle ([5]).

▼B

Article 3

Other definitions

For the purposes of this Regulation:

1. ‘food law’ means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;

2. ‘food business’ means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

3. ‘food business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

4. ‘feed’ (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

([1]) OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
([2]) OJ L 297, 13.10.1992, p. 8.
([3]) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).
([4]) OJ L 359, 8.12.1989, p. 1. Directive as last amended by Directive 92/41/EEC) (OJ L 158, 11.6.1992, p. 30).
([5]) Rialachán (AE) 2017/745 ó Pharlaimint na hEorpa agus ón gComhairle an 5 Aibreán 2017 maidir le feistí leighis, agus lena leasaítear Treoir 2001/83/CE, Rialachán (CE) Uimh. 178/2002 agus Rialachán (CE) Uimh. 1223/2009 (IO L 117, 5.5.2017, lch. 1).

▼B

5. ‘feed business’ means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

6. ‘feed business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

7. ‘retail’ means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

8. ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;

9. ‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

10. ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

11. ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

12. ‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

13. ‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

14. ‘hazard’ means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

15. ‘traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

▼B

16. ‘stages of production, processing and distribution’ means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;

17. ‘primary production’ means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;

18. ‘final consumer’ means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

CHAPTER II

GENERAL FOOD LAW

Article 4

Scope

1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.

2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.

3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.

4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

SECTION 1

GENERAL PRINCIPLES OF FOOD LAW

Article 5

General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant

▼B

parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

Article 6

Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

▼M9

4. Comhlíonfaidh cumarsáid maidir le riosca na cuspóirí agus urramóidh sí na prionsabail ghinearálta a leagtar amach in Airtegail 8a agus 8b.

▼B

Article 7

Precautionary principle

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Article 8

Protection of consumers' interests

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

(a) fraudulent or deceptive practices;

(b) the adulteration of food; and

(c) any other practices which may mislead the consumer.

▼M9

ROINN 1A

CUMARSÁID MAIDIR LE RIOSCA

Airteagal 8a

Cuspóirí na cumarsáide maidir le riosca

Agus na róil atá ag measúnóirí riosca agus ag bainisteoirí riosca faoi seach á gcur san áireamh, saothrófar leis an gcumarsáid maidir le riosca na cuspóirí seo a leanas:

(a) feasacht agus tuiscint ar na saincheisteanna sonracha atá á mbreithniú a chur chun cinn, lena n-áirítear in éagsúlachtaí sa mheasúnú eolaíoch, le linn phróiseas na hanailíse riosca ina iomláine;

(b) comhsheasmhacht, trédhearcacht agus soiléireacht a áirithiú agus moltaí á ndéanamh maidir le moltaí cinntí agus bainistithe riosca;

(c) bunús fónta, lena n-áirítear, i gcás inarb iomchuí, bunús eolaíoch, a sholáthar le cinntí maidir le bainistiú riosca a thuiscint;

(d) feabhas a chur ar éifeachtacht agus ar éifeachtúlacht fhoriomlán na hanailíse riosca;

(e) tuiscint maidir le hanailís riosca a chothú i measc an phobail, lena n-áirítear tuiscint ar chúraimí agus freagrachtaí na measúnóirí riosca agus na mbainisteoirí riosca. chun muinín a mhéadú as an toradh a bheidh air;

(f) rannpháirteachas iomchuí tomhaltóirí, gnólachtaí bia agus beatha, an lucht léinn agus na bpáirtithe leasmhara eile go léir a áirithiú;

(g) malartú iomchuí trédhearcach faisnéise le páirtithe leasmhara a áirithiú i dtaca leis na rioscaí a bhaineann leis an mbiashlabhra;

(h) cur ar fáil faisnéise do thomhaltóirí maidir le straitéisí cosanta rioscaí a áirithiú; agus

(i) cur leis an gcomhrac in aghaidh scaipeadh na faisnéise bréagaí agus a bhfoinsí.

Airteagal 8b

Prionsabail ghinearálta na cumarsáide maidir le riosca

Agus na róil faoi leith atá ag measúnóirí riosca agus ag bainisteoirí riosca á gcur san áireamh, bainfear an méid seo a leanas amach leis an gcumarsáid maidir le riosca:

(a) áiritheofar go ndéantar an fhaisnéis chruinn iomchuí uile a mhalartú, go hidirghníomhach agus go tráthúil leis na páirtithe leasmhara uile, bunaithe ar thrédhearcacht, oscailteacht agus freagrúlacht;

(b) cuirfear faisnéis thrédhearcach ar fáil ag gach céim de phróiseas na hanailíse rioscaí, ó cheapadh na n-iarratas ar chomhairle eolaíoch go soláthar na hanailíse riosca agus glacadh na gcinntí maidir le bainistiú riosca, lena n-áirítear faisnéis i ndáil leis an gcaoi ar thángthas ar chinntí maidir le bainistiú riosca; agus na gnéithe a ndearnadh meas orthu;

▼M9

(c) cuirfear brath riosca na bpáirtithe leasmhara go léir san áireamh;

(d) éascófar tuiscint agus idirphlé i measc na bpáirtithe leasmhara go léir; agus

(e) beidh sí soiléir agus beidh rochtain uirthi, lena n-áirítear acu siúd nach bhfuil baint dhíreach acu leis an bpróiseas nó nach bhfuil cúlra eolaíochta acu, agus san am céanna urramófar go cuí na forálacha dlíthiúla is infheidhme maidir le rúndacht agus cosaint sonraí pearsanta.

Airteagal 8c

An plean ginearálta le haghaidh na cumarsáide maidir le riosca

1. Glacfaidh an Coimisiún, trí bhíthin gníomhartha cur chun feidhme, plean ginearálta le haghaidh na cumarsáide maidir le riosca chun na cuspóirí a leagtar amach in Airteagal 8a a bhaint amach, i gcomhréir leis na prionsabail ghinearálta a leagtar amach in Airteagal 8b. Déanfaidh an Coimisiún an plean ginearálta sin a nuashonrú, ag cur san áireamh an dul chun cinn teicniúil agus eolaíoch agus an taithí a fhaightear. Déanfar na gníomhartha cur chun feidhme sin a ghlacadh i gcomhréir leis an nós imeachta dá dtagraítear in Airteagal 58(2). Rachaidh an Coimisiún i gcomhairle leis an Údarás agus é ag ullmhú na ngníomhartha cur chun feidhme sin.

2. Leis an bplean ginearálta don chumarsáid maidir le riosca, cuirfear creat comhtháite cumarsáide maidir le riosca chun cinn a mbeidh ar na measúnóirí riosca agus na bainisteoirí riosca cloí leis ar bhealach córasach comhleanúnach, ar leibhéal an Aontais agus ar leibhéal náisiúnta araon. Déanfar an méid seo a leanas leis:

(a) sainaithneofar na príomhthosca is gá a chur san áireamh agus cineál agus leibhéal na ngníomhaíochtaí cumarsáide maidir le riosca atá de dhíth á meas;

(b) na cineálacha agus leibhéil éagsúla gníomhaíochtaí cumarsáide, agus na príomhuirlisí iomchuí agus na príomhchainéil iomchuí a bheidh le húsáid chun críocha na cumarsáide maidir le riosca a shainaithint, ag cur san áireamh na riachtanas atá ag na grúpaí a bhfuiltear ag díriú orthu;

(c) sásraí iomchuí chun comhordú agus comhoibriú a dhéanamh a bhunú, d'fhonn comhsheasmhacht na cumarsáide maidir le riosca a neartú i measc measúnóirí riosca agus bainisteoirí riosca; agus

(d) sásraí iomchuí a bhunú chun idirphlé oscailte i measc tomhaltóirí, gnólachtaí bia agus beatha, an lucht léinn, agus na páirtithe leasmhara uile eile, mar aon lena rannpháirteachas iomchuí, a áirithiú.

▼B

SECTION 2

PRINCIPLES OF TRANSPARENCY

Article 9

Public consultation

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

▼B

Article 10

Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

SECTION 3

GENERAL OBLIGATIONS OF FOOD TRADE

Article 11

Food and feed imported into the Community

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

Article 12

Food and feed exported from the Community

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.

Article 13

International standards

Without prejudice to their rights and obligations, the Community and the Member States shall:

▼B

(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;

(b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations;

(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;

(d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;

(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.

SECTION 4

GENERAL REQUIREMENTS OF FOOD LAW

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

▼B

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 15

Feed safety requirements

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

2. Feed shall be deemed to be unsafe for its intended use if it is considered to:

— have an adverse effect on human or animal health;

— make the food derived from food-producing animals unsafe for human consumption.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

▼B

Article 16

Presentation

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Article 17

Responsibilities

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

▼B

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19

Responsibilities for food: food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Article 20

Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall

▼B

be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

Article 21

Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ([1]).

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

([1]) OJ L 210, 7.8.1985, p. 29. Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

▼B

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.

6. 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.

7. 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.

▼M9

Gníomhóidh sé i ndlúthchomhar leis na comhlachtaí inniúla sna Ballstáit a dhéanann cúraimí atá cosúil le cúraimí an Údaráis, agus, i gcás inarb iomchuí, gníomhóidh sé leis na gníomhaireachtaí ábhartha de chuid an Aontais.

▼B

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;

▼B

(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;

(l) to undertake any other task assigned to it by the Commission within its mission.

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

▼M9

1. Ainmneoidh gach Ballstát comhalta agus comhalta malartach mar ionadaithe air chuig an mBord Bainistíochta. Is í an Chomhairle a cheapfaidh na comhaltaí agus na comhaltaí malartacha a ainmneofar ar an mbealach sin agus beidh cearta vótála acu.

1a. Sa bhreis ar na comhaltaí agus na comhaltaí malartacha dá dtagraítear i mír 1, beidh na daoine seo a leanas ar an mBord Bainistíochta freisin:

(a) beirt chomhaltaí agus beirt chomhaltaí malartacha a cheapfaidh an Coimisiún mar a ionadaithe, agus a mbeidh ceart vótála acu;

(b) beirt chomhaltaí a cheapfaidh Parlaimint na hEorpa, agus a mbeidh ceart vótála acu;

▼M9

(c) ceathrar comhalta agus ceathrar comhalta malartacha a mbeidh ceart vótála acu agus a dhéanfaidh ionadaíocht ar leasanna na sochaí sibhialta agus an bhiashlabhra eadhon, comhalta amháin agus comhalta malartach amháin ó eagraíochtaí tomhaltóirí, comhalta amháin agus comhalta malartach amháin ó eagraíochtaí comhshaoil neamh-rialtasacha, comhalta amháin agus comhalta malartach amháin ó eagraíochtaí feirmeoirí, agus comhalta amháin agus comhalta malartach amháin ó eagraíochtaí tionsclaíochta.

Is í an Chomhairle a cheapfaidh na comhaltaí agus na comhaltaí malartacha dá dtagraítear i bpointe (c) den chéad fhomhír i gcomhairle le Parlaimint na hEorpa ar bhonn liosta a tharraingeoidh an Coimisiún suas, agus a seoladh chuig an gComhairle. Beidh níos mó ainmneacha ar an liosta ná mar a bheidh poist le líonadh. Seolfaidh an Chomhairle an liosta a chuirfidh an Coimisiún i dtoll a chéile chuig Parlaimint na hEorpa, mar aon leis na doiciméid tagartha ábhartha. Féadfaidh Parlaimint na hEorpa, a luaithe is féidir agus laistigh de 3 mhí ón liosta sin a fháil ar a dhéanaí, a tuairimí a chur faoi bhráid na Comhairle lena mbreithniú, agus ceapfaidh an Chomhairle na comhaltaí sin ansin.

1b. Déanfar comhaltaí agus comhaltaí malartacha an Bhoird Bainistíochta a ainmniú agus a cheapadh ar bhonn a gcuid taithí agus saineolais ábhartha i réimse reachtaíocht agus bheartas an bhiashlabhra, lena n-áirítear measúnú riosca, agus áiritheofar san am céanna go mbeidh saineolas ábhartha ann laistigh den Bhord Bainistíochta in ábhair bhainistíochta, riaracháin, airgeadais agus dhlíthiúla.

2. Ceithre bliana a bheidh i dtéarma oifige na gcomhaltaí agus na gcomhaltaí malartacha agus féadfar an téarma a athnuachan. Ní fhéadfar téarma oifige na gcomhaltaí agus na gcomhaltaí malartacha dá dtagraítear i bpointe (c) den chéad fhomhír de mhír 1 a athnuachan ach aon uair amháin.

▼B

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.

▼M9

Mura bhforáiltear a mhalairt, gníomhóidh an Bord Bainistíochta trí thromlach dá chomhaltaí. Déanfaidh na comhaltaí malartacha ionadaíocht ar na comhaltaí nuair atá siad as láthair agus caithfidh siad vóta thar a gceann.

▼B

6. 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.

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.

▼B

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

▼M1

9. 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 [1] unless such departure is specifically required for the Authority's operation and the Commission has given its prior consent.

▼B

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.

Article 26

Executive Director

1. 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;

▼M1

(f) the preparation of the Authority's draft statement of estimates of revenue and expenditure, and the execution of its budget;

[1] OJ L 357, 31.12.2002, p. 72; corrigendum in OJ L 2, 7.1.2003, p. 39.

▼B

(g) all staff matters;

(h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

▼M1

3. 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.

_____

▼B

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.

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;

▼B

(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.

5. 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.

7. 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.

2. 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.

4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:

▼M6

(a) the Panel on food additives and flavourings;

▼B

(b) the Panel on additives and products or substances used in animal feed;

▼M1

(c) the Panel on plant protection products and their residues;

▼B

(d) the Panel on genetically modified organisms;

▼M6

(e) the Panel on nutrition, novel foods and food allergens;

▼B

(f) the Panel on biological hazards;

(g) the Panel on contaminants in the food chain;

(h) the Panel on animal health and welfare;

▼M2

(i) the Panel on plant health;

▼M6

(j) the Panel on food contact materials and enzymes and processing aids.

▼M8

Tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh i gcomhréir le hAirteagal 57a lena leasaítear an chéad fhomhír maidir le líon agus ainmneacha na bPainéal Eolaíoch, agus i bhfianaise an dul chun cinn eolaíoch agus theicniúil, arna iarraidh sin don Údarás.

▼M9

5. Is é an Bord Bainistíochta, ag gníomhú ar thogra ón Stiúrthóir Feidhmiúcháin, a cheapfaidh na comhaltaí sin den Choiste Eolaíoch nach comhaltaí de na Painéil Eolaíocha iad agus comhaltaí na bPainéal Eolaíoch le haghaidh téarma oifige 5 bliana is féidir a athnuachan, tar éis glao ar léiriú spéise a bheith foilsithe in *Iris Oifigiúil an Aontais Eorpaigh*, i bpríomhfhoilseacháin ábhartha eolaíocha agus ar shuíomh gréasáin an Údaráis. Foilseoidh an tÚdarás an glao ar léiriú spéise sin tar éis dó na Ballstáit a chur ar an eolas maidir leis na critéir agus na réimsí saineolais is gá.

Maidir leis na Ballstáit:

(a) foilseoidh siad na glaonna ar léiriú spéise ar shuíomhanna gréasáin a n-údarás inniúil agus a gcomhlachtaí inniúla a dhéanann cúraimí atá cosúil le cúraimí an Údaráis;

(b) cuirfidh siad na heagraíochtaí eolaíocha ábhartha atá lonnaithe ar a gcríoch ar an eolas;

(c) spreagfaidh siad iarrthóirí féideartha le cur isteach; agus

(d) glacfaidh siad aon bhearta iomchuí eile chun tacú leis an nglao ar léiriú spéise.

5a. Déanfar na comhaltaí den Choiste Eolaíoch nach comhaltaí de na Painéil Eolaíocha agus Comhaltaí na bPainéal Eolaíoch a roghnú agus a cheapadh i gcomhréir leis an nós imeachta seo a leanas:

(a) ar bhonn na n-iarratas a gheofar ar ghlao ar léiriú spéis, déanfaidh an Stiúrthóir Feidhmiúcháin dréachtliosta d'iarrthóirí oiriúnacha a tharraingt suas ar a mbeidh ar a laghad dhá oiread an líon iarrthóirí a mbeadh gá leo chun na poist ar an gCoiste Eolaíoch agus ar na

▼M9

Painéil Eolaíocha a líonadh agus seolfar an liosta chuig an mBord Bainistíochta, lena léireofar an saineolas sonrach ildisciplíneach a theastaíonn i ngach Painéal Eolaíoch;

(b) ar bhonn an dréachtliosta sin, déanfaidh an Bord Bainistíochta comhaltaí an Choiste Eolaíoch nach comhaltaí de na Painéil Eolaíocha iad agus comhaltaí na bPainéal Eolaíoch a cheapadh agus tarraingeoidh sé suas sé an painéal iarrthóirí don Choiste Eolaíoch agus do na Painéil Eolaíocha;

(c) déanfar comhaltaí an Choiste Eolaíoch nach comhaltaí de na Painéil Eolaíocha iad agus comhaltaí na bPainéal Eolaíoch a roghnú agus a cheapadh bunaithe ar na critéir seo a leanas:

(i) ardleibhéal saineolais eolaíoch;

(ii) neamhspleáchas agus easpa coinbhleacht leasa i gcomhréir le hAirteagal 37(2) agus le beartas neamhspleáchais an Údaráis agus cur chun feidhme an bheartais sin maidir le comhaltaí na bPainéal Eolaíoch;

(iii) comhlíonadh na riachtanas le haghaidh saineolas sonrach ildisciplíneach an Phainéil Eolaíoch chuig a mbeidh siad le ceapadh agus an réim teanga infheidhme;

(d) i gcás ina mbeidh an saineolas eolaíoch céanna ag iarrthóirí, áiritheoidh an Bord Bainistíochta go mbainfear an dáileadh geografach is fairsinge is féidir amach sna ceapacháin.

5b. I gcás ina sainaithníonn an tÚdarás go bhfuil saineolas sonrach ag teastáil ó Phainéal Eolaíoch amháin nó ó phainéil éagsúla, molfaidh an Stiúrthóir Feidhmiúcháin don Bhord Bainistíochta, i gcomhréir leis an nós imeachta a leagtar síos i mír 5 agus i mír 5a, comhaltaí breise den Phainéal Eolaíoch/de na Painéil Eolaíocha ábhartha a cheapadh.

5c. Glacfaidh an Bord Bainistíochta, ar bhonn togra ón Stiúrthóir Feidhmiúcháin, rialacha maidir le heagrú mionsonraithe agus am na nósanna imeachta a leagtar amach i mír 5a agus i mír 5b.

5d. Staonfaidh na Ballstáit agus fostóirí chomhaltaí an Choiste Eolaíoch agus na bPainéal Eolaíoch ó aon treoir a thabhairt do na comhaltaí sin den Choiste Eolaíoch nó den Phainéal Eolaíoch, nó do na saineolaithe seachtracha a bhíonn rannpháirteach ina gcuid meithleacha, ar treoir í nach mbeadh ag teacht le cúraimí aonair na gcomhaltaí nó na saineolaithe sin nó le cúraimí, freagrachtaí agus neamhspleáchas an Údaráis.

5e. Tacóidh an tÚdarás le tascanna an Choiste Eolaíoch agus na bPainéal Eolaíoch trína gcuid oibre a eagrú, go háirithe an obair ullmhúcháin a bheidh le déanamh ag foireann an Údaráis nó ag eagraíochtaí eolaíocha náisiúnta ainmnithe dá dtagraítear in Airteagal 36, lena náirítear an t-eagrúchán a dhéanamh chun an deis a chur ar fáil tuairimí eolaíocha a ullmhú lena bpiar-athbhreithniú ag na Painéil Eolaíocha sula nglacfaidh siad iad.

5f. Beidh uasmhéid de 21 chomhalta ar gach Painéal Eolaíoch.

5g. Beidh rochtain ag comhaltaí na bPainéal Eolaíoch ar oiliúint chuimsitheach maidir leis an measúnú riosca.

▼B

6. The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.

▼B

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;

▼M9

(b) líon na gcomhaltaí i ngach Painéal Eolaíoch ach ní níos mó ná an líon uasta dá bhforáiltear i mír 5f;

▼B

(c) 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;

(e) 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.

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

▼B

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.

▼M8

6. Chun an tAirteagal seo a chur i bhfeidhm, glacfaidh an Coimisiún, tar éis dó dul i gcomhairle leis an Údarás, na nithe seo a leanas:

(a) gníomhartha tarmligthe i gcomhréir le hAirteagal 57a chun an Rialachán seo a fhorlíonadh tríd an nós imeachta atá le cur i bhfeidhm ag an Údarás maidir le hiarrataí ar thuairim eolaíoch a bhunú;

(b) gníomhartha cur chun feidhme lena leagtar síos na treoirlínte lena rialaítear an mheastóireacht eolaíoch ar shubstaintí, táirgí nó próisis atá faoi réir, faoi reachtaíocht an Aontais, córas réamhúdarúcháin nó iontrála ar liosta dearfach, go háirithe i gcás ina bhforáiltear nó ina gceadaítear i reachtaíocht an Aontais, go bhféadfaidh iarratasóir sainchomhad a thíolacadh chun na críche sin. Déanfar na gníomhartha cur chun feidhme sin a ghlacadh i gcomhréir leis an nós imeachta dá dtagraítear in Airteagal 58(2).

▼B

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.

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.

▼B

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.

▼M9

Airteagal 32a

Comhairle réamhthíolactha

1. I gcás ina bhfuil forálacha i ndlí an Aontais maidir leis an Údarás do sholáthar aschur eolaíoch, lena n-áirítear tuairim eolaíoch, soláthróidh foireann an Údaráis comhairle, arna hiarraidh sin ag iarratasóir nó fógróir féideartha, i dtaca leis na rialacha is infheidhme agus an t-inneachar atá riachtanach don iarratas nó don fhógra, sula dtíolacfar é. Ní dochar an chomhairle sin a thabharfaidh foireann an Údaráis don mheasúnú a dhéanfaidh na Painéil Eolaíocha ina dhiaidh sin ar aon iarratas nó aon fhógraí, agus beidh sí neamhcheangailteach ina leith freisin. Ní bheidh baint ag foireann an Údaráis a chuireann an chomhairle ar fáil in aon obair ullmhúcháin eolaíoch nó teicniúil a bhaineann go díreach nó go hindíreach leis an iarratas nó leis an bhfógra is ábhar don chomhairle.

2. Foilseoidh an tÚdarás treoir ghinearálta ar a shuíomh gréasáin maidir leis na rialacha is infheidhme agus an t-inneachar atá riachtanach d'iarratais agus fógraí, lena n-áirítear i gcás inarb iomchuí treoir ghinearálta maidir le dearadh staidéir riachtanacha.

▼M9

Airteagal 32b

Fógra a thabhairt faoi staidéir

1. Bunóidh agus bainisteoidh an tÚdarás bunachar staidéar a choimisiúnaigh oibreoirí gnó nó a chuir oibreoirí gnó i gcrích chun tacú le hiarratas nó fógra a bhfuil forálacha ina leith i ndlí an Aontais maidir leis an Údarás do sholáthar aschur eolaíoch, lena n-áirítear tuairim eolaíoch.

2. Chun críocha mhír 1, tabharfaidh oibreoirí gnó fógra don Údarás gan mhoill faoi theideal agus raon feidhme an staidéir maidir le haon staidéar a dhéanfadh siad a choimisiúnú nó a chur i gcrích chun tacú le hiarratas nó fógra, chomh maith le fógra faoin saotharlann nó saoráid tástála atá i mbun an staidéir, agus dáta tosaithe agus an dáta pleanáilte críochnaithe.

3. Chun críocha mhír 1, tabharfaidh saotharlanna agus saoráidí tástála eile atá suite san Aontas fógra, gan mhoill, don Údarás faoi theideal agus faoi raon feidhme aon staidéir a choimisiúnóidh oibreoirí gnó agus a dhéanfaidh saotharlanna den sórt sin nó saoráidí tástála eile chun tacú le hiarratas nó fógra, a dháta tosaithe agus an dáta críochnaithe atá beartaithe don staidéar sin, chomh maith le hainm an oibreora gnó a choimisiúnaigh an staidéar sin.

Beidh feidhm ag an mír seo, *mutatis mutandis*, maidir le saoráidí tástála eile atá lonnaithe i dtríú tíortha a mhéid a leagtar amach i gcomhaontuithe agus socruithe ábhartha leis na tríú tíortha sin, lena n-áirítear amhail dá dtagraítear in Airteagal 49.

4. Ní mheasfar iarratas nó fógra a bheith bailí nó inghlactha, i gcás go bhfuil sé á thacú ag staidéir nár tugadh fógra fúthu roimhe sin i gcomhréir le mír 2 nó mír 3, ach amháin má chuireann an t-iarratasóir nó an fógróir foras bailí ar fáil maidir le neamh-fhógra staidéar den sórt sin.

I gcás nár tugadh fógra faoi na staidéir roimh ré i gcomhréir le mír 2 nó 3, agus i gcás nár tugadh bonn cirt bailí, féadfar iarratas nó fógra a thíolacadh an athuair, ar choinníoll go dtabharfaidh an t-iarratasóir nó an fógróir fógra don Údarás faoi na staidéir, agus, go háirithe, a dteideal agus a raon feidhme, an tsaotharlann nó an tsaoráid tástála atá i mbun na staidéar, mar aon le dátaí tosaithe agus críochnaithe beartaithe na staidéar.

Cuirfear tús le measúnú ar bhailíocht nó ar inghlacthacht an iarratais sin a cuireadh isteach athuair 6 mhí tar nó an fhógra éis fógra a thabhairt faoi na staidéir de bhun an dara fomhír roimhe.

5. Ní mheasfar iarratas nó fógra a bheith bailí nó inghlactha, i gcás nach ndéantar staidéir ar tugadh fógra fúthu roimhe sin i gcomhréir le mír 2 nó mír 3 a áireamh san iarratas nó san fhógra, ach amháin má chuireann an t-iarratasóir nó an fógróir foras bailí ar fáil maidir le neamháireamh staidéir den sórt sin.

I gcás nár tugadh fógra faoi na staidéir roimh ré i gcomhréir le mír 2 nó 3, agus i gcás nár tugadh bonn cirt bailí, agus nár áiríodh iad san iarratas nó san fhógra féadfar iarratas nó fógra a thíolacadh an athuair agus i gcás nár soláthraíodh foras bailí, féadfar iarratas nó fógra a thíolacadh an athuair, ar choinníoll go dtíolacann an t-iarratasóir nó an fógróir na staidéir uile ar tugadh fógra fúthu i gcomhréir le mír 2 agus mír 3.

▼M9

Cuirfear tús le measúnú ar bhailíocht nó ar inghlacthacht an iarratais nua nó le fógra 6 mhí tar éis na staidéir a thíolacadh de bhun na fomhíre roimhe seo.

6. I gcás ina mbraithfidh an tÚdarás, le linn a mheasúnaithe ar riosca, nach n-áirítear staidéir ar tugadh fógra fúthu i gcomhréir le mír 2 agus mír 3 go huile is go hiomlán san iarratas nó san fhógra comhfhreagrach, agus mura bhfuil foras bailí ann chuige sin, déanfar na teorainneacha ama is infheidhme lena gceanglaítear ar an Údarás a aschur eolaíoch a sholáthar a chur ar fionraí. Beidh deireadh leis an bhfionraíocht 6 mhí tar éis sonraí uile na staidéar ábhartha a thíolacadh.

7. Ní dhéanfar an fhaisnéis ar tugadh fógra fúithi a chur ar fáil don phobal ach amháin i gcás ina bhfuil iarratas comhfhreagrach faighte agus tar éis don Údarás cinneadh a dhéanamh i dtaca le nochtadh na staidéar a ghabhann leis i gcomhréir le hAirteagal 38 agus Airteagal 39 go hAirteagal 39e.

8. Leagfaidh an tÚdarás síos na socruithe praiticiúla chun forálacha an Airteagail seo a chur chun feidhme, lena n-áirítear na socruithe chun forais bhailí a iarraidh agus dhéanamh poiblí sna cásanna dá dtagraítear i mír 4, mír 5 agus mír 6. Beidh na socruithe sin i gcomhréir leis an Rialachán seo agus le dlí ábhartha eile de chuid an Aontais.

Airteagal 32c

Comhairliúchán le tríú páirtithe

1. I gcás ina ndéantar foráil i ndlí ábhartha an Aontais gur féidir ceadú nó údarú, lena n-áirítear trí bhithín fógra, a athnuachan, tabharfaidh an t-iarratasóir nó fógróir féideartha ar athnuachan fógra don Údarás faoi na staidéir atá i gceist aige a dhéanamh chun na críche sin, lena n-áirítear faisnéis maidir leis an gcaoi a ndéanfar na staidéir éagsúla chun comhlíonadh na gceanglas rialála a áirithiú. Tar éis dó an fógra staidéar sin a fháil, seolfaidh an tÚdarás comhairliúchán le páirtithe leasmhara agus leis an bpobal maidir leis na staidéir atá beartaithe i dtaca leis an athnuachan, lena n-áirítear maidir le dearadh beartaithe na staidéar. Ag cur san áireamh na nótaí tráchta ó na páirtithe leasmhara agus ón bpobal atá ábhartha maidir le measúnú riosca na hathnuachana atá beartaithe, cuirfidh an tÚdarás comhairle ar fáil maidir le hinneachar an iarratais atá beartaithe ar athnuachan nó fógra, mar aon le dearadh na staidéar. Ní dochar an chomhairle a thabharfaidh an tÚdarás don mheasúnú a dhéanfaidh na Painéil Eolaíocha ina dhiaidh sin ar an iarratas nó fógra ar athnuachan, agus beidh sí neamhcheangailteach ina leith freisin.

2. Rachaidh an tÚdarás i mbun comhairle le páirtithe leasmhara agus leis an bpobal ar bhonn an leagain neamhrúnda den iarratas nó den fhógra arna chur ar fáil don phobal ag an Údarás i gcomhréir le hAirteagal 38 go hAirteagal 39e, agus go díreach tar éis nochtadh den sórt sin chuig an bpobal, chun a shainaithint an bhfuil sonraí nó staidéir ábhartha eolaíocha eile ar fáil ar an ábhar lena mbaineann an t-iarratas nó an fógra. I gcásanna a bhfuil údar cuí leo, nuair is baol nach mbeifí in ann cuí-aird a thabhairt ar thorthaí an chomhairliúcháin phoiblí i gcomhréir leis an mír seo i ngeall ar na spriocdhátaí is infheidhme lena gceanglaítear ar an Údarás a aschur eolaíoch a sholáthar, féadfar síneadh suas le huastréimhse 7 seachtaine a chur leis na spriocdhátaí sin.

▼M9

Ní dochar an mhír seo d'oibleagáidí an Údaráis faoi Airteagal 33 agus níl feidhm aici maidir le haon fhaisnéis fhorlíontach a chuirfidh na hiarratasóirí nó na fógróirí ar fáil le linn an phróisis mheasúnaithe riosca.

3. Leagfaidh an tÚdarás síos ina rialacha inmheánacha an socrú praiticiúil leis na nósanna imeachta dá dtagraítear san Airteagal seo agus in Airteagal 32a a chur chun feidhme.

Airteagal 32d

Staidéir fíorúcháin

Gan dochar don oibleagáid ar iarratasóirí sábháilteacht ábhair arna chur faoi chóras údaraithe a léiriú, féadfaidh an Coimisiún, i gcúinsí eisceachtúla ina mbíonn conspóidí tromchúiseacha nó torthaí a thagann salach ar a chéile, iarraidh ar an Údarás staidéir eolaíocha a choimisiúnú a bhfuil sé mar chuspóir leo fianaise arna húsáid ina phróiseas measúnaithe riosca a fhíorú. Féadfaidh scóip na staidéar a choimisiúnófar a bheith níos leithne ná an fhianaise atá le fíorú.

▼B

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.

▼B

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.

▼B

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.

▼M4

3. ►M8 Tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh i gcomhréir le hAirteagal 57a chun an Rialachán seo a fhorlíonadh trí na critéir maidir le hinstitiúid a áireamh ar liosta na n-eagraíochtaí inniúla arna n-ainmniú ag na Ballstáit, na socruithe maidir leis na ceanglais cháilíochta chomhchuibhithe a leagan amach agus na rialacha airgeadais lena rialaítear aon tacaíocht airgeadais a bhunú. ◄

Tar éis don Choimisiún dul i gcomhairle leis an Údarás, leagfaidh sé síos rialacha eile cur chun feidhme maidir le cur i bhfeidhm mhír 1 agus mhír 2 i gcomhréir leis an nós imeachta dá dtagraítear in Airteagal 58(2).

▼B

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.

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

▼B

direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. 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

▼M9

1. Cuirfidh an tÚdarás a ghníomhaíochtaí i gcrích le hardleibhéal trédhearcachta. Déanfaidh sé an méid seo a leanas a phoibliú:

(a) cláir oibre, liostaí rannpháirtithe agus miontuairiscí an Bhoird Bainistíochta, an Fhóraim Chomhairligh, an Choiste Eolaíoch agus na bPainéal Eolaíoch agus a ngrúpaí oibre;

(b) a aschur eolaíoch go léir, lena n-áirítear tuairimí an Choiste Eolaíoch agus na bPainéal Eolaíoch tar éis a nglactha, tuairimí mionlaigh agus torthaí comhairliúchán a reáchtáladh le linn an phróisis measúnaithe riosca san áireamh i gcónaí;

(c) sonraí eolaíocha, staidéir agus faisnéis eile a thacaíonn le hiarratais, lena n-áirítear faisnéis fhorlíontach a sholáthróidh, chomh maith le sonraí eolaíocha agus faisnéis a thacaíonn le hiarrataí ó Pharlaimint na hEorpa, ón gCoimisiún agus ó na Ballstáit ar aschur eolaíoch, lena n-áirítear tuairimí eolaíocha, ag cur cosaint faisnéise rúnda agus cosaint sonraí pearsanta san áireamh, i gcomhréir le hAirteagal 39 go hAirteagal 39e;

(d) an fhaisnéis ar a bhfuil a aschur eolaíoch bunaithe, lena n-áirítear tuairimí eolaíocha, ag cur cosaint faisnéise rúnda agus cosaint faisnéis phearsanta sonraí pearsanta san áireamh, i gcomhréir le hAirteagal 39 go hAirteagal 39e;

(e) na dearbhuithe bliantúla maidir le leasanna arna ndéanamh ag comhaltaí an Bhoird Bainistíochta, ag an Stiúrthóir Feidhmiúcháin, agus ag comhaltaí an Fhóraim Comhairliúcháin agus an Choiste Eolaíoch, agus na bPainéal Eolaíoch chomh maith le comhaltaí a nGrúpaí Oibre, agus na dearbhuithe maidir le leasanna arna ndéanamh i dtaca le míreanna ar chláir oibre cruinnithe;

(f) a staidéir eolaíocha i gcomhréir le hAirteagal 32 agus Airteagal 32d;

(g) tuarascáil bhliantúil ar a ghníomhaíochtaí;

(h) na hiarrataí a fuarthas ó Pharlaimint na hEorpa, ón gCoimisiún nó ó Bhallstát ar thuairimí eolaíocha, a diúltaíodh nó a modhnaíodh agus réasúnú an diúltaithe nó an mhodhnaithe sin;

(i) achoimre ar an gcomhairle arna cur ar fáil ag an Údarás d'iarratasóirí féideartha le linn na céime réamhthíolactha de bhun Airteagal 32a agus Airteagal 32c.

▼M9

Déanfar faisnéis dá dtagraítear i bhfomhír 1 a chur ar fáil go poiblí gan mhoill, cé is moite d'fhaisnéis dá dtagraítear i bpointe (c) di, a mhéid a bhaineann le hiarratais, agus pointe (i) di, a chuirfear ar fáil go poiblí gan mhoill tar éis d'iarratas a mheas a bheith bailí nó inghlactha.

Déanfar an fhaisnéis dá dtagraítear sa dara fomhír a chur ar fáil don phobal ar chuid ar leith de shuíomh gréasáin an Údaráis. Beidh an chuid ar leith sin ar fáil go poiblí agus inrochtana gan stró. Beidh na nithe ábhartha ar fáil lena n-íoslódáil, lena gcur i gcló agus lena gcuardach i bhformáid leictreonach.

1a. Ní dochar nochtadh na faisnéise dá dtagraítear i bpointí (c), (d) agus (i) den chéad fhomhír de mhír 1 don phobal don mhéid seo a leanas:

(a) aon rialacha atá ann cheana maidir le cearta maoine intleachtúla lena leagtar amach teorainneacha maidir le húsáid éagsúil na ndoiciméad a nochtadh nó a bhfuil iontu; agus,

(b) aon fhorálacha a leagtar amach i ndlí an Aontais agus lena gcosnaítear an infheistíocht arna déanamh ag nuálaithe agus an fhaisnéis agus na sonraí a thacaíonn le hiarratais ábhartha ar údaruithe á mbailiú acu (“rialacha maidir le heisiachas sonraí”).

Ní mheasfar gurb ionann nochtadh na faisnéise dá dtagraítear i bpointe (c) den chéad fhomhír de mhír 1 don phobal agus cead ná ceadúnas sainráite ná intuigthe chun na sonraí ábhartha agus an fhaisnéis ábhartha agus a n-inneachar a úsáid, a atáirgeadh, nó leas a bhaint astu ar aon slí eile a sháródh aon rialacha maidir le cearta maoine intleachtúla nó maidir le heisiachas sonraí, agus ní an tAontas Eorpach freagrach as an úsáid a bhaineann tríú páirtithe aisti. Áiritheoidh an tÚdarás go dtabharfaidh na daoine a bheidh ag rochtain na faisnéise ábhartha gealltanais shoiléire nó ráitis shínithe chuige sin, roimh an nochtadh.

▼B

2. 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.

▼M9

3. Leagfaidh an tÚdarás síos na socruithe praiticiúla chun na rialacha maidir le trédhearcacht dá dtagraítear i mír 1, mír 1a agus mír 2 den Airteagal seo a chur chun feidhme, ag cur Airteagal 39 go hAirteagal 39g agus Airteagal 41 san áireamh.

Airteagal 39

Rúndacht

1. De mhaolú ar Airteagal 38, ní phoibleoidh an tÚdarás faisnéis ar iarradh go gcaithfí léi i modh rúin ar na coinníollacha a leagtar síos san Airteagal seo.

2. Arna iarraidh sin ag iarratasóir, ní fhéadfaidh an tÚdarás a cheadú go gcaithfí i modh rúin ach amháin leis na míreanna faisnéise seo a leanas atá liostaithe sa mhír seo, i gcás ina dtaispeánfaidh an t-iarratasóir go bhféadfadh nochtadh na faisnéise sin dochar nár bheag a dhéanamh dá leasanna:

(a) an próiseas monaraíochta nó táirgthe, lena n-áirítear an modh agus na gnéithe nuálacha i ndáil leis sin, chomh maith leis na sonraíochtaí teicniúla agus tionsclaíocha eile a bhaineann go dlúth leis an bpróiseas nó leis an modh sin, seachas faisnéis atá ábhartha maidir leis an tsábháilteacht a mheas;

▼M9

(b) naisc thráchtála idir táirgeoir nó allmhaireoir agus an t-iarratasóir nó sealbhóir an údaraithe, i gcás inarb infheidhme;

(c) faisnéis tráchtála lena nochtar foinsiú, sciar den mhargadh nó straitéis ghnó an iarratasóra; agus

(d) comhdhéanamh cainníochtúil ábhar na hiarrata, seachas faisnéis atá ábhartha don mheasúnú sábháilteachta.

3. Ní dochar an liosta faisnéise dá dtagraítear i mír 2 d'aon dlí earnála de chuid an Aontais.

4. D'ainneoin mhír 2 agus mhír 3:

(a) i gcás ina bhfuil gá le gníomh práinneach chun sláinte an duine, sláinte ainmhithe nó an comhshaol a chosaint, amhail cásanna éigeandála, féadfaidh an tÚdarás an fhaisnéis dá dtagraítear i míreanna 2 agus 3 a nochtadh;

(b) poibleofar, ina ainneoin sin, faisnéis atá mar chuid de chonclúidí na n-aschur eolaíoch, lena n-áirítear tuairimí eolaíocha, arna dtabhairt ag an Údarás, agus a bhaineann le héifeachtaí intuartha ar shláinte an duine, ar shláinte ainmhithe, nó ar an gcomhshaol.

Airteagal 39a

Iarraidh ar rúndacht

1. Agus iarratas á thíolacadh ina mbeidh sonraí eolaíocha tacaíochta agus faisnéis fhorlíontach eile i gcomhréir le dlí an Aontais, féadfaidh an t-iarratasóir a iarraidh go gcaithfear mar rún le codanna áirithe den fhaisnéis sin i gcomhréir le Airteagal 39(2) agus (3). Ag gabháil leis an iarraidh sin beidh réasúnú atá infhíoraithe lena léirítear conas a dhéanfar dochar suntasach do na leasanna lena mbaineann má chuirtear an fhaisnéis lena mbaineann ar fáil don phobal i gcomhréir le Airteagal 39 (2) agus (3).

2. I gcás ina ndéanfaidh iarratasóir iarraidh ar rúndacht a chur isteach, soláthrófar ann leagan neamhrúnda agus leagan rúnda den fhaisnéis arna tíolacadh i gcomhréir le formáidí caighdeánacha sonraí, i gcás inarb ann dóibh, de bhun Airteagal 39f. Ní áireofar an fhaisnéis a mheasann an t-iarratasóir a bheith rúnda san áireamh leis an leagan neamhrúnda ar bhonn Airteagal 39(2) agus (3) agus léireofar ann na háiteanna inar scriosadh faisnéis den chineál sin. Beidh an fhaisnéis go léir arna tíolacadh, lena n-áirítear an fhaisnéis a mheasfaidh an t-iarratasóir a bheith rúnda, san áireamh leis an leagan rúnda. An fhaisnéis ar iarradh go gcaithfí i modh rúin léi, beidh sí marcáilte go soiléir sa leagan rúnda. Léireoidh an t-iarratasóir go soiléir na forais ar a bhfuil rúndacht á hiarraidh i leith na bpíosaí éagsúla faisnéise.

Airteagal 39b

Cinneadh maidir le rúndacht

1. Déanfaidh an tÚdarás an méid seo a leanas:

(a) an leagan neamhrúnda den iarratas mar a thíolaic an t-iarratasóir é a chur ar fáil go poiblí gan mhoill a luaithe a mheasfar go bhfuil an t-iarratas sin bailí nó inghlactha;

▼M9

(b) dul ar aghaidh, gan mhoill, le scrúdú nithiúil aonair ar an iarraidh ar rúndacht i gcomhréir leis an Airteagal seo;

(c) é a chur in iúl don iarratasóir i scríbhinn go bhfuil sé beartaithe aige faisnéis a nochtadh agus na cúiseanna leis sin a thabhairt, sula ndéanfaidh an tÚdarás cinneadh go foirmiúil maidir leis an iarraidh ar rúndacht. Mura n-aontóidh an t-iarratasóir le measúnú an Údaráis féadfaidh an t-iarratasóir a thuairimí a chur in iúl nó a iarratas a tharraingt siar laistigh de 2 sheachtain ón dáta ar a dtabharfar fógra dó faoi sheasamh an Údaráis;

(d) cinneadh réasúnaithe a ghlacadh maidir leis an iarraidh ar rúndacht, ag cur barúlacha an iarratasóra san áireamh, laistigh de 10 seachtaine ón dáta a bhfuarthas an iarraidh ar rúndacht i leith iarratas ar údarú agus gan mhoill i gcás sonraí forlíontacha agus faisnéis fhorlíontach, fógra a thabhairt don iarratasóir faoina chinneadh faisnéis a thabhairt maidir leis an gceart atá ag an iarratasóir iarratas daingniúcháin a thíolacadh i gcomhréir le mír 2 agus fógra a thabhairt don Choimisiún agus do na Ballstáit, i gcás inarb iomchuí, faoina chinneadh sin; agus

(e) poibliú a dhéanamh ar aon sonraí breise agus ar aon fhaisnéis bhreise nár glacadh leis go raibh údar leis an iarraidh go gcaithfí léi i modh rúin, ar a luaithe 2 sheachtain tar éis fógra a thabhairt don iarratasóir faoina chinneadh, de bhun phointe (d).

2. Laistigh de choicís tar éis an fógra a fháil faoi chinneadh an Údaráis i ndáil leis an iarraidh ar rúndacht de bhun mhír 1, féadfaidh an t-iarratasóir iarratas daingniúcháin a thíolacadh lena n-iarrfar ar an Údarás a chinneadh a athbhreithniú. Beidh éifeacht fhionraitheach ag an iarratas daingniúcháin. Déanfaidh an tÚdarás forais an iarratais daingniúcháin a scrúdú agus glacfaidh sé cinneadh réasúnaithe ar an iarratas daingniúcháin sin. Tabharfaidh sé fógra don iarratasóir faoin gcinneadh sin laistigh de 3 seachtaine tar éis an t-iarratas daingniúcháin a thíolacadh agus áireoidh sé sa fógra sin faisnéis faoi na leigheasanna atá ar fáil, eadhon caingean os comhair Chúirt Bhreithiúnais an Aontais Eorpaigh (‘an Chúirt Bhreithiúnais’) in aghaidh an Údaráis de bhun mhír 3. Aon sonraí breise agus aon fhaisnéis bhreise nár ghlac an tÚdarás leis go raibh údar leis an iarraidh ar rúndacht a rinneadh ina leith, poibleoidh an tÚdarás iad ar a luaithe 2 sheachtain tar éis fógra faoin chinneadh réasúnaithe an Údaráis i ndáil leis an iarratas daingniúcháin a thabhairt don iarratasóir de bhun na míre seo.

3. D'fhéadfadh cinntí arna ndéanamh ag an Údarás de bhun an Airteagail seo a bheith faoi réir caingne os comhair na Cúirte Breithiúnais, ar na coinníollacha a leagtar síos in Airteagal 263 agus Airteagal 278 den Chonradh ar Fheidhmiú an Aontais Eorpaigh (CFAE), faoi seach.

Airteagal 39c

Athbhreithniú ar rúndacht

Sula n-eiseoidh an tÚdarás a aschur eolaíoch, lena n-áirítear tuairimí eolaíocha, déanfaidh sé athbhreithniú an féidir faisnéis ar glacadh léi roimhe mar fhaisnéis rúnda a chur ar fáil don phobal mar sin féin, i gcomhréir le pointe (b) d'Airteagal 39(4). Más amhlaidh gur féidir, leanfaidh an tÚdarás an nós imeachta a leagtar síos in Airteagal 39b, ag a mbeidh feidhm *mutatis mutandis*.

▼M9

Airteagal 39d

Oibleagáidí maidir le rúndacht

1. Nuair a iarrfar air é, déanfaidh an tÚdarás an fhaisnéis uile atá ina sheilbh a bhaineann le hiarratas nó le hiarraidh ar aschur eolaíoch ó Pharlaimint na hEorpa, ón gCoimisiún, nó ó na Ballstáit, lena n-áirítear iarraidh ar thuairim eolaíoch, a chur ar fáil don Choimisiún agus do na Ballstáit, mura dtabharfar a mhalairt le fios i ndlí sonrach de chuid an Aontais.

2. Déanfaidh an Coimisiún agus na Ballstáit na bearta is gá ionas nach gcuirfear faisnéis a gheobhaidh siad faoi dhlí an Aontais, ar iarradh go gcaithfí i modh rúin léi, ar fáil don phobal go mbeidh cinneadh déanta ag an Údarás faoin iarraidh ar rúndacht agus go mbeidh an cinneadh sin cinntitheach. Déanfaidh an Coimisiún agus na Ballstáit na bearta is gá freisin ionas nach gcuirfear ar fáil don phobal faisnéis ar thoiligh an tÚdarás go gcaithfí i modh rúin léi.

3. Má dhéanann iarratasóir, iarratas a tharraingt siar nó más rud é go bhfuil iarratas tarraingthe siar aige, urramóidh an tÚdarás, an Coimisiún agus na Ballstáit rúndacht na faisnéise mar a cheadaigh an tÚdarás í i gcomhréir le hAirteagal 39 go hAirteagal 39f. Measfar an t-iarratas a bheith tarraingthe siar ón tráth a mbeidh an iarraidh i scríbhinn chuige sin faighte ag an gcomhlacht inniúil a fuair an t-iarratas bunaidh. I gcás ina dtarraingeofar an t-iarratas siar sula mbeidh cinneadh deiridh faoin iarraidh ar rúndacht glactha ag an Údarás de bhun, i gcás inarb iomchuí, Airteagal 39b(1) nó (2), ní dhéanfaidh, an Coimisiún, na Ballstáit ná an tÚdarás an fhaisnéis a bhfuil rúndacht iarrtha ina leith a phoibliú.

4. Beidh comhaltaí an Bhoird Bainistíochta, an Stiúrthóir Feidhmiúcháin, comhaltaí an choiste eolaíoch agus na bpainéal eolaíoch chomh maith le saineolaithe seachtracha atá ag glacadh páirt ina ngrúpaí oibre, comhaltaí an Fhóraim Chomhairligh agus baill foirne an Údaráis, fiú amháin nuair a bheidh deireadh lena gcuid dualgas, faoi réir ceanglais na rúndachta gairmiúla dá bhforáiltear in Airteagal 339 CFAE.

5. Leagfaidh an tÚdarás síos, i gcomhairliúchán leis an gCoimisiún, na socruithe praiticiúla do chur chun feidhme na rialacha maidir le rúndacht a leagtar síos in Airteagal 39, Airteagal 39a, Airteagal 39b, Airteagal 39e agus san Airteagal seo, lena n-áirítear aon socruithe a bhaineann le hiarrataí ar rúndacht a chur isteach agus a láimhseáil i dtaca le faisnéis atá le cur ar fáil don phobal faoi Airteagal 38, agus ag cur Airteagal 39f agus Airteagal 39g san áireamh. I dtaca le hAirteagal 39b(2), áiritheoidh an tÚdarás go gcuirfear deighilt chuí na gcúraimí i bhfeidhm chun na hiarratais daingniúcháin a mheasúnú.

Airteagal 39e

Sonraí pearsanta a chosaint

1. Maidir le hiarrataí ar aschur eolaíoch, lena n-áirítear tuairimí eolaíocha faoi dhlí an Aontais, poibleoidh an tÚdarás an méid seo a leanas i gcónaí:

(a) ainm agus seoladh an iarratasóra;

(b) ainmneacha údair na staidéar atá foilsithe nó atá ar fáil go poiblí a thacaíonn leis na hiarrataí sin; agus

▼M9

(c) ainmneacha na rannpháirtithe agus na mbreathnóirí go léir i gcruinnithe an choiste eolaíoch agus na bpainéal eolaíoch, a meithleacha agus aon chruinnithe meithle *ad hoc* eile ar an ábhar.

2. D'ainneoin mhír 1, measfar go ndéanfaí dochar suntasach do phríobháideacht agus sláine daoine nádúrtha a bhfuil baint acu le tástáil ar ainmhithe veriteabracha nó le faisnéis thocsaineolaíoch a fháil dá nochtfaí a n-ainmneacha agus a seoltaí agus ní chuirfear ar fáil don phobal iad, murar sonrófar a mhalairt sna gníomhartha tarmligthe dá dtagraítear i Rialachán (AE) 2016/679 ([1]) agus Rialachán (AE) 2018/1725 ([2]) ó Pharlaimint na hEorpa agus ón gComhairle.

3. Beidh feidhm ag Rialachán (AE) 2016/679 agus Rialachán (AE) 2018/1725 maidir le próiseáil sonraí pearsanta a dhéanfar de bhun an Rialacháin seo. Ní úsáidfear aon sonraí pearsanta a chuirfear ar fáil don phobal de bhun Airteagal 38 den Rialachán seo agus an Airteagail seo ach amháin chun trédhearcacht an mheasúnaithe riosca faoin Rialachán seo a áirithiú agus ní dhéanfar tuilleadh próiseála orthu ar bhealach nach bhfuil ag teacht leis na críocha sin, i gcomhréir le pointe (b) d'Airteagal 5(1) de Rialachán (AE) 2016/679 agus le pointe (b) d'Airteagal 4(1) de Rialachán (AE) 2018/1725, de réir mar a bheidh.

Airteagal 39f

Formáidí caighdeánacha sonraí

1. Chun críocha phointe (c) d'Airteagal 38(1) agus chun a áirithiú go ndéanfar próiseáil éifeachtúil ar na hiarrataí a gheobhaidh an tÚdarás ar aschur eolaíoch, glacfar formáidí caighdeánacha sonraí i gcomhréir le mír 2 den Airteagal seo chun deis a thabhairt doiciméid a thíolacadh, a chuardach, a chóipeáil agus a chur i gcló, ag áirithiú, ag an am céanna, go gcomhlíonfar na ceanglais rialála a leagtar amach i ndlí an Aontais. Maidir leis na formáidí caighdeánacha sonraí sin:

(a) ní bunaithe ar chaighdeáin dilseánaigh a bheidh siad;

(b) áiritheofar leo idir-inoibritheacht, a mhéid is féidir, leis na modhanna atá ann cheana le haghaidh sonraí a chur isteach;

(c) beidh siad éasca le húsáid agus oiriúnaithe d'úsáid na bhfiontar beag agus meánmhéide.

2. Leanfar na nósanna imeachta seo a leanas chun formáidí caighdeánacha sonraí dá dtagraítear i mír 1 a ghlacadh:

([1]) Rialachán (AE) 2016/679 ó Pharlaimint na hEorpa agus ón gComhairle an 27 Aibreán 2016 maidir le daoine nádúrtha a chosaint i ndáil le sonraí pearsanta a phróiseáil agus maidir le saorghluaiseacht sonraí den sórt sin, agus lena n-aisghairtear Treoir 95/46/CE (An Rialachán Ginearálta maidir le Cosaint Sonraí) (IO L 119, 4.5.2016, lch. 1).

([2]) Rialachán (AE) 2018/1725 ó Pharlaimint na hEorpa agus ón gComhairle an 23 Deireadh Fómhair 2018 maidir le daoine nádúrtha a chosaint i ndáil le sonraí pearsanta a phróiseáil ag institiúidí, comhlachtaí, oifigí agus gníomhaireachtaí an Aontais agus maidir le saorghluaiseacht sonraí den sórt sin, agus lena n-aisghairtear Rialachán (CE) Uimh. 45/2001 agus Cinneadh Uimh. 1247/2002/CE (IO L 295, 21.11.2018, lch. 39).

▼M9

(a) tarraingeoidh an tÚdarás suas dréachtfhormáidí caighdeánacha sonraí chun críocha na nósanna imeachta éagsúla údarúcháin agus na n-iarrataí ábhartha ar aschur eolaíoch ó Pharlaimint na hEorpa, ón gCoimisiún agus ó na Ballstáit;

(b) agus na ceanglais is infheidhme sna nósanna imeachta údarúcháin éagsúla agus creataí dlíthiúla eile agus tar éis aon oiriúnuithe riachtanacha, glacfaidh an Coimisiún formáidí caighdeánacha sonraí trí bhíthin gníomhartha cur chun feidhme. Glacfar na gníomhartha cur chun feidhme sin i gcomhréir leis an nós imeachta dá dtagraítear in Airteagal 58(2);

(c) cuirfidh an tÚdarás na formáidí caighdeánacha sonraí, de réir mar a ghlacfar iad, ar fáil ar a shuíomh gréasáin;

(d) i gcás inar glacadh formáidí sonraí caighdeánacha de bhun an Airteagail seo, ní dhéanfar iarratais ná iarrataí ar aschur eolaíoch, lena n-áirítear tuairimí eolaíocha, ó Pharlaimint na hEorpa, ón gCoimisiún agus ó na Ballstáit a thíolacadh ach amháin i gcomhréir leis na formáidí caighdeánacha sonraí sin.

Airteagal 39g

Córais faisnéise

Beidh na córais faisnéise a bheidh i bhfeidhm ag an Údarás lena shonraí a stóráil, lena n-áirítear sonraí rúnda agus pearsanta, ceaptha ar bhealach ina dtabharfar ráthaíocht go mbeidh aon rochtain air iomlán in-iniúchta agus go mbainfear amach na caighdeáin is airde slándála atá oiriúnach do na rioscaí slándála atá i gceist, ag cur Airteagal 39 go hAirteagal 39f san áireamh.

▼B

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.

▼M9

Poibleoidh an tÚdarás gach aschur eolaíoch lena n-áirítear na tuairimí eolaíocha arna n-eisiúint aige agus sonraí eolaíocha tacaíochta agus faisnéis eile i gcomhréir le hAirteagal 38 go hAirteagal 39e.

▼B

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.

▼M1

Article 41

Access to documents

▼M9

1. D'ainneoin na rialacha maidir le rúndacht dá bhforáiltear in Airteagal 39 go hAirteagal 39d den Rialachán seo, beidh feidhm ag Rialachán (CE) Uimh. 1049/2001 ó Pharlaimint na hEorpa agus ón gComhairle [1] maidir le doiciméid atá i seilbh an Údaráis.

Maidir le faisnéis ar an gcomhshaol, beidh feidhm freisin ag Rialachán (CE) Uimh. 1367/2006 ó Pharlaimint na hEorpa agus ón gComhairle [2]. Beidh feidhm ag Treoir 2003/4/CE ó Pharlaimint na hEorpa agus ón gComhairle [3] maidir le faisnéis chomhshaoil atá ag na Ballstáit, d'ainneoin na rialacha maidir le rúndacht ghairmiúil dá bhforáiltear de bhun Airteagal 39 go hAirteagal 39d.den Rialachán seo.

2. Glacfaidh an Bord Bainistíochta leis na socruithe praiticiúla chun Rialachán (CE) Uimh. 1049/2001 a chur chun feidhme chomh maith le hAirteagal 6 agus Airteagal 7 de Rialachán (CE) Uimh. 1367/2006, faoin 27 Márta 2020, lena n-áiritheofar go mbeidh rochtain chomh forleathan agus is féidir ar dhoiciméid atá ina sheilbh.

▼M1

3. 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.

▼B

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.

([1]) Rialachán (CE) Uimh. 1049/2001 ó Pharlaimint na hEorpa agus ón gComhairle an 30 Bealtaine 2001 maidir le rochtain phoiblí ar dhoiciméid de chuid Pharlaimint na hEorpa, na Comhairle agus an Choimisiúin (IO L 145, 31.5.2001, lch. 43).

([2]) Rialachán (CE) Uimh. 1367/2006 ó Pharlaimint na hEorpa agus ón gComhairle an 6 Meán Fómhair 2006 maidir le forálacha Choinbhinsiún Aarhus maidir le Rochtain ar Fhaisnéis, Rannpháirtíocht Phoiblí i gCinnteoireacht agus Rochtain ar Cheartas i gCúrsaí Comhshaoil a chur i bhfeidhm ar institiúidí agus ar chomhlachtaí Comhphobail (IO L 264, 25.9.2006, lch. 13).

([3]) Treoir 2003/4/CE ó Pharlaimint na hEorpa agus ón gComhairle an 28 Eanáir 2003 maidir le rochtain ag an bpobal ar fhaisnéis chomhshaoil agus lena n-aisghairtear Treoir 90/313/CEE ón gComhairle (IO L 41, 14.2.2003, lch. 26).

▼B

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.

2. 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.

▼M1

3. 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.

5. 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.

6. 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.

7. 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.

10. 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

▼M1

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.

Article 44

Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.

2. 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.

6. 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.

8. 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.

10. 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.

▼B

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

▼B

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

1. 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.

2. 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.

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.

▼B

CHAPTER IV

RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES

SECTION 1

RAPID ALERT SYSTEM

Article 50

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;

(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;

(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

▼B

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Article 51

Implementing measures

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

Article 52

Confidentiality rules for the rapid alert system

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.

However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

▼B

SECTION 2

EMERGENCIES

Article 53

Emergency measures for food and feed of Community origin or imported from a third country

1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

(a) in the case of food or feed of Community origin:

(i) suspension of the placing on the market or use of the food in question;

(ii) suspension of the placing on the market or use of the feed in question;

(iii) laying down special conditions for the food or feed in question;

(iv) any other appropriate interim measure;

(b) in the case of food or feed imported from a third country:

(i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit;

(ii) laying down special conditions for the food or feed in question from all or part of the third country concerned;

(iii) any other appropriate interim measure.

2. However, in eMERGENCIES, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.

Article 54

Other emergency measures

1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

▼B

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.

SECTION 3

CRISIS MANAGEMENT

Article 55

General plan for crisis management

1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as'the general plan').

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

Article 56

Crisis unit

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.

Article 57

Tasks of the crisis unit

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.

2. The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.

3. The crisis unit shall keep the public informed of the risks involved and the measures taken.

▼B

CHAPTER V

PROCEDURES AND FINAL PROVISIONS

▼M8

ROINN 1

AN TARMLIGEAN A FHEIDHMIÚ, NÓSANNA IMEACHTA COISTE AGUS IDIRGHABHÁLA

Airteagal 57a

An tarmligean a fheidhmiú

1. Is faoi réir na gcoinníollacha a leagtar síos san Airteagal seo a thugtar an chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh.

2. Tabharfar na cumhachtaí chun gníomhartha tarmligthe dá dtagraítear in Airteagal 28(4), Airteagal 29(6) agus Airteagal 36(3) a ghlacadh don Choimisiún go ceann tréimhse 5 bliana ón 26 Iúil 2019. Déanfaidh an Coimisiún, tráth nach déanaí ná 9 mí roimh dheireadh na tréimhse 5 bliana, tuarascáil a tharraingt suas maidir le tarmligean na cumhachta. Déanfar tarmligean na cumhachta a fhadú go hintuigthe go ceann tréimhsí comhfhaid, mura rud é go gcuireann Parlaimint na hEorpa nó an Chomhairle in aghaidh an fhadaithe sin tráth nach déanaí ná 3 mhí roimh dheireadh gach tréimhse.

3. Féadfaidh Parlaimint na hEorpa nó an Chomhairle tarmligean na cumhachta dá dtagraítear in Airteagal 28(4), in Airteagal 29(6) agus in Airteagal 36(3) a chúlghairm aon tráth. Déanfaidh cinneadh chun cúlghairm a dhéanamh deireadh a chur le tarmligean na cumhachta atá sonraithe sa chinneadh sin. Gabhfaidh éifeacht leis an lá tar éis fhoilsiú an chinnidh in *Iris Oifigiúil an Aontais Eorpaigh* nó ar dháta is déanaí a shonrófar sa chinneadh. Ní dhéanfaidh sé difear do bhailíocht aon ghníomhartha tarmligthe atá i bhfeidhm cheana.

4. Roimh dó gníomh tarmligthe a ghlacadh, rachaidh an Coimisiún i mbun comhairliúchán le saineolaithe arna n-ainmniú ag gach Ballstát i gcomhréir leis na prionsabail a leagtar síos i gComhaontú Idirinstitiúideach an 13 Aibreán 2016 maidir le Reachtóireacht Níos Fearr ([1]).

5. A luaithe a ghlacfaidh sé gníomh tarmligthe, tabharfaidh an Coimisiún fógra, an tráth céanna, do Pharlaimint na hEorpa agus don Chomhairle faoi.

6. Ní thiocfaidh gníomh tarmligthe a ghlactar de bhun Airteagal 28(4), Airteagal 29(6) agus Airteagal 36(3) i bhfeidhm ach amháin mura mbeidh aon agóid curtha in iúl ag Parlaimint na hEorpa ná ag an gComhairle laistigh de thréimhse 2 mhí tar éis fógra faoin ngníomh sin a thabhairt do Pharlaimint na hEorpa agus don Chomhairle nó más rud é, roimh dhul in éag na tréimhse sin, go mbeidh Parlaimint na hEorpa agus an Chomhairle araon tar éis a chur in iúl don Choimisiún nach ndéanfaidh siad aon agóid. Déanfar an tréimhse sin a fhadú 2 mhí ar thionscnamh Pharlaimint na hEorpa nó na Comhairle.

([1]) IO L 123, 12.5.2016, lch. 1.

▼B

Article 58

Committee

▼M5

1. Beidh de chúnamh ag an gCoimisiún an Buanchoiste um Plandaí, Ainmhithe, Bia agus Beatha, dá ngairtear an "Coiste" anseo feasta. Beidh an Coiste sin ina choiste de réir bhrí Rialachán (AE) Uimh. 182/2011 ó Pharlaimint na hEorpa agus ón gComhairle ([1]). Eagrófar an Coiste i rannóga chun déileáil leis na nithe ábhartha go léir.

Déanfar gach tagairt i ndlí an Aontais don Bhuanchoiste um an mBiashlabhra agus um Shláinte Ainmhithe a fhorléiriú mar thagairtí don Choiste dá dtagraítear in Airteagal 58(1) de Rialachán (CA) Uimh. 178/2002.

▼M4

2. I gcás ina ndéantar tagairt don mhír seo, beidh feidhm ag Airteagal 5 agus ag Airteagal 7 de Chinneadh 1999/468/CE, ag féachaint d'fhorálacha Airteagal 8 de.

Trí mhí a bheidh sa tréimhse a leagtar síos in Airteagal 5(6) de Chinneadh 1999/468/CE.

▼M8

_____

▼B

Article 59

Functions assigned to the Committee

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.

Article 60

Mediation procedure

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

([1]) Rialachán (AE) Uimh. 182/2011 ó Pharlaimint na hEorpa agus ón gComhairle an 16 Feabhra 2011 lena leagtar síos na rialacha agus na prionsabail ghinearálta a bhaineann leis na sásraí maidir le rialú ag na Ballstáit ar fheidhmiú cumhachtaí cur chun feidhme ag an gCoimisiún (IO L 55, 28.2.2011, lch. 13).

▼B

SECTION 2

FINAL PROVISIONS

▼M9

Airteagal 61

Clásal athbhreithniúcháin

1. Áiritheoidh an Coimisiún go ndéanfar cur i bhfeidhm an Rialacháin seo a athbhreithniú go rialta.

2. Faoin 28 Márta 2026, agus gach 5 bliana ina dhiaidh sin, déanfaidh an Coimisiún meastóireacht ar fheidhmíocht an Údaráis a mheas i dtaca lena chuspóirí, lena shainordú, lena thascanna, lena nósanna imeachta agus lena shuíomh i gcomhréir le treoirlínte an Choimisiúin. Cumhdófar freisin sa mheastóireacht sin tionchar Airteagal 32a ar fheidhmiú an Údaráis agus aird ar leith á tabhairt ar ualach oibre agus imscaradh ábhartha na foirne, aon athrú i leithdháileadh acmhainní an Údaráis a d'fhéadfadh tarlú chun dochair do ghníomhaíochtaí leas an phobail. Sa mheastóireacht sin, féachfar ar an ngá féideartha le sainordú an Údaráis a mhodhnú, agus féachfar ar na himpleachtaí airgeadais a bheadh ag aon mhodhnú den sórt sin.

3. Sa mheastóireacht dá dtagraítear i mír 2, déanfaidh an Coimisiún meastóireacht go háirithe ar gá creat eagraíochtúil an Údaráis a nuashonrú a thuilleadh i ndáil le cinntí maidir le hiarrataí rúndachta agus iarratais daingniúcháin, eadhon trí Bhord Achomhairc sonrach a bhunú nó trí mhodh iomchuí eile.

4. I gcás ina measfaidh an Coimisiún nach bhfuil údar a thuilleadh leis an Údarás leanúint de shaothrú na gcuspóirí, an tsainordaithe agus na gcúraimí atá sannta dó, féadfaidh sé a mholadh forálacha ábhartha an Rialacháin seo a leasú dá réir nó a aisghairm.

5. Déanfaidh an Coimisiún torthaí a athbhreithnithe agus a mheastóireachtaí faoin Airteagal seo a chur faoi bhráid Pharlaimint na hEorpa, na Comhairle agus an bhoird bainistíochta. Cuirfear na torthaí sin ar fáil don phobal.

Airteagal 61a

Misin aimsithe fíricí

Rachaidh saineolaithe an Choimisiúin i mbun misin aimsithe fíricí sna Ballstáit chun measúnú a dhéanamh ar chur i bhfeidhm na gcaighdeáin ábhartha, i saotharlanna agus saoráidí tástála eile, lena ndéantar tástálacha agus staidéir a chuirtear faoi bhráid an Údaráis agus iarratas á dhéanamh, chomh maith le comhlíonadh an cheanglais fógartha a leagtar amach in Airteagal 32b(3), faoin 28 Márta 2025. Faoin dáta sin, rachaidh saineolaithe an Choimisiúin i mbun misin aimsithe fíricí chun measúnú a dhéanamh ar an gcaoi a gcuireann saotharlanna agus saoráidí eile tástála i dtríú tíortha na caighdeáin sin i bhfeidhm a mhéid a leagtar amach iad i gcomhaontuithe agus socruithe ábhartha leis na tríú tíortha sin, lena n-áirítear amhail dá dtagraítear in Airteagal 49.

▼M9

Neamh-chomhlíonadh a shainaithnítear le linn na misean aimsithe fíricí, tarraingeofar aird na saotharlanna agus na saoráidí tástála eile ar a ndearnadh measúnú air, agus tarraingeofar aird an Choimisiúin, na mBallstát agus an Údaráis air freisin. Áiritheoidh an Coimisiún, an tÚdarás agus na Ballstáit go ndéanfar obair leantach chuí ar neamh-chomhlíonadh den sórt sin a sainaithníodh.

Cuirfear toradh na misean aimsithe fíricí sin i láthair i dtuarascáil forléargais. Ar bhonn na tuarascála sin tíolacfaidh an Coimisiún togra reachtach, más iomchuí, go háirithe maidir le haon nósanna imeachta rialaithe atá riachtanach, lena n-áirítear iniúchtaí.

▼B

Article 62

References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community Regulations, Directives and Decisions.

4. Decisions 68/361/EEC, 69/414/EEC and 70/372/EEC are hereby repealed.

Article 63

Competence of the European Agency for the Evaluation of Medicinal Products

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC ([1]) and Council Directive 81/851/EEC ([2]).

([1]) OJ L 147, 9.6.1975, p. 13. Directive amended by Directive 2001/83/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 67).
([2]) OJ L 317, 6.11.1981, p. 1. Directive amended by Directive 2001/82/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 1).

▼B

Article 64

Commencement of the Authority's operation

The Authority shall commence its operations on 1 January 2002.

Article 65

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.

Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the 'C' series of the Official Journal.

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