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INFORMATION NOTE

From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods]

- Outcome of the European Parliament's proceedings
(Strasbourg, 10 to 13 December 2018)

I. INTRODUCTION

The rapporteur, Renate SOMMER (EPP, DE), presented a report consisting of 130 amendments (amendments 1-104 and 106-131) to the proposal for a Regulation on behalf of the Committee on the Environment, Public Health and Food Safety.

In addition, the EPP political group tabled 26 amendments (amendments 132-157) and the Greens/GUE group tabled 13 amendments (amendments 158-170).

II. VOTE

When it voted on 11 December 2018, the plenary adopted amendments 1-5, 7-20, 22-68, 70-80, 82-94, 96-99, 101-104, 106-117, 119-124, 126-131, 140, 158-159, 161, 163, 167 and 170 to the proposal for a Regulation. The amendments adopted are set out in the annex.

At the end of the vote, the rapporteur advised against referring the report back to the Committee, asked for her name to be withdrawn from the report and resigned as rapporteur. However, upon request of the S&D group, the proposal was referred back to the Committee, pursuant to Rule 59(4)(4) of the European Parliament's Rules of Procedure, thereby not bringing the Parliament's first reading to a close and opening the negotiations with the Council.

Transparency and sustainability of the EU risk assessment in the food chain *****I**

Amendments adopted by the European Parliament on 11 December 2018 on the proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods] (COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))¹

(Ordinary legislative procedure: first reading)

Amendment 1

Proposal for a regulation **Citation 1**

Draft legislative resolution

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, **and** 168(4)(b) thereof,

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(b) **and 192(1)** thereof,

Amendment 2

Proposal for a regulation **Recital 2 a (new)**

Text proposed by the Commission

Amendment

(2a) Risk management, assessment and communication activities should be based

¹ The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A8-0417/2018).

on a thorough application of, inter alia, the precautionary principle.

Amendment 3

Proposal for a regulation

Recital 4

Text proposed by the Commission

(4) It is therefore necessary to ensure a **comprehensive and** continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should **be combined with an** open dialogue between all interested parties to ensure **the coherence and** consistency within the risk analysis process.

Amendment

(4) It is therefore necessary to ensure a **transparent, independent, continuous and inclusive** risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should **regain citizens' trust that the whole process is underpinned by the objective of this Regulation, which is to ensure high level of human life and health and the protection of consumers' interests. That process should also be capable of contributing to a participatory and** open dialogue between all interested parties, **particularly the public,** to ensure **prevalence of public interest only, accuracy, comprehensiveness, transparency, consistency, and accountability** within the risk analysis process.

Amendment 4

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) On signing trade agreements, the Union needs to ensure that the food

legislation of third-country partners is at least as protective of food safety as Union law, so as to guarantee consumer safety and prevent unfair competition with European products.

Amendment 5

Proposal for a regulation Recital 5

Text proposed by the Commission

(5) Particular emphasis should be placed on explaining in *a coherent, appropriate* and timely manner not only risk assessment findings themselves but also how these are utilized to help inform risk management decisions along with other legitimate factors, where relevant.

Amendment

(5) Particular emphasis should be placed on explaining in *an accurate, clear, objective* and timely manner not only risk assessment findings themselves but also how these are utilized to help inform risk management decisions along with other legitimate factors, where relevant.

Amendment 7

Proposal for a regulation Recital 6

Text proposed by the Commission

(6) To this effect, it is necessary to establish general objectives and principles of risk communication, *taking into account* the respective roles of risk assessors and managers.

Amendment

(6) To this effect, it is necessary to establish general objectives and principles of risk communication. *In this connection*, the respective roles of risk assessors and managers *should be taken into account, while guaranteeing their independence.*

Amendment 8

Proposal for a regulation Recital 8

Text proposed by the Commission

(8) The general plan should identify the key factors to be taken into account when risk communications' activities are considered, such as the different levels of risk, the nature of the risk and its potential public health impact, who and what are directly or indirectly affected by the risk, the levels of risk exposure, the ability to control risk and other factors that influence risk perception including the level of urgency as well as the applicable legislative framework and relevant market context. The general plan should also identify the tools and channels to be used and should establish appropriate mechanisms to ensure coherent risk communication.

Amendment

(8) The general plan ***should lay down the practical arrangements for making available to the public the necessary information to achieve a high level of transparency in the risk management process.*** It should identify the key factors to be taken into account when risk communications' activities are considered, such as the different levels of risk, the nature of the risk and its potential ***impact on public health, animal health and the environment,*** who and what are directly or indirectly affected by the risk, the levels of risk exposure, the ability to ***minimise or*** control risk and other factors that influence risk perception including the level of urgency as well as the applicable legislative framework and relevant market context. The general plan should also identify the tools and channels to be used and should establish appropriate mechanisms to ensure coherent risk communication.

Amendment 9

Proposal for a regulation

Recital 9

Text proposed by the Commission

(9) Transparency of the risk assessment process ***contributes*** to the Authority acquiring greater legitimacy in the eyes of the consumers and general public in pursuing its mission, increases their confidence in its work and ensures that the Authority is more accountable to the Union citizens in a democratic system. It is therefore essential to ***maintain*** the confidence of the general public and other interested parties in the risk analysis

Amendment

(9) ***Improving*** transparency of the risk assessment process ***would contribute*** to the Authority acquiring greater legitimacy in the eyes of the consumers and general public in pursuing its mission, increase their confidence in its work and ensure that the Authority is more accountable to the Union citizens in a democratic system. It is therefore essential to ***rebuild*** the confidence of the general public and other interested parties in the risk analysis

process underpinning Union food law and in particular in the risk assessment, including the organisation and independence of the Authority and transparency.

process underpinning Union food law and in particular in the risk assessment, including the organisation, **functioning** and independence of the Authority and transparency.

Amendment 10

Proposal for a regulation Recital 10

Text proposed by the Commission

(10) It is appropriate to align the composition of the Management Board of the Authority to the Common Approach on decentralised agencies, in accordance with the Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies of 2012²².

²² https://europa.eu/european-union/sites/europa.eu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

Amendment

deleted

Amendment 11

Proposal for a regulation Recital 11

Text proposed by the Commission

(11) Experience shows that the role of the Management Board of the Authority is focussed on administrative and financial aspects and does not impact on the independence of the scientific work performed by the Authority. It is thus appropriate to include representatives of all Member States in the Management Board

Amendment

(11) Experience shows that the role of the Management Board of the Authority is focussed on administrative and financial aspects and does not impact on the independence of the scientific work performed by the Authority. It is thus appropriate to include representatives of all Member States, **the Commission, the**

of the Authority, while providing that those representatives should have experience in particular on risk assessment.

European Parliament, as well as civil society and industry associations in the Management Board of the Authority, while providing that those representatives should have experience in particular on risk assessment ***and that any conflict of interest is avoided.***

Amendment 12

Proposal for a regulation

Recital 12

Text proposed by the Commission

(12) The Management Board should be selected in such a way as to secure the highest standards of competence and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

Amendment

(12) The Management Board should be selected in such a way as to secure the highest standards of competence ***and commitment to the protection of health and the environment*** and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

Amendment 13

Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) The Fitness Check of the General Food Law identified certain shortcomings in the long-term ***capability*** of the Authority to maintain its high-level expertise. ***In particular***, there has been a decrease in the number of candidates applying to be members of the Scientific Panels. The system has thus to be strengthened ***and*** Member States should ***take a more active role*** to ensure that a sufficient pool of experts is available ***to meet the needs of the Union risk assessment system in terms***

Amendment

(13) The Fitness Check of the General Food Law identified certain shortcomings in the long-term ***capacity*** of the Authority to maintain its high-level expertise ***through expert personnel. Moreover***, there has been a decrease in the number of candidates applying to be members of the Scientific Panels, ***and the reason for this decline should be examined. Six Member States provide two thirds of the experts on the scientific panels. As the United Kingdom currently provides***

of high level of scientific expertise, independence and multidisciplinary expertise.

approximately 20% of the national experts, the problem will be further exacerbated with the withdrawal of the United Kingdom from the Union. In order to tackle this phenomenon more effectively, the system has thus to be strengthened and promoted, must encourage candidates to apply and Member States should support the dissemination of the Authority's calls for expressions of interest for membership of the Scientific Panels and Scientific Committee, to ensure that a sufficient pool of independent experts is available, by undertaking support actions and using incentives and rewards to increase the level of participation and the degree of interest in seeking to engage in it.

Amendment 14

Proposal for a regulation Recital 14

Text proposed by the Commission

(14) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels **by the Member States**, their selection by the Executive Director of the Authority and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to defend EFSA's interests and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures should also be put in place to ensure that scientific experts have the

Amendment

(14) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels, their selection by the Executive Director of the Authority and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director, **who is the legal representative of the Authority and** whose function is to defend EFSA's interests **and to monitor its performance** and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures, **including proper financial**

means to act independently.

compensation, should also be put in place to ensure that scientific experts have the means to act independently *and to dedicate sufficient time to their risk assessment work for the Authority*.

Amendment 15

Proposal for a regulation Recital 15

Text proposed by the Commission

(15) It is essential to ensure the efficient operation of the Authority and to improve the sustainability of its expertise. It is therefore necessary to strengthen the support provided by the Authority and the Member States to the work of the Authority's Scientific Panels. In particular, the Authority should organise the preparatory work supporting the Panels' tasks, including by requesting the Authority's staff or national scientific organisations networking with the Authority to draft preparatory scientific opinions to be peer-reviewed and adopted by the Panels.

Amendment

(15) It is essential to ensure the efficient operation of the Authority and to improve the sustainability of its expertise. It is therefore necessary to strengthen the support provided by the Authority and the Member States to the work of the Authority's Scientific Panels. In particular, the Authority should organise the preparatory work supporting the Panels' tasks, including by requesting the Authority's staff or national scientific organisations networking with the Authority to draft preparatory scientific opinions to be peer-reviewed and adopted by the Panels. *This should be without prejudice to the independence of the Authority's scientific assessments.*

Amendment 16

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This

Amendment

(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This

principle is based on the premise that public health *is* better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.

principle is based on the premise that public health ***and the environment are*** better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.

Amendment 17

Proposal for a regulation Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) A comparison of Union agencies shows that the Authority needs up to 55 months for an authorisation procedure or five times longer than the European Medicines Agency (EMA). This discourages firms from investing in innovative products and reduces Union's competitiveness in the long run. In addition, long authorisation procedures weaken confidence in the Authority. It is therefore urgently advisable to ensure the efficiency of the risk assessment by means of better human and financial resources.

Amendment 18

Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) Provisions exist on the content of applications for authorisations. It is essential that the application for authorisation submitted to the Authority for its risk assessment meets the applicable specifications to ensure the best quality scientific assessment by the Authority. Applicants and in particular small- and medium-sized enterprises do not always have a clear understanding of these specifications. It should be thus appropriate that the Authority provides advice to a potential applicant, upon request, on the applicable rules and the required content of an application for authorisation, before an application is formally submitted, ***while not entering into the design of the studies to be submitted that remain the applicant's responsibility. To ensure the transparency of this process, the advice of the Authority should be made public.***

Amendment

(17) Provisions exist on the content of applications for authorisations. It is essential that the application for authorisation submitted to the Authority for its risk assessment meets the applicable specifications to ensure the best quality scientific assessment by the Authority. Applicants and in particular small- and medium-sized enterprises do not always have a clear understanding of these specifications. It should be thus appropriate that the Authority provides advice to a potential applicant, upon request, on the applicable rules and the required content of an application for authorisation, before an application is formally submitted. ***By ... [36 months after the entry into force of this amending Regulation], the Commission should evaluate the impact of the general advice provided on the functioning of the Authority. In particular, the Commission should evaluate its impact on the allocation of the Authority's resources and on its independence.***

Amendment 19

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The Authority should have knowledge of the subject matter of all studies performed by an applicant with a view to a future application for an authorisation under Union food law. To this end, it is necessary and appropriate that business operators commissioning the studies and laboratories carrying them out

Amendment

(18) The Authority should have knowledge of the subject matter of all studies performed by an applicant with a view to a future application for an authorisation ***or renewal*** under Union food law. To this end, it is necessary and appropriate that business operators commissioning the studies and laboratories

notify those studies to the Authority when commissioned. Information about the notified studies should be made public only once a corresponding application for authorisation has been made public in accordance with the applicable rules on transparency.

carrying them out notify those studies to the Authority when commissioned ***in the Union or beyond***. Information about the notified studies should be made public only once a corresponding application for authorisation ***or renewal*** has been made public in accordance with the applicable rules on transparency.

Amendment 20

Proposal for a regulation Recital 20

Text proposed by the Commission

(20) There are certain public concerns about the Authority's assessment in the area of authorisation being primarily based on industry studies. The Authority ***already makes*** searches in scientific literature to be able to consider other data and studies existing on the subject matter submitted to its assessment. In order to provide an additional level of guarantee ensuring that the Authority can have access to all relevant scientific data and studies available on a subject matter of an authorisation procedure, it is appropriate to provide for a consultation of third parties in order to identify whether other relevant scientific data or studies are available. To increase the effectiveness of the consultation, the consultation should take place ***when*** the studies submitted by industry included in an application for authorisation ***are*** made public, under the transparency rules of this Regulation.

Amendment

(20) There are certain public concerns about the Authority's assessment in the area of authorisation being primarily based on industry studies. ***In the case of a new application for an authorisation or a renewal procedure, the Authority should always conduct*** searches in scientific literature to be able to consider other data and studies existing on the subject matter submitted to its assessment ***and, where necessary, demand additional studies. The Authority should provide public access to all relevant scientific literature on the matter, which it holds.*** In order to provide an additional level of guarantee ensuring that the Authority can have access to all relevant scientific data and studies available on a subject matter of an authorisation procedure, it is appropriate to provide for a consultation of third parties in order to identify whether other relevant scientific data or studies are available. To increase the effectiveness of the consultation, the consultation should take place ***immediately after*** the studies submitted by industry included in an application for authorisation ***have been*** made public, under the transparency rules of this Regulation.

Amendment 158

Proposal for a regulation Recital 21

Text proposed by the Commission

(21) Studies, including tests, submitted by business operators in support of applications for authorisations under Union sectoral food law **usually** comply with internationally recognised principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, issues of compliance with the applicable standards may arise in some cases and this is why national systems are in place to verify such compliance. It is appropriate to provide an additional level of guarantees to reassure the general public on the quality of studies and to lay down an enhanced auditing system whereby Member State controls on the implementation of those principles by the laboratories carrying out such studies and tests would be verified by the Commission.

Amendment

(21) Studies, including tests, submitted by business operators in support of applications for authorisations under Union sectoral food law **should be based on independent peer-reviewed literature or standards and Good Laboratory Practice (GLP)** principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, issues of compliance with the applicable standards may arise in some cases and this is why national systems are in place to verify such compliance. It is appropriate to provide an additional level of guarantees to reassure the general public on the quality of studies and to lay down an enhanced auditing system whereby Member State **or third-country** controls, **in collaboration with the Commission's Directorate for Health and Food Audits and Analysis** on the implementation of those principles by the laboratories carrying out such studies and tests **in the Union and in third countries** would be verified by the Commission.

Amendment 22

Proposal for a regulation Recital 21 a (new)

Text proposed by the Commission

Amendment

(21a) Sufficient flexibility ought to be built into the process so that new insights into serious health adverse effects can be promptly taken into consideration, even when they are not specifically covered by

regulatory data requirements.

Amendment 23

Proposal for a regulation Recital 22

Text proposed by the Commission

(22) Food safety is a sensitive matter of prime interest for all Union citizens. While maintaining the principle that the burden is on the industry to prove compliance with Union requirements, it is important to establish an additional verification tool to address specific cases of high societal importance where there is a controversy on safety issues, namely the commissioning of additional studies with the objective of verifying evidence used in the context of risk assessment. Considering that it would be financed by the Union budget and that the use of this exceptional verification tool should remain proportionate, the Commission should be responsible for triggering the commissioning of such verification studies. Account should be taken of the fact that in some specific cases the studies commissioned may need to have a wider scope than the evidence at stake (for example new scientific developments becoming available).

Amendment

(22) Food safety is a sensitive matter of prime interest for all Union citizens. While maintaining the principle that the burden is on the industry to prove compliance with Union requirements, it is important to establish an additional verification tool to address specific cases of high societal importance where there is a controversy on safety issues, namely the commissioning of additional studies with the objective of verifying evidence used in the context of risk assessment. Considering that it would be financed by the Union budget and that the use of this exceptional verification tool should remain proportionate, the Commission should, ***in case of divergent scientific findings***, be responsible for triggering the commissioning of such verification studies. Account should be taken of the fact that in some specific cases the studies commissioned may need to have a wider scope than the evidence at stake ***in the risk assessment process*** (for example new scientific developments becoming available).

Amendment 24

Proposal for a regulation Recital 23 a (new)

Text proposed by the Commission

Amendment

(23a) The Aarhus Convention establishes a number of rights of the public with

regard to the environment. The Aarhus Convention provides for the right of everyone to receive environmental information that is held by public authorities, the right to participate in environmental decision-making, and the right to review procedures to challenge public decisions that have been made without respecting the two aforementioned rights or environmental law in general.

Amendment 25

Proposal for a regulation Recital 24

Text proposed by the Commission

(24) The European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" further confirmed concerns regarding transparency with respect to studies commissioned by the industry and submitted in authorisation application²³.

²³ Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.

Amendment

(24) *As a Party to the Aarhus Convention, the Union has recognised that, in the field of the environment, improved access to information and public participation in decision-making enhance the quality and the implementation of decisions, contribute to public awareness of environmental issues, give the public the opportunity to express its concerns and enable public authorities to take due account of such concerns.* The European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" further confirmed concerns regarding transparency with respect to studies commissioned by the industry and submitted in authorisation application²³.

²³ Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.

Amendment 26

Proposal for a regulation Recital 25 a (new)

Text proposed by the Commission

Amendment

(25a) Using the Board of Appeal of the European Chemicals Agency as its model, as set out in Articles 89 to 93 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council^{1a}, an EFSA Board of Appeal should be established by means of delegated acts.

^{1a} Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1).

Amendment 27

Proposal for a regulation Recital 27

Text proposed by the Commission

Amendment

(27) To determine what level of disclosure strikes the appropriate balance, the ***relevant rights of the public to*** transparency in the risk assessment process, should be weighted up against the rights of commercial applicants, taking into account the objectives of Regulation (EC)

(27) To determine what level of ***proactive*** disclosure strikes the appropriate balance, the ***need to ensure*** transparency in the risk assessment process, should be weighted up against the rights of commercial applicants, taking into account the objectives of Regulation (EC) No 178/2002, ***of a high***

level of protection of human life and health, the protection of consumers' interests, as well as the protection of animal health and welfare, plant health and the environment.

Amendment 28

Proposal for a regulation Recital 27 a (new)

Text proposed by the Commission

Amendment

(27a) The provisions on active dissemination laid down in this Regulation are not meant to limit, in any manner, the scope of the rights provided for by Regulations (EC) No 1049/2001 and (EC) No 1367/2006.

Amendment 29

Proposal for a regulation Recital 30

Text proposed by the Commission

Amendment

(30) It is also necessary to **set out specific requirements with respect to** the protection of personal data for the purposes of the transparency of the risk assessment process **taking into account** Regulation (EC) No 45/2001 of the European Parliament and of the Council²⁴ and Regulation (EU) 2016/679 of the European Parliament and of the Council²⁵. Accordingly, no personal data should be made publicly available under this Regulation, unless it is necessary and proportionate for the purposes of ensuring the transparency, independence and the reliability of the risk assessment process, while preventing conflicts of interests.

(30) It is also necessary to **refer, for** the protection **and confidentiality** of personal data for the purposes of the transparency of the risk assessment process, **to** Regulation (EC) No 45/2001 of the European Parliament and of the Council²⁴ and Regulation (EU) 2016/679 of the European Parliament and of the Council²⁵. Accordingly, no personal data should be made publicly available under this Regulation, unless it is necessary and proportionate for the purposes of ensuring the transparency, independence and the reliability of the risk assessment process, while preventing conflicts of interests. **For the purpose of ensuring the transparency, independence, sustainability and**

reliability of the risk assessment process, in particular to avoid conflicts of interest, it is considered necessary and proportionate to publish the names of any individual designated by the Authority to contribute to the Authority's decision making process, including in the context of the adoption of guidance documents.

²⁴ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

²⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

²⁴ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

²⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Amendment 30

Proposal for a regulation Recital 31

Text proposed by the Commission

(31) For the purposes of increased transparency and in order to ensure that requests for scientific outputs received by the Authority are processed in an effective manner, standard data formats and software packages should be developed. In order to ensure uniform conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of standard data formats and software packages, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the

Amendment

(31) For the purposes of increased transparency and in order to ensure that requests for scientific outputs received by the Authority are processed in an effective manner, standard data formats and software packages should be developed. In order to ensure uniform **and harmonised** conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of standard data formats and software packages, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation

European Parliament and of the Council²⁶.

(EU) No 182/2011 of the European Parliament and of the Council²⁶.

²⁶ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

²⁶ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment 31

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) Furthermore, in order to assess the effectiveness and efficiency of the different provisions applying to the Authority, it is also appropriate to **provide for a Commission** evaluation of the Authority, **in accordance with the Common Approach on Decentralised Agencies**. The evaluation should, in particular, review the procedures for selecting the members of Scientific Committee and Panels, for their degree of transparency, cost-effectiveness, and suitability to ensure independence and competence, and to prevent conflicts of interests.

Amendment

(33) Furthermore, in order to assess the effectiveness and efficiency of the different provisions applying to the Authority, it is also appropriate to **conduct an independent** evaluation of the Authority. The evaluation should, in particular, review the procedures for selecting the members of Scientific Committee and Panels, for their degree of transparency, cost-effectiveness, and suitability to ensure independence and competence, and to prevent conflicts of interests.

Amendment 32

Proposal for a regulation

Recital 33 a (new)

Text proposed by the Commission

Amendment

(33a) The Seventh European Environment Action Programme has prioritised the development and realisation of pathways to address the combined effects of chemicals on human health and the environment. Assessment of ‘cocktail effects’ requires a cross-sectoral approach, closer cooperation between monitoring agencies at European level and the formulation of suitable procedures.

Amendment 33

Proposal for a regulation

Recital 35

Text proposed by the Commission

Amendment

(35) For the purposes of ensuring transparency of the risk assessment process, it is also necessary to extend the scope of Regulation (EC) No 178/2002, currently limited to food law, to also cover applications for authorisations in the context of Regulation (EC) No 1831/2003 as regards feed additives, Regulation (EC) No 1935/2004 as regards food contact materials and Regulation (EC) No 1107/2009 as regards plant protection products.

(35) For the purposes of ensuring ***the*** transparency ***and independence*** of the risk assessment process, it is also necessary to extend the scope of Regulation (EC) No 178/2002, currently limited to food law, to also cover applications for authorisations in the context of Regulation (EC) No 1831/2003 as regards feed additives, Regulation (EC) No 1935/2004 as regards food contact materials and Regulation (EC) No 1107/2009 as regards plant protection products.

Amendment 34

Proposal for a regulation

Recital 36

Text proposed by the Commission

Amendment

(36) To ensure that sectoral specificities

(36) To ensure that sectoral specificities

with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency *in* the risk assessment process, ***including those flowing from the Aarhus Convention***³⁵, against the rights of commercial applicants, taking into account the specific objectives of sectoral Union legislation as well as experienced gained. Accordingly, it is necessary to amend Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004 and Regulation (EC) No 1107/2009 to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.

with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency, ***including the right to benefit from proactive information related to*** the risk assessment process, against the rights of commercial applicants, taking into account the specific objectives of sectoral Union legislation as well as experienced gained. Accordingly, it is necessary to amend Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004 and Regulation (EC) No 1107/2009 to provide for additional confidential items to those set out in Regulation (EC) No 178/2002. ***The provisions on active dissemination laid down in this Regulation and the assessment of a confidentiality request by the Authority should not in any manner limit the scope of the rights provided by Regulations (EC) No 1049/2001 and (EC) No 1367/2006.***

³⁵ ***Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p.13).***

Amendment 35

Proposal for a regulation Recital 36 a (new)

Text proposed by the Commission

Amendment

(36a) The Fitness Check of the General Food Law also highlighted a lack of transparency of the risk management process. There is a need to better inform the public on the risk management

options under consideration, the level of protection to consumer and animal health and the environment that each of these options would achieve, as well as on the factors, other than the results of the risk assessment, which are taken into account by the risk managers, and how they are weighed up against each other in the decision-making process.

Amendment 36

Proposal for a regulation

Recital 37

Text proposed by the Commission

(37) In order to **further strengthen the link between** risk assessors and risk managers at Union and national levels as well as **the coherence and consistency of risk communication**, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to adopt a general plan on risk communication on matters covering the agri-food chain. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Amendment

(37) In order to **improve the interactive exchange of information, throughout the risk analysis process, amongst the** risk assessors and risk managers at Union and national levels, as well as **with other stakeholders of the food chain such as economic operators, consumer and other civil society organisations**, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to adopt a general plan on risk communication on matters covering the agri-food chain. **The general plan on risk communication should lay down the practical arrangements for making available to the public the necessary information to achieve a high level of transparency of the risk management process.** Therefore, it is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as

Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Amendment 37

Proposal for a regulation Recital 37 a (new)

Text proposed by the Commission

Amendment

(37a) Provisions regarding what information should be made public should be without prejudice to Regulation (EC) No 1049/2001, as well as national or Union law regarding public access to official documents.

Amendment 38

Proposal for a regulation Recital 38

Text proposed by the Commission

Amendment

(38) In order to enable the Authority and the business operators to adapt to the new requirements while ensuring that the Authority continues its smooth operation, it is necessary to provide for transitional measures for the application of this Regulation.

(38) In order to enable the Authority, ***Member States, the Commission*** and the business operators to adapt to the new requirements while ensuring that the Authority continues its smooth operation, it is necessary to provide for transitional measures for the application of this Regulation.

Amendment 39

Proposal for a regulation Recital 39 a (new)

(39a) Since the amendments contained in this proposal serve to transfer far-reaching competencies for risk assessment and confidentiality checks to the Authority, a significant increase in the budget for the Authority pursuant to Annex 3 of the Commission's proposal is necessary. The financing proposal is compatible with the current multiannual financial framework but may entail the use of special instruments as defined in Council Regulation (EU, Euratom) No 1311/2013. Should discussions between the European Parliament and the Member States on the Union budget not leave sufficient room for the necessary budgetary resources, then the Commission would have to propose an alternative financing proposal under a delegated act.

Amendment 40

Proposal for a regulation Recital 40 a (new)

(40a) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. This comprehensive approach to emergency food safety measures should enable effective action to be taken, avoiding artificial disparities in the treatment of any serious risk to food or feed through a harmonised joint food

Amendment 41

Proposal for a regulation

Article 1 – paragraph – point -1 (new)

Regulation (EC) No 178/2002

Article 6 – paragraph 2

Present text

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

Amendment

(-1) In Article 6, paragraph 2 is replaced as follows:

“2. "Risk assessment shall be based on *all* available scientific evidence and undertaken in an independent, objective and transparent manner.”

(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Amendment 42

Proposal for a regulation

Article 1 – paragraph 1 – point -1 a (new)

Regulation (EC) No 178/2002

Article 7 – paragraph 1

Present text

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific

Amendment

(-1a) In Article 7, paragraph 1 is replaced as follows:

“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.

uncertainty persists, risk management measures necessary to ensure the high level of health protection chosen in the Community *shall* be adopted, pending further scientific information for a more comprehensive risk assessment."

Amendment 43

Proposal for a regulation

Article 1 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 8a

Text proposed by the Commission

Article 8a

Objectives of risk communication

Risk communication shall pursue the following objectives, while taking into account the respective roles of risk assessors and risk managers:

- (a) *promote* awareness and understanding of the specific issues under consideration during the entire risk analysis process;
- (b) *promote* consistency *and* transparency in formulating risk management recommendations;
- (c) *provide* a sound basis for understanding risk management decisions;

Amendment

Article 8a

Objectives of risk communication

Risk communication shall pursue the following objectives, while taking into account the respective roles of risk assessors and risk managers:

- (a) *promoting* awareness and understanding of the specific issues under consideration during the entire risk analysis *and management* process;
- (b) *promoting* consistency, transparency *and clarity* in formulating risk management *options*, recommendations *and decisions*;
- (c) *providing* a sound *scientific* basis for understanding risk management decisions, *including information on:*
 - (i) *how the risk management option chosen reflects the degree of uncertainty of the risk assessment, and the level of consumer and animal health and environmental protection it would achieve;*
 - (ii) *as referred to in Article 6(3), the factors, other than the results of the risk*

(d) *foster* public understanding of the risk analysis process so as to enhance confidence in its outcome;

(e) *promote appropriate* involvement of all interested parties; *and*,

(f) *ensure appropriate* exchange of information with interested parties in relation to risks associated with the agri-food chain.

assessment, which were considered by the risk managers, and how these factors were weighed up against each other;

(d) *fostering* public understanding of the risk analysis process so as to enhance confidence in its outcome, *including the provision of clear and consistent information regarding the respective tasks, powers and responsibilities of risk assessors and risk managers;*

(e) *promoting the balanced* involvement of all interested parties, *including economic operators of the food chain, consumers and other civil society organisations;*

(f) *ensuring a transparent and equitable* exchange of information with *the* interested parties *referred to in point (e)* in relation to risks associated with the agri-food chain;

(fa) informing consumers about risk prevention strategies; and

(fb) combating the dissemination of false information and the sources thereof.

Amendment 44

Proposal for a regulation

Article 1 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 8b

Text proposed by the Commission

Article 8b

General principles of risk communication

Taking into account the respective roles of risk assessors and risk managers, risk communication shall:

(a) ensure that accurate, *appropriate* and

Amendment

Article 8b

General principles of risk communication

Taking into account the respective roles of risk assessors and risk managers, risk communication shall:

(a) ensure that accurate, *complete* and

timely information is interactively exchanged, based on the principles of transparency, openness, and responsiveness;

(b) provide transparent information at each stage of the risk analysis process from the framing of requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions;

(c) **take into account** risk perceptions;

(d) facilitate understanding and dialogue amongst all interested parties; **and,**

(e) be accessible, including to those not directly involved in the process, while taking into account confidentiality and protection of personal data.

timely information is interactively exchanged **with all interested parties**, based on the principles of transparency, openness, and responsiveness;

(b) provide transparent information at each stage of the risk analysis process from the framing of requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions;

(c) **address** risk perceptions;

(d) facilitate understanding and dialogue amongst all interested parties;

(e) be accessible, including to those not directly involved in the process, while taking into account confidentiality and protection of personal data; **and**

(ea) formulate approaches to better communicate the difference between hazard and risk.

Amendment 45

Proposal for a regulation

Article 1 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 8c

Text proposed by the Commission

Article 8c

General plan for risk communication

1. The Commission, in close cooperation with the Authority, the Member States and following appropriate public consultations **shall be empowered to adopt** delegated acts in accordance with Article 57a establishing a general plan for risk communication on matters relating to the agri-food chain, taking into account the relevant objectives and general principles

Amendment

Article 8c

General plan for risk communication

1. The Commission **is empowered to adopt**, in close cooperation with the Authority, the Member States and following appropriate public consultations, delegated acts in accordance with Article 57a **which supplement this Regulation by** establishing a general plan for risk communication on matters relating to the agri-food chain, taking into account the relevant objectives and general principles

set out in Articles 8a and 8b.

2. The general plan for risk communication shall promote an integrated risk communication framework to be followed both by the risk assessors and the risk managers in a coherent and systematic manner both at Union and national level. It shall:

(a) identify the key factors that need to be taken into account when considering the type and level of risk communications' activities needed;

(b) identify the appropriate main tools and channels to be used for risk communication purposes, taking into account the needs *of relevant target audience groups; and,*

(c) establish appropriate mechanisms in order to strengthen coherence of risk communication amongst risk assessors and risk managers *and ensure an open dialogue amongst all interested parties.*

3. The Commission shall adopt the general plan for risk communication within [two years from the date of application of this Regulation] and shall keep it updated, taking into account technical and scientific progress and experience gained.

set out in Articles 8a and 8b.

2. The general plan for risk communication shall promote an integrated risk communication framework to be followed both by the risk assessors and the risk managers in a coherent and systematic manner both at Union and national level. It shall:

(a) identify the key factors that need to be taken into account when considering the type and level of risk communications' activities needed;

(b) identify the appropriate main tools and channels to be used for risk communication purposes, taking into account the need *to ensure the balanced involvement of all interested parties, including economic operators of the food chain, and consumer and other civil society organisations;*

(c) establish appropriate mechanisms in order to strengthen coherence of risk communication amongst risk assessors and risk managers, *including by systematically acknowledging and explaining divergences in scientific assessment or in the perception of the acceptable level of risk;*

(ca) lay down the practical arrangements and a timeline for making the information referred to in Article 55a(1) available to the public.

3. The Commission shall adopt the general plan for risk communication within [two years from the date of application of this Regulation] and shall keep it updated, taking into account technical and scientific progress and experience gained.

Amendment 46

Proposal for a regulation

Article 1 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 8 d (new)

Text proposed by the Commission

Amendment

Article 8d

Transparency of risk communication

1. The Commission, the Authority and the Member States shall carry out their tasks as regards risk communication in relation to food law with a high level of transparency.

2. The Commission may issue appropriate guidelines.

Amendment 47

Proposal for a regulation

Article 1 – paragraph 1 – point 1 a (new)

Regulation (EC) No 178/2002

Article 9

Present text

Amendment

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.

(1a) Article 9 is replaced by the following:

"Article 9

Public consultation

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

Amendment 48

Proposal for a regulation

Article 1 – paragraph 1 – point 1 b (new)

Regulation (EC) No 178/2002

Article 10

Present text

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.

Amendment

(1b) Article 10 is replaced by the following:

“Article 10

Public information

- 1.*** 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 public authorities shall take appropriate ***and timely*** steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible ***the concerned products***, the risk that ***they*** may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk. ***This paragraph shall also apply in case of suspected non-compliances resulting from possible intentional violations of applicable Union legislation perpetrated through fraudulent or deceptive practices.***
- 2.*** ***For the purpose of ensuring the uniform implementation of paragraph 1, the Commission shall adopt implementing acts on the modalities of its application by ... [12 months after the entry into force of this amending Regulation].***

Amendment 49

Proposal for a regulation

Article 1 – paragraph 1 – point 1 c (new)

Regulation (EC) No 178/2002

Article 22 – paragraph 7

Present text

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

Amendment

(1c) In Article 22(7), the second subparagraph is replaced by the following:

“It shall act in cooperation with the *other European Union evaluation agencies*.”

Amendment 50

Proposal for a regulation

Article 1 – paragraph 1 – point 1 d (new)

Regulation (EC) No 178/2002

Article 23 – paragraph 1 – point b

Present text

(b) to promote and coordinate the development of uniform risk assessment *methodologies* in the *fields falling* within its mission;

Amendment

(1d) In the first paragraph of Article 23, point (b) is replaced by the following:

“(b) to promote and coordinate *in a cross-cutting approach* the development of uniform *methods for* risk assessment in the *areas* within its mission, *in particular taking into account the “cocktail effects” of chemical substances which may have an impact on human health and the environment*.”

Amendment 51

Proposal for a regulation

Article 1 – paragraph 1 – point 2 – point b

Regulation (EC) No 178/2002

Article 25 – paragraph 1a

Text proposed by the Commission

1a. In addition to members and alternate members referred to in paragraph 1, the Management Board shall include:

(a) two members and the alternate members appointed by the Commission and representing the Commission, with the right to vote.

(b) **one member** appointed by the European Parliament, with the right to vote.

(c) **four** members with the right to vote representing civil society and food chain interests namely, one from consumers organisations, one from environmental non-governmental organisations, one from farmers organisations and one from industry organisations. Those members shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint those members.

Amendment

1a. In addition to members and alternate members referred to in paragraph 1, the Management Board shall include:

(a) two members and the alternate members appointed by the Commission and representing the Commission, with the right to vote.

(b) **two representatives** appointed by the European Parliament, with the right to vote.

(c) **six** members with the right to vote representing civil society and food chain interests namely, one from consumers organisations, one from environmental non-governmental organisations, **one from public health non-governmental organisations**, one from farmers organisations, **one from the agro-chemical organisations** and one from **food** industry organisations. Those members shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint those members.

Amendment 52

Proposal for a regulation

Article 1 – paragraph 1 – point 2 – point c

Regulation (EC) No 178/2002

Article 25 – paragraph 2

Text proposed by the Commission

2. The term of office of members *and alternate members* shall be *four* years. *However*, the term of office of the members referred to in paragraph 1a (*a*) *and (b)* shall *not be limited in duration*. The term of office of the members referred to in paragraph 1a(*c*) may be renewable only once.

Amendment

2. The term of office of members *referred to in point (b) of paragraph 1a* shall be *maximum 2,5* years. The term of office of the members referred to in *points (a) and (c) of* paragraph 1a shall *be five years*. The term of office of the members referred to in *point (c) of* paragraph 1a may be renewable only once.

Amendment 159

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – point -a (new)

Regulation (EC) No 178/2002

Article 28– paragraph 4 – subparagraph 1 - introductory part

Text proposed by the Commission

Amendment

(-a) In Article 28(4), the introductory part is replaced by the following:

"4. The Scientific Panels shall be composed of independent scientists who are actively conducting research, and publishing their research findings in peer-reviewed scientific journals."

Amendment 53

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – points a and b

Regulation (EC) No 178/2002

Article 28 – paragraphs 5 to 5g

Text proposed by the Commission

5. The members of the Scientific Committee who are not members of Scientific Panels and the **additional members referred to in paragraph 5b** shall be appointed by the Management Board, **acting upon a proposal from the Executive Director**, for a five year term of office, **which may be renewable**, following **publication in the Official Journal of the European Union, in relevant leading scientific publications and on the Authority’s website of a call for expressions of interest.**”

5a. The members of the Scientific Panels shall be appointed by the Management Board for a renewable five year term of office in accordance with the following procedure:

(a) The Executive Director, after consulting the Management Board, shall **send to** the Member States **the request for** the specific multidisciplinary expertise needed in each Scientific Panel and shall indicate the number of experts **to be nominated by the Member States. The Executive Director shall notify the Member States of the Authority’s independence policy and implementing rules applicable to Scientific Panels’ members. Member States shall launch a call for interest as a basis for their nominations. The Executive Director shall inform the Management Board of the requests sent to the Member States.**

(b) Member States shall nominate experts **with a view to collectively reach the number indicated by the Executive Director. Each Member State shall nominate at least 12 scientific experts.**

Amendment

5. The members of the Scientific Committee who are not members of Scientific Panels and the members **of the Scientific Panels** shall be appointed by the Management Board for a **renewable** five year term of office **in accordance with the following procedure:**

(a) The Executive Director, after consulting the Management Board, shall **publish a call for expression of interest in the Official Journal of the European Union, in relevant leading scientific publications and on the Authority’s website, and shall inform** the Member States. **The call shall lay down** the specific multidisciplinary expertise needed in each Scientific Panel and shall indicate the number of experts **required.**

(b) Member States shall **ensure the broad dissemination of the call for expression of interest across the scientific community. They may also** nominate experts **for the fields indicated, provided**

Member States may nominate nationals of other Member States.

(c) On the basis of the nominations ***made by Member States***, the Executive Director shall draw for each Scientific Panel a list of experts larger than the number of members to be appointed. The Executive Director may not draw up such a list where ***he/she*** can justify that the nominations received do not allow him, given the criteria for selection set up in point d) of this paragraph, to draw up a larger list. The Executive Director shall submit the list to the Management Board for appointment.

(d) The nominations by the Member States, the selection by the Executive Director and the appointments by the Management Board shall be made on the basis of the following criteria:

- (i) A high level of scientific expertise;
- (ii) Independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members;
- (iii) Meeting the needs for the specific multi-disciplinary expertise of the Panel to which they will be appointed and the applicable language regime.

(e) The Management Board shall ensure that the broadest possible geographical distribution is achieved in the final appointments.

5b. When the Authority identifies that specific expertise is missing in a Panel or several Panels, the Executive Director shall propose additional members of the Panel(s) for appointment to the Management Board in accordance with the procedure laid down in paragraph 5.

5c. The Management Board shall adopt,

that such nominations are made on the basis of a national call for expression of interest.

(c) On the basis of the ***applications and nominations received and in accordance with the Authority's independence policy and implementing rules applicable to Scientific Panels' members***, the Executive Director shall draw for each Scientific Panel a list of experts larger than the number of members to be appointed. The Executive Director may not draw up such a list where ***he or she*** can justify that the ***applications and*** nominations received do not allow him ***or her***, given the criteria for selection set up in point (d) of this paragraph, to draw up a larger list. The Executive Director shall submit the list to the Management Board for appointment.

(d) The nominations by the Member States, the selection by the Executive Director and the appointments by the Management Board shall be made on the basis of the following criteria:

- (i) A high level of scientific expertise;
- (ii) Independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members;
- (iii) Meeting the needs for the specific multi-disciplinary expertise of the Panel to which they will be appointed and the applicable language regime.

(e) The Management Board shall ensure that the broadest possible geographical distribution is achieved in the final appointments.

5a. When the Authority identifies that specific expertise is missing in a Panel or several Panels, the Executive Director shall propose additional members of the Panel(s) for appointment to the Management Board in accordance with the procedure laid down in paragraph 5.

5b. The Management Board shall adopt,

on the basis of a proposal of the Executive Director, rules on the detailed organisation and timing of the procedures set up in paragraphs **5a** and **5b** of the present Article.

5d. *The Member States shall put in place measures ensuring that the members of the Scientific Panels act independently and remain free from conflict of interests as provided for in Article 37(2) and the Authority's internal measures. Member States shall ensure that the members of the Scientific Panels have the means to dedicate the necessary time and effort to contribute to the work of the Authority. Member States shall ensure that the members of the Scientific Panels do not receive any instruction at any national level and that their independent scientific contribution to the risk assessment system at Union level is recognised as a priority task for the protection of the safety of the food chain.*

5e. Member States shall ensure that the public bodies employing those scientific experts and those having responsibility for the setting of priorities of the scientific bodies employing those experts implement the measures *provided for* in paragraph **5d**.

5f. The Authority shall support the tasks of the Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in the Article 36 including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Panels before they adopt them.

5g. Each Panel shall include a maximum of 21 members.

on the basis of a proposal of the Executive Director, rules on the detailed organisation and timing of the procedures set up in paragraphs **5** and **5a** of the present Article.

5c. Members of the Scientific Panels *shall* act independently and remain free from conflict of interests as provided for in Article 37(2) and the Authority's internal measures. *They* shall have the means to dedicate the necessary time and effort to contribute to the work of the Authority, shall not receive any instruction at any national level, and their independent scientific contribution to the risk assessment system at Union level *shall be* recognised as a priority task for the protection of the safety of the food chain.

5d. *As appropriate*, Member States shall ensure that the public bodies employing those scientific experts and those having responsibility for the setting of priorities of the scientific bodies employing those experts implement the measures *which are necessary to ensure that the conditions referred to* in paragraph **5c** *are met*.

5e. The Authority shall support the tasks of the Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in the Article 36 including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Panels before they adopt them.

5f. Each Panel shall include a maximum of 21 members.

5fa. *The Authority shall offer members of Panels comprehensive training on the risk assessment process.*

Amendment 54

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – point c

Regulation (EC) No 178/2002

Article 28 – paragraph 9 – point b

Text proposed by the Commission

The number of members in each Scientific Panel within the maximum provided for in paragraph 5g.

Amendment

(b) The number of members in each Scientific Panel within the maximum provided for in paragraph 5f.

Amendment 55

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – point c a (new)

Regulation (EC) No 178/2002

Article 28 – paragraph 9 – point g a (new)

Text proposed by the Commission

Amendment

(ca) *In Article 28(9), the following point is added:*

“(ga) the possibility for applicants to address, in a maximum period of six months unless otherwise agreed with the Authority, and previous to the publication of the draft opinion of the Authority, critical areas of concern by new data.”

Amendment 56

Proposal for a regulation

Article 1 – paragraph 1 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) The following sentence is added at the end of Article 29(6):

"They shall not allow a priori exclusion of certain scientific evidences, especially when these have been published after a peer-review process.";

Amendment 57

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32a

Text proposed by the Commission

Amendment

At the request of a potential applicant for a food law authorisation, the ***staff of the*** Authority shall ***advise on the relevant provisions and the*** required ***content*** of the ***application for authorisation***. The advice provided by ***the staff of*** the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

The Authority shall publish a guidance document that includes a list of questions and answers regarding the administrative and scientific requirements of an application for authorisation. At the request of a potential applicant for a food law authorisation, the Authority shall ***also offer consultation sessions to explain what information is required and how the various tests and studies necessary to prove the quality, safety and efficacy of the planned product are to be carried out.*** The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels. ***The staff of the Authority providing the advice shall not be involved in any preparatory scientific***

work that is directly or indirectly relevant to the application that is the subject of the advice.

Within ... [36 months after the entry into force of the amending Regulation], the Commission shall assess the impact of this Article on the functioning of the Authority. Particular attention shall be paid to the additional workload and mobilisation of staff, and whether it has led to any shift in the allocation of the Authority's resources, at the expense of activities of public interest.

Amendment 58

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 1

Text proposed by the Commission

1. A Union register of studies commissioned by business operators to obtain an authorisation under Union food law is hereby established. Business operators shall notify, without delay, to the Authority the subject matter of any study commissioned to support a future application for an authorisation under Union food law. The register shall be managed by the Authority.

Amendment

1. A Union register of studies commissioned by business operators ***seeking*** to obtain an authorisation ***or renewal*** under Union food law is hereby established. Business operators shall notify, without delay, to the Authority the subject matter of any study commissioned ***in the Union and beyond*** to support a future application for an authorisation ***or renewal*** under Union food law. The register shall be managed by the Authority.

Amendment 59

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Any studies commissioned shall take account of Directive 2010/63/EU of the European Parliament and of the Council^{1a}.

^{1a} Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

Amendment 60

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 2

Text proposed by the Commission

Amendment

2. The notification obligation under paragraph 1, also applies to **Union laboratories** carrying out **those** studies.

2. The notification obligation under paragraph 1 also applies to **any institution** carrying out **the** studies, **including laboratories, institutes or universities**.

Amendment 61

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Data from a test commissioned but not registered shall not be used in a risk assessment.

Amendment 62

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. The subject matter shall not be authorised unless all data from all registered studies are submitted.

Amendment 63

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Where the Authority requests and receives additional data by an applicant, this data is, marked as such, also added to

the Union register and made available to the public.

Amendment 64

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Commission shall adopt delegated acts in accordance with Article 57a supplementing this Regulation by establishing penalties for breaches of the notification obligation.

Amendment 65

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32b – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4b. This Article shall not be applicable to studies commissioned before ... [the date of entry into force of this amending Regulation].

Amendment 66

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32c – paragraph 1

Text proposed by the Commission

1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal and shall provide advice on the content of the intended renewal application taking into account the received comments. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.

Amendment

1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal and shall provide advice on the content of the intended renewal application taking into account the received comments ***which are relevant for the risk assessment of the intended renewal***. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.

Amendment 67

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32c – paragraph 2

Text proposed by the Commission

2. The Authority shall consult stakeholders and the public regarding the studies supporting applications for authorisation once they are made public by the Authority in accordance with Article 38 and Articles 39 to 39f in order to identify

Amendment

2. The Authority shall, ***within two months***, consult stakeholders and the public regarding the studies supporting applications for authorisation once they are made public by the Authority in accordance with Article 38 and Articles 39

whether other relevant scientific data or studies are available on the subject matter concerned by the application for authorisation. This provision does not apply to the submission of any supplementary information by the applicants during the risk assessment process.

to 39f in order to identify whether other relevant scientific data or studies ***that are based on independent peer-reviewed literature or have been carried out in accordance with international guidelines and Good Laboratory Practices (GLP)*** are available on the subject matter concerned by the application for authorisation, ***and are without prejudice to the Authority's own obligations under Article 33.*** This provision does not apply to the submission of any supplementary information by the applicants during the risk assessment process.

Amendment 68

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32d

Text proposed by the Commission

The **Commission** experts shall perform controls, including audits, to obtain assurance that testing facilities comply with relevant standards for carrying out tests and studies submitted to the Authority as part of an application for an authorisation under Union food law. These controls shall be organised in cooperation with the competent authorities of the Member States.

Amendment

The **Commission's Directorate for Health and Food Audits and Analysis** experts shall perform controls, including audits, to obtain assurance that testing facilities ***in the Union and in third countries*** comply with relevant standards for carrying out tests and studies submitted to the Authority as part of an application for an authorisation under Union food law. These controls shall be organised in cooperation with the competent authorities of the Member States ***or of the third countries concerned.***

Amendment 161

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32e

Text proposed by the Commission

Without prejudice to the obligation of applicants for authorisations under food law to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, **in exceptional circumstances**, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Amendment

Without prejudice to the obligation of applicants for authorisations under food law to demonstrate the safety of a subject matter submitted to a system of authorisation, **in the event of divergent scientific findings**, the Commission may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification **in the risk assessment process. Verification studies shall be funded via the contributions of applicants to a common fund. The Commission shall adopt a delegated act in accordance with Article 57a to determine the modalities of that fund.**

Amendment 70

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32e – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Any studies commissioned shall take into account Directive 2010/63/EU.

Amendment 71

Proposal for a regulation

Article 1 – paragraph 1 – point 4 a (new)

Regulation (EC) No 178/2002

Article 33 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(4a) In Article 33(1), the following point is added:

“(da) combinatorial and accumulated effects.”

Amendment 72

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:

1. The Authority shall carry out its activities with a high level of transparency ***in line with Regulation (EC) No 1367/2006 and without prejudice to Regulation (EC) No 1049/2001.*** It shall in particular make public without delay:

Amendment 73

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Text proposed by the Commission

(a) agendas and minutes of the Scientific Committee and the Scientific Panels and their Working Groups;

Amendment

(a) agendas, *participants lists*, and minutes of the *Management Board, the Advisory Committee*, the Scientific Committee and the Scientific Panels and their Working Groups;

Amendment 74

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Text proposed by the Commission

(c) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account protection of confidential information and protection of personal data in accordance with Articles 39 to 39f.

Amendment

(c) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account *the overriding public interest in disclosure and the* protection of confidential information and protection of personal data in accordance with Articles 39 to 39f.

Amendment 75

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002

Article 38 – paragraph 1 – point d

Text proposed by the Commission

(d) the information on which its scientific outputs, including scientific opinions are based, taking into account protection of confidential data and protection of personal data in accordance with Articles 39 to 39f;

Amendment

(d) the information on which its scientific outputs, including scientific opinions are based, taking into account ***the overriding public interest in disclosure and the*** protection of confidential data and protection of personal data in accordance with Articles 39 to 39f;

Amendment 76

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – point h a (new)

Text proposed by the Commission

Amendment

(ha) information on the name of the applicant and the title of the application;

Amendment 77

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – point i

Text proposed by the Commission

(i) advice provided by the Authority to potential applicants at pre-submission phase pursuant to **Article** 32a and 32c.

Amendment

(i) **the general** advice provided by the Authority to potential applicants at pre-submission phase pursuant to **Articles** 32a and 32c.

Amendment 78

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.

Amendment

Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible ***subject to clear undertakings recorded electronically by those accessing it and subject to measures and penalties which are effective, proportionate and dissuasive against any commercial use.*** The relevant items shall be available to download, print ***with a watermark for traceability*** and search through in an electronic format, ***which is machine-readable. Those measures shall focus on the commercial use of documents and their submission. Such measures shall be designed to protect effectively against commercial use of items referred to in the first subparagraph both within the Union and in third countries.***

Amendment 79

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point b

Regulation (EC) No 178/2002

Article 38 – paragraph 1a – subparagraph 1 – introductory part

Text proposed by the Commission

1a. The disclosure of the information mentioned in **paragraph (1)(c)** to the public shall be without prejudice:

Amendment

1a. The disclosure of the information mentioned in **points (c), (d) and (i) of paragraph 1** to the public shall be without prejudice:

Amendment 80

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point b

Regulation (EC) No 178/2002

Article 38 – paragraph 1a – subparagraph 1 – point a

Text proposed by the Commission

(a) to any intellectual property right which may exist over documents or their content; and,

Amendment

deleted

Amendment 163

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point b

Regulation (EC) No 178/2002

Article 38 – paragraph 1a – subparagraph 2

Text proposed by the Commission

The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third parties shall not engage the responsibility of the *European* Union.

Amendment

The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be ***commercially*** used, reproduced, or otherwise exploited ***for commercial purposes. For the avoidance of doubt, the information published may be used for the purpose of public and academic scrutiny of the results, including a better understanding of the potential adverse effects on health and the environment,*** and its use by third parties shall not engage the responsibility of the Union.

Amendment 82

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point c a (new)

Regulation (EC) No 178/2002

Article 38 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

(ca) the following paragraph is added:

“3a. This Article is without prejudice to Directive 2003/4/EC and to Regulations (EC) No 1049/2001 and (EC) No 1367/2006.”

Amendment 83

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 38, the Authority shall not make public information for which confidential treatment has been requested **under** the conditions laid down in this Article.

Amendment

1. By way of derogation from Article 38 **and without prejudice to Regulation (EC) No 1049/2001 and Directive 2003/4/EC and the general principle that the interests of public health always prevail over private interests**, the Authority shall not make public information for which confidential treatment has been requested **and granted in fulfilment of** the conditions laid down in this Article.

Amendment 84

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 2 – point 1

Text proposed by the Commission

(1) the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion;

Amendment

(1) the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion, **except when relevant to understanding the potential effects on health and the environment, and provided that the applicant demonstrates with verifiable justification that such method does not entail information about emissions in the environment and about impacts on health and environment**;

Amendment 85

Proposal for a regulation
Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 2 – point 3

Text proposed by the Commission

(3) commercial information revealing sourcing, market shares or business strategy of the applicant; **and**

Amendment

(3) commercial information revealing sourcing, **innovative ideas for the product/substance**, market shares or business strategy of the applicant;

(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Amendment 86

Proposal for a regulation
Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 2 – point 4

Text proposed by the Commission

(4) quantitative composition of the subject matter of the request for a scientific output, including a scientific opinion.

Amendment

(4) quantitative composition of the subject matter of the request for a scientific output, including a scientific opinion, **except when relevant to understanding the potential effects on health and the environment.**

Amendment 87

Proposal for a regulation
Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 4 – point a

Text proposed by the Commission

(a) Where urgent action is essential to protect public health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to paragraphs 2 and 3; **and,**

Amendment

(a) Where urgent action is essential to protect public health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to paragraphs 2 and 3; **or,**

Amendment 88

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 4 – point b

Text proposed by the Commission

(b) information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable **health** effects.

Amendment

(b) information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable effects **on public health, animal health and the environment.**

Amendment 89

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 4 – point b a (new)

Text proposed by the Commission

Amendment

(ba) where an overriding public interest

in disclosure exists.

Amendment 90

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 4 – point b b (new)

Text proposed by the Commission

Amendment

(bb) any information for which there is an overriding public interest in disclosure under Article 4(2) of Regulation (EC) No 1049/2001 and Article 6 of Regulation (EC) No 1367/2006, in particular where the information relates to emissions into the environment.

Amendment 91

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 178/2002

Article 39 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. This Article is without prejudice to Directive 2003/4/EC and Regulations (EC) No 1049/2001 and (EC) No 1367/2006.

Amendment 92

Proposal for a regulation
Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39a – paragraph 2

Text proposed by the Commission

2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall **be without** the information **the applicant deems confidential** in accordance with paragraphs 2 and 3 of Article 39. The confidential version shall contain all information submitted, including information the applicant **deems** confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate **the grounds** on the basis of which confidentiality is requested for the different pieces of information.

Amendment

2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall **edit, with black bars,** the information, **for which confidential treatment has been requested by the applicant** in accordance with paragraphs 2 and 3 of Article 39. The confidential version shall contain all information submitted, including information the applicant **considers as** confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate **verifiable justifications and evidence** on the basis of which confidentiality is requested for the different pieces of information.

Amendment 167

Proposal for a regulation
Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 - subparagraph 1 - point a

Text proposed by the Commission

(a) make public, without delay, the non-confidential version, as submitted by the applicant;

Amendment

(a) make public, without delay, the non-confidential version **of the application,** as submitted by the applicant, **once that application has been considered**

admissible;

Amendment 93

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission

(c) inform the applicant in writing of its intention to disclose information and the reasons for it, before the Authority formally takes a decision on the confidentiality request. If the applicant **disagrees with** the assessment of the Authority it may state its views **or** withdraw its application within **two** weeks from the date on which it was notified of the Authority's position.

Amendment

(c) inform the applicant in writing of its intention to disclose information and the reasons for it, before the Authority formally takes a decision on the confidentiality request. If the applicant **objects to** the assessment of the Authority it may **(1)** state its views, **(2)** withdraw its application, **or (3) request a review to the Authority's Board of Appeal** within **four** weeks from the date on which it was notified of the Authority's position. **The applicant may provide written notice to the Authority that it wishes to request a re-examination of the opinion to the Authority's Board of Appeal. In that case, the applicant shall forward to the Authority the detailed grounds for the request within 60 days after receipt of the opinion. Within 60 days after receipt of the grounds for the request, the Authority's Board of Appeal shall re-examine its opinion;**

Amendment 94

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – subparagraph 1 – point d

Text proposed by the Commission

(d) adopt a reasoned decision on the confidentiality request taking into account the observations of the applicant within **ten** weeks from the date of receipt of the confidentiality request with respect to applications for authorisation and without undue delay in the case of supplementary data and information and notify the applicant and inform the Commission and the Member States, **as appropriate**, of its decision; and,

Amendment

(d) adopt a reasoned decision on the confidentiality request taking into account the observations of the applicant within **eight** weeks from the date of receipt of the confidentiality request with respect to applications for authorisation and without undue delay in the case of supplementary data and information and notify the applicant and inform the Commission and the Member States, **in every case**, of its decision; and,

Amendment 140

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – subparagraph 1 - point e

Text proposed by the Commission

(e) **make public any additional** data and information **for which** the confidentiality request **has not been accepted as justified not earlier than two weeks after the notification of its decision to** the applicant **has taken place, pursuant to point (d).**

Amendment

(e) **publish non-confidential** data and information **relating to the application only once a final decision has been taken in respect of** the confidentiality request **pursuant to this Article and the Authority has published its draft scientific opinion in line with Article 38. Where an applicant withdraws the application pursuant to Article 39(c) because the applicant deems the publication of the information planned by the Authority to be too comprehensive, the Authority, the Commission and the Member States shall refrain from publishing any information on the application for authorisation.**

Amendment 96

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – subparagraph 2

Text proposed by the Commission

Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice of the European Union, under the conditions laid down in *Articles 263 and 278* of the Treaty *respectively*.

Amendment

Decisions taken by the Authority pursuant to this Article may be subject to an action before the *Authority's Board of Appeal, which shall be established by the Commission by means of delegated acts. Those delegated acts shall be adopted in accordance with Article 57a of this Regulation. A submission of an appeal pursuant to this paragraph shall have suspensive effect. The applicant may provide written notice to the Authority that he or she wishes to request a re-examination of the opinion to the Authority's Board of Appeal. In that case the applicant shall forward to the Authority the detailed grounds for the request within 60 days after receipt of the opinion. Within 60 days after receipt of the grounds for the request, the Authority's Board of Appeal shall re-examine its opinion. In case of a contesting decision taken by the Authority's Board of appeal, a case may be brought before the Court of Justice of the European Union under the conditions laid down in Article 263 of the Treaty.*

Amendment 97

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39d – paragraph 2

Text proposed by the Commission

2. The Commission and the Member States shall take the necessary measures so that information received by them under Union food law for which confidential treatment has been requested is not made public until a decision on the confidentiality request has been taken by the Authority and has become definitive. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public.

Amendment

2. The Commission and the Member States shall take the necessary measures so that information received by them under Union food law for which confidential treatment has been requested is not made public until a decision on the confidentiality request has been taken by the Authority and has become definitive, ***except for when access to information is requested in accordance with Directive 2003/4/EC or national law on access to documents***. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public, ***except for when access to information is requested in accordance with Directive 2003/4/EC or national law on access to documents***.

Amendment 98

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39d – paragraph 3

Text proposed by the Commission

3. If an applicant in the context of an authorisation procedure withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39 to 39f. The application shall be considered withdrawn as of the moment the written request is received by

Amendment

3. If an applicant in the context of an authorisation procedure withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39 to 39f. The application shall be considered withdrawn as of the moment the written request is received by

the competent body that had received the original application. *Where the withdrawal of the application takes place before the Authority has decided on the relevant confidentiality request, the Authority, the Commission and the Member States shall not make public the information for which confidentiality has been requested.*

the competent body that had received the original application. The Authority shall not *publish any* information, *confidential or non-confidential, should an applicant decide to withdraw its application.*

Amendment 99

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39e – paragraph 1 – point c

Text proposed by the Commission

(c) the names of all participants in meetings of the Scientific Committee and the Scientific Panels *and* their Working Groups.

Amendment

(c) the names of all participants *and observers* in meetings of the Scientific Committee and the Scientific Panels, their Working Groups *and any other ad hoc Group meeting on the subject.*

Amendment 101

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39f – paragraph 1

Text proposed by the Commission

1. For the purposes of Article 38(1)(c) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats

Amendment

1. For the purposes of Article 38(1)(c) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats

and software packages shall be adopted to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union food law. These draft standard data formats and software packages shall not be based on proprietary standards and shall ensure interoperability with existing data submission approaches to the extent possible.

and software packages shall be adopted to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union food law ***and feasibility for small and medium-sized enterprises***. These draft standard data formats and software packages shall not be based on proprietary standards and shall ensure interoperability with existing data submission approaches to the extent possible.

Amendment 102

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39f – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The standard data formats and software packages shall only apply to data generated after adoption of the implementing acts in accordance with point (b) of paragraph 2.

Amendment 103

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39g – paragraph 1

Text proposed by the Commission

Amendment

The information systems operated by the Authority to store its data, including

The information systems operated by the Authority to store its data, including

confidential and personal data shall be designed **to a high level** of security appropriate to the security risks at stake, taking into account Articles 39 to 39f of this Regulation. Access shall be based at the minimum on a system requiring two factor authentication or providing an equivalent level of security. The system shall ensure that any access to it is fully auditable.

confidential and personal data shall be designed **in a way that guarantees that the highest standards** of security appropriate to the security risks at stake **will be attained**, taking into account Articles 39 to 39f of this Regulation. Access shall be based at the minimum on a system requiring two factor authentication or providing an equivalent level of security. The system shall ensure that any access to it is fully auditable.

Amendment 104

Proposal for a regulation

Article 1 – paragraph 1 – point 9

Regulation (EC) No 178/2002

Article 41 – paragraph 1

Text proposed by the Commission

Where environmental information is concerned, **Articles 6 and Article 7 of** Regulation (EC) No 1367/2006 of the European Parliament and of the Council³⁹ shall also apply.

³⁹ Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

Amendment

The Authority shall ensure wide access to the documents held by it. Where environmental information is concerned, Regulation (EC) No 1367/2006 of the European Parliament and of the Council³⁹ shall also apply. ***Articles 38 to 39 of this Regulation shall apply without prejudice to the application of Regulations (EC) No 1049/2001 and (EC) No 1367/2006.***

³⁹ Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

Amendment 106

Proposal for a regulation

Article 1 – paragraph 1 – point 9 b (new)

Regulation (EC) No 178/2002

Article 51 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(9b) In Article 51, the following paragraph is inserted:

“1a. The Commission shall adopt a delegated act in accordance with Article 57a to develop a harmonised food alert network management system between the Commission and the Member States.”

Amendment 107

Proposal for a regulation

Article 1 – paragraph 1 – point 10

Regulation (EC) No 178/2002

Article 57a – paragraph 2

Text proposed by the Commission

Amendment

2. The powers to adopt delegated acts referred to in Article 8(c) shall be conferred upon the Commission for ***an indeterminate*** period of ***time*** from [date of entry into force of this Regulation].

2. The powers to adopt delegated acts referred to in Article 8(c), ***32b(4a), subparagraph 2 of Article 39b(1) and Article 51(1a)*** shall be conferred upon the Commission for ***a*** period of ***five years*** from [date of entry into force of this Regulation].

Amendment 108

Proposal for a regulation

Article 1 – paragraph 1 – point 11

Regulation (EC) No 178/2002

Article 61

Text proposed by the Commission

Article 61

Review clause

1. The Commission shall ensure the regular review of the application of this Regulation.
2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall *assess the Authority's* performance in relation to *its* objectives, *mandate*, tasks, procedures and *location*, *in accordance with Commission guidelines*. The evaluation shall address the possible need to modify the mandate of the Authority, *and* the financial implications of any such modification.

Amendment

Article 61

Review clause

1. The Commission shall ensure the regular review of the application of this Regulation.
2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the *Authority jointly with the* Commission shall *commission an independent external evaluation of their* performance *and achievements* in relation to *their* objectives, *mandates*, tasks, procedures and *locations*. The evaluation shall *be based on the Management Board's work programme in agreement with the Commission. It shall assess the working practices and the impact of the Authority and* address the possible need to modify the mandate of the Authority, *including* the financial implications of any such modification. *It shall, furthermore, address the possible need to coordinate and dovetail the Authority's activities more closely with those of the competent bodies in the Member States and other Union agencies. The evaluation shall take into account the views of the stakeholders, at both Union and national level.*
 - 2a. *The Management Board shall examine the conclusions of the evaluation and issue recommendations to the Commission, which may concern changes in the Authority.*

3. *Where the Commission considers that the continuation of the Authority is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.*

4. The Commission *shall report to* the European Parliament, *the Council* and the Management Board *on the evaluation findings*. The findings of the evaluation shall be made public.

4. *The evaluations and recommendations referred to in paragraphs 2 and 2a shall be forwarded to* the Commission, *the Council*, the European Parliament and the Management Board. The findings of the evaluation *and the recommendations* shall be made public.

Amendment 109

Proposal for a regulation

Article 2 – paragraph 1 – point 2 a (new)

Directive 2001/18/EC

Article 24 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(2a) In Article 24, the following paragraph is added:

“2a. The obligation to proactively disseminate the information set out in paragraph 1 of this Article, in line with Article 25 of this Directive, and in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulations (EC) No 1049/2001 and (EC) No 1367/2006.”

Amendment 110

Proposal for a regulation

Article 3 – paragraph 1 – point 9

Article 29 – paragraph 1

Text proposed by the Commission

1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions and opinions from the competent authorities referred to in Article 4 of Directive 2001/18/EC, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and taking into account Article 30 of this Regulation.

Amendment

1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, **monitoring reports** as well as its scientific opinions and opinions from the competent authorities referred to in Article 4 of Directive 2001/18/EC, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and taking into account Article 30 of this Regulation.

Amendment 111

Proposal for a regulation

Article 3 – paragraph 1 – point 9

Regulation (EC) No 1829/2003

Article 29 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The obligation to proactively disseminate the information set out in paragraph 1 of this Article, in line with Article 30 of this Regulation, and in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulations (EC) No 1049/2001 and (EC) No 1367/2006.

Amendment 112

Proposal for a regulation
Article 4 – paragraph 1 – point 1 a (new)
Regulation (EC) No 1831/2003

Article 17 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(1a) In Article 17, the following paragraph is added:

“2a. The obligation to proactively disseminate information set out in this Article and in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulations (EC) No 1049/2001 and (EC) No 1367/2006.”

Amendment 113

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EC) No 1831/2003

Article 18 – paragraph 3

Text proposed by the Commission

Amendment

3. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

deleted

(a) the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its

intended use as defined in Article 6(1) and Annex I to this Regulation; and,

(b) specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.

Amendment 114

Proposal for a regulation

Article 4 – paragraph 1 – point 2

Regulation (EC) No 1831/2003

Article 18 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Authority shall apply the principles of Regulation (EC) No 1049/2001 when handling applications for access to documents held by the Authority.

Amendment 115

Proposal for a regulation

Article 4 – paragraph 1 – point 2

Regulation (EC) No 1831/2003

Article 18 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraph 2 of this Article except where it is appropriate for such information to be made public in

order to protect human health, animal health or the environment. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Amendment 116

Proposal for a regulation

Article 5 – paragraph 1 – point 2

Regulation (EC) No 2065/2003

Article 14 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulations (EC) No 1049/2001 and (EC) No 1367/2006.

Amendment 117

Proposal for a regulation

Article 6 – paragraph 1 – point 2 a (new)

Regulation (EC) No 1935/2004

Article 19 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(2a) In Article 19, the following paragraph is added:

“2a. The obligation to proactively

disseminate information set out in paragraph 1 of this Article, including Article 20 of this Regulation, and Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulations (EC) No 1049/2001 and (EC) No 1367/2006.”

Amendment 119

Proposal for a regulation

Article 6 – paragraph 1 – point 3

Regulation No 1935/2004

Article 20 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) the trademark under which the substance, shall be marketed as well as the tradename of the preparations, material or articles in which it shall be used, where applicable; and,

deleted

Amendments 120 and 121

Proposal for a regulation

Article 7 – paragraph 1 – point 2

Regulation (EC) No 1331/2008

Article 11 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, in line with Article 12 of this Regulation and Articles 38 and 39 of Regulation (EC) No

178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulations (EC) No 1049/2001 and (EC) No 1367/2006.

Amendment 122

Proposal for a regulation

Article 7 – paragraph 1 – point 3

Regulation (EC) No 1331/2008

Article 12 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. *The provisions on active dissemination laid down in Articles 11 and 12 of this Regulation, and Articles 38 and 39 of Regulation (EC) No 178/2002, are without prejudice to the right of access to documents upon request set in Regulation (EC) No 1049/2001.*

Amendment 170

Proposal for a regulation

Article 8 – paragraph 1 – point 4

Regulation (EC) No 1107/2009

Article 16

Text proposed by the Commission

Amendment

The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which

The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which

confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation.

confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation, ***unless there is an overriding public interest in its disclosure.***

Amendment 123

Proposal for a regulation

Article 8 – paragraph 1 – point 4 a (new)

Regulation (EC) No 1107/2009

Article 23 – paragraph 1 – last sentence

Present text

For the purpose of this Regulation, an active substance which fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as ***a basic*** substance.

Amendment

(4a) In Article 23(1), the last sentence is replaced by the following:

“For the purpose of this Regulation, an active substance which fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as ***an approved*** basic substance.”

Amendment 124

Proposal for a regulation

Article 8 – paragraph 1 – point 5

Regulation (EC) No 1107/2009

Article 63 – paragraph 1

Text proposed by the Commission

1. In accordance with the conditions

Amendment

1. In accordance with the conditions

and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this article, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification.

and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this Article, ***except for information that is considered toxicologically, ecotoxicologically or environmentally relevant***, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by ***adequate and*** verifiable justification. ***The justification shall include verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.***

Amendment 126

Proposal for a regulation

Article 8 – paragraph 1 – point 5 a (new)

Regulation (EC) No 1107/2009

Article 63 – paragraph 3

Present text

3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information

Amendment

(5a) in Article 63, paragraph 3 is replaced by the following:

“3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information ***and to Regulations (EC) No 1049/2001 and (EC) No 1367/2006.***”

Amendment 127

Proposal for a regulation

Article 9 – paragraph 1 – point 1 – point a

Regulation (EC) No 2015/2283

Article 10 – paragraph 1

Text proposed by the Commission

1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States without delay.

Amendment

1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States ***and the summary of the application publicly available*** without delay.

Amendment 128

Proposal for a regulation

Article 9 – paragraph 1 – point 4

Regulation (EC) No 2015/2283

Article 23 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The provisions on active dissemination laid down in Article 23 of this Regulation, and Articles 38 and 39 of Regulation (EC) No 178/2002, are without prejudice to the right of access to documents upon request set in Regulation (EC) No 1049/2001.

Amendment 129

Proposal for a regulation

Article 9 – paragraph 1 – point 4

Regulation (EC) No 2015/2283

Article 23 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4b. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 4 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

Amendment 130

Proposal for a regulation

Article 9 – paragraph 1 – point 4 a (new)

Regulation (EU) No 2015/2283

Article 25 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(4a) In Article 25, the following paragraph is added:

“1a. The obligation to proactively disseminate the information set out in this Regulation, in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulations (EC) No 1049/2001 and (EC) No 1367/2006.”

Amendment 131

Proposal for a regulation

Article 9 a (new)

Article 9a

Transparency of risk management

1. The Commission and the Member States shall carry out their risk management activities in the context of the legislative acts referred to in Articles 1 to 9 with a high level of transparency. They shall in particular make public without undue delay:

(a) at an early stage of the risk management process, any envisaged the draft risk management measures;

(b) the agendas and proceedings, detailed summary reports of meetings, and the draft measures, to be adopted, as appropriate, in the form of delegated or implementing acts, including the results and explanations of votes by individual Member States in committees within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council ^{1a}, including the appeal committees, which assist the Commission in the implementation of [Regulation (EC) No 178/2002, Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 2065/2003, Regulation (EC) No 1935/2004, Regulation (EC) No 1331/2008, Regulation (EC) No 1107/2009 and Regulation No 2015/2283], where and in which the risk management measures are discussed and put to a vote; and

(c) the agendas and the detailed minutes of meetings of the Member States working groups in which the risk management measures are discussed.

2. For the purposes of paragraph 1 of this Article, the Commission shall attach to each draft measure to be adopted on in accordance with Article 58 [of the GFL Regulation], Article 30 of Directive

2001/18/EC, Article 35 of Regulation (EC) No 1829/2003, Article 22 of Regulation (EC) No 1831/2003, Article 19 of Regulation (EC) No 2065/2003, Article 23 of Regulation (EC) 1935/2004, Article 14 of Regulation (EC) 1331/2008, Article 79 of Regulation (EC) No 1107/2009, and Articles 30 and 32 of Regulation EU (No) 2015/2283 an explanatory statement comprising:

(a) the reasons for and objectives of the measure;

(b) the justification of the measure taking into consideration both need and proportionality;

(c) the impact of the measure on public and animal health, the environment, on the society and on food manufacturers as indicated by the impact assessment; and

(d) the results of any public consultation, including pursuant to Article 9 of [the GFL Regulation].

^{1a} Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).
