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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 first reading (Strasbourg, 15 to 18 April 2019)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

In this context, the rapporteur, Pilar AYUSO (EPP, ES), presented a compromise amendment (amendment number 171) to the proposal for a Regulation on behalf of the Committee on the Environment, Public Health and Food Safety. This amendment had been agreed during the informal contacts referred to above.

II. VOTE

When it voted on 17 April 2019, the plenary adopted the compromise amendment (amendment number) to the proposal for a Regulation. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto².

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

¹ OJ C 145, 30.6.2007, p. 5.

² The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics***. The symbol "■" indicates deleted text.

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

European Parliament legislative resolution of 17 April 2019 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))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2018)0179),
- having regard to Article 294(2) and Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0144/2018),
- having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 19 September 2018¹,
- having regard to the opinion of the Committee of the Regions of 10 October 2018²,
- having regard to the provisional agreement approved by the committee responsible under Rule 69f(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 15 February 2019 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
- having regard to Rules 59 and 39 of its Rules of Procedure,
- having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Fisheries and the Committee on Legal Affairs (A8-0417/2018),

¹ OJ C 440, 6.12.2018, p. 158.

² OJ C 461, 21.12.2018, p. 225.

1. Adopts its position at first reading hereinafter set out¹;
2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ This position replaces the amendments adopted on 11 December 2018 (Texts adopted, P8_TA(2018)0489).

P8_TC1-COD(2018)0088

Position of the European Parliament adopted at first reading on 17 April 2019 with a view to the adoption of Regulation (EU) 2019/... of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article **43(2)**, Article 114 and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure³,

¹ OJ C 440, 6.12.2018, p. 158.

² OJ C 461, 21.12.2018, p. 225.

³ Position of the European Parliament of 17 April 2019.

Whereas:

- (1) Regulation (EC) No 178/2002 of the European Parliament and of the Council¹ lays down the general principles and requirements of food law, so as to form a common basis for measures governing food law at both Union and national level. It provides, inter alia, that food law is to be based on risk analysis, except where this is not appropriate to the circumstances or the nature of the measure.
- (2) Regulation (EC) No 178/2002 defines risk analysis as a process consisting of three interconnected components: risk assessment, risk management, and risk communication. For the purposes of risk assessment at Union level, it establishes the European Food Safety Authority (the ‘Authority’), as the responsible Union risk assessment body in matters relating to food and feed safety.

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (3) Risk communication is an essential part of the risk analysis process. ■ The REFIT evaluation of the general food law (Regulation (EC) No 178/2002) of 2018 ('Fitness Check of the General Food Law') found that risk communication is not considered to be effective enough overall. This has an impact on consumers' confidence in the outcome of the risk analysis process.
- (4) It is necessary, therefore, to ensure **transparent**, continuous **and inclusive** risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers. Such risk communication should **strengthen citizens' trust that the risk analysis is underpinned by the objective of ensuring a high level of protection of human health and consumers' interests. That risk communication should also be capable of contributing to a participatory and** open dialogue between all interested parties in order to ensure that the **prevalence of the public interest, and accuracy, comprehensiveness, transparency**, consistency **and accountability** are taken into account in the risk analysis process.

- (5) *Risk communication should place particular emphasis ■ on explaining in **an accurate, clear, comprehensive**, coherent, appropriate and timely manner not only risk assessment findings themselves but also how such findings are **used** to help inform risk management decisions along with other legitimate factors, where relevant. **Information should be provided on how risk management decisions were reached and on the factors, other than the results of the risk assessment, which were considered by the risk managers, as well as how those factors were weighed up against each other.***
- (6) *Given the ambiguity in the public perception of the difference between hazard and risk, risk communication should endeavour to clarify that distinction and thereby ensure that such distinction is better understood by the general public.*
- (7) *Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health due to non-compliance resulting from intentional violations of applicable Union law perpetrated through fraudulent or deceptive practices, public authorities, identifying to the fullest extent possible the products concerned and the risk that they may present, should inform the public accordingly as soon as possible.*

- (8) ***It is necessary to establish general objectives and principles of risk communication, taking into account the respective roles of risk assessors and managers, while guaranteeing their independence.***
- (9) On the basis of the general objectives and principles, a general plan on risk communication should be established in close cooperation with the Authority and Member States, and following relevant public consultations. ***That general plan should promote an integrated risk communication framework for all risk assessors and risk managers at Union and national level on all matters relating to the food chain. It should also allow for the necessary flexibility and should not deal with situations specifically covered by the general plan for crisis management.***
- (10) The general plan on risk communication should identify the key factors to be taken into account when ***considering the type and level of*** risk communication activities ***needed***, such as the different levels of risk, the nature of the risk and its potential ***impact on*** human health, ***animal health and, where relevant, the environment***, who and what are directly or indirectly affected by the risk, the levels of exposure ***to a hazard, the level of urgency and*** the ability to control risk, and other factors that influence risk perception, including the applicable legal framework and relevant market context.

- (11) The general plan on risk communication should also identify the tools and channels to be used and should establish appropriate mechanisms ***of coordination and cooperation between the risk assessors and risk managers at Union and national level involved in the risk analysis process, in particular where several Union agencies provide scientific outputs on the same or on related subject matters,*** to ensure coherent risk communication ***and an open dialogue amongst all interested parties.***
- (12) Transparency of the risk assessment process contributes to greater legitimacy of the Authority being acquired in the eyes of the consumers and general public in the pursuit of 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 ***strengthen*** the confidence of the general public and other interested parties in the risk analysis underpinning the relevant Union law, and in particular in the risk assessment, including the transparency thereof as well as the organisation, ***functioning*** and independence of the Authority.
- (13) It is appropriate to ***increase the role of Member States as well as the effort and engagement of all parties involved in*** the Management Board of the Authority (the ‘Management Board’).

- (14) Experience shows that the role of the Management Board is focused 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, *of the European Parliament and of the Commission as well as of civil society and industry organisations* in the Management Board, ■ while providing that those representatives should have experience *and expertise not only in the fields of food chain law and policy, including risk assessment, but also in the fields of managerial, administrative, financial and legal matters and ensuring that they act independently in the public interest.*
- (15) The *members of the* Management Board should be selected and appointed in such a way as to secure the highest standards of competence and the broadest range of relevant experience available.

- (16) 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 Authority's 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 of high level of scientific expertise, independence and multidisciplinary expertise.
- (17) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the *selection by the Authority's Executive Director and the appointment by the Management Board* of the members of the Authority's Scientific *Committee and Scientific* Panels ■ be based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Scientific Panel. It is essential to that end that the Executive Director, whose function is to defend *the Authority's* interests and in particular the independence of its expertise, have a role in the selection ■ of those scientific experts. *The Management Board should endeavour to ensure, to the largest extent possible, that experts appointed as members of the Scientific Panels are scientists who are also actively conducting research, and publishing their research findings in peer-reviewed scientific journals, provided that they comply with the strict criteria of excellence and independence. Proper financial compensation of the experts should be ensured.* Further measures should also be put in place to ensure that scientific experts have the means to act independently.

- (18) 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 Scientific Committee and the Scientific Panels. In particular, the Authority should organise the preparatory work supporting the tasks of the Scientific Panels, 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 those Scientific Panels. *That should be without prejudice to the independence of the Authority's scientific assessments.*
- (19) Authorisation procedures are based on the principle that it is for the applicant *or the notifier* to prove that the subject matter of an *application or notification* complies with Union **■** requirements. That principle is based on the premise that human health, animal health *and, where relevant, the environment* are better protected where the burden of proof is on the applicant *or the notifier* since it has to prove that the subject matter of its application or notification is safe prior to its placing on the market, instead of the public authorities having to prove that that subject matter is unsafe in order to be able to ban it from the market. **■** In accordance with that principle and the applicable regulatory requirements, in support of applications *or notifications* under Union sectoral **■** law, applicants *or notifiers* are required to submit relevant studies, including tests, to demonstrate the safety and, in some cases, the efficacy of a subject matter.

- (20) Union law provides for the content of applications *and notifications*. It is essential that the application *or notification* ■ submitted to the Authority for its risk assessment meet the applicable specifications to ensure the best quality scientific assessment by the Authority. Applicants or notifiers and in particular small and medium-sized enterprises do not always have a clear understanding of those specifications. It *is* thus appropriate that, *where* the Authority *may be requested to provide a scientific output, it should provide* advice to a potential applicant or notifier upon request, before an application *or notification* is formally submitted. *Such pre-submission advice should relate to* the rules applicable to, and the content required for, an application *or notification* and should not address the design of the studies to be submitted, as that remains the applicant's responsibility. ■

- (21) *Where the Authority may be requested to provide a scientific output, it should have knowledge ■ of all studies performed by an applicant with a view to supporting an application ■ under Union ■ law. To that end, it is necessary and appropriate that, when business operators commission or carry out studies with a view to submitting an application or notification, they notify those studies to the Authority. The obligation to notify such studies should also apply to the laboratories and other testing facilities carrying them out. Information about the notified studies should be made public only once a corresponding application ■ has been made public in accordance with the applicable rules on transparency. In order to ensure effective implementation of that obligation, it is appropriate to provide for certain procedural consequences in the event of non-compliance . The Authority should, in that context, lay down practical arrangements to implement that obligation, including procedures for requesting and making public the justifications for the non-compliance.*

- (22) *In accordance with Directive 2010/63/EU of the European Parliament and of the Council¹, tests on animals should be replaced, reduced or refined. Therefore, within the scope of this Regulation, duplication of animal testing should be avoided, where possible.*
- (23) In the case of applications or notifications to request the renewal of an authorisation or an approval, the authorised or approved substance or product has already been on the market for several years. Experience and knowledge therefore already exist with regard to that substance or product. *Where the Authority may be requested to provide a scientific output, it is* ■ *appropriate for studies planned for supporting requests for renewals, including information on the proposed design, that have been notified by the applicant or the notifier to the Authority, to be submitted for consultation of third parties. The Authority should systematically provide advice to the applicants or to the notifiers on the content of the intended renewal application or notifications, as well as on the design of studies, taking into account the comments received.*

¹ 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).

- (24) There are certain public concerns about the Authority's assessment in the area of ***authorisation procedures*** being primarily based on industry studies. ***It is of utmost importance that the*** Authority ***carry out*** 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 to ensure that the Authority can have access to all relevant scientific data and studies available on a subject matter of an ***application or a notification for an*** authorisation ***or a renewal of an authorisation or an approval***, it is appropriate to provide for 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 or a notification ***are made public, under the applicable transparency rules. Where there is a risk that the results of a public consultation cannot be given proper consideration because of the applicable deadlines, it is appropriate to provide for a limited extension of those deadlines.***

- (25) Food safety is a sensitive matter of prime interest for all Union citizens. While maintaining the principle that the burden to prove compliance with Union requirements is on the industry, it is important to establish an additional verification tool, namely the commissioning of additional studies with the objective of verifying evidence used in the context of risk assessment to address specific cases of high societal importance where there ***are serious controversies or conflicting results*** . Considering that those verification studies would be financed from the Union budget and that the use of this exceptional verification tool should remain proportionate, the Commission, ***taking into account the views expressed by the European Parliament and by Member States***, should be responsible for triggering the commissioning of such verification studies. Account should be taken of the fact that in some specific cases the verification studies commissioned may need to have a wider scope than the evidence at stake, for example, in cases where new scientific developments become available.

- (26) The Fitness Check of the General Food Law demonstrated that, although the Authority has made considerable progress in terms of transparency, the risk assessment process, especially in the context of authorisation procedures covering the food chain, is not always perceived as fully transparent. That is also partly due to the different transparency and confidentiality rules that are laid down in Regulation (EC) No 178/2002 and in other Union *sectoral* legislative acts ■ . The interplay among those acts can have an impact on the acceptance of the risk assessment by the general public.
- (27) The European citizens' initiative entitled '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 ■ procedures.

- (28) It is therefore necessary to strengthen the transparency of the risk assessment in a proactive manner. **All** scientific data and information supporting requests for authorisations or for approvals under Union ■ law as well as other requests for scientific output should be ***made publicly available in a proactive manner and be easily accessible*** as early as possible in the risk assessment process. However, such disclosure to the public should be without prejudice to ***any rules concerning*** intellectual property rights or to any provisions of Union ■ law protecting the investment made by innovators in gathering the information and data supporting relevant applications or notifications. ***It should be ensured that such disclosure to the public is not considered to be permission for further uses or exploitation, without jeopardising the proactive character of disclosure to the public and the easy public access to the disclosed data and information.***
- (29) ***To ensure the transparency of the risk assessment, a summary of the pre-submission advice should be made public only once a corresponding application or notification has been made public in accordance with the applicable rules on transparency.***
- (30) Where the opinion of the Authority is requested in relation to ***applications or notifications submitted*** under Union ■ law, and having regard to its obligation to ensure public access to all supporting information with respect to the provision of its scientific outputs, the Authority should have responsibility for assessing confidentiality requests.

- (31) To determine what level of **proactive** disclosure to the public strikes the appropriate balance, the relevant rights of the public to transparency in the risk assessment process, should be weighed up against the rights of ■ applicants or notifiers, taking into account the objectives of Regulation (EC) No 178/2002.
- (32) With respect to the **application or notification** procedures provided for in Union ■ law, experience gained so far has shown that certain items of information are generally considered sensitive and should remain confidential across the different sectoral ■ procedures. It is therefore appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of items of information whose disclosure, as **demonstrated by the applicant or the notifier, will potentially** harm the commercial interests concerned **to a significant degree** and which should not therefore be disclosed to the public . **Those items should include the manufacturing and production process, including the method and innovative aspects thereof, as well as technical and industrial specifications, such as impurities, inherent to that process other than information which is relevant to the assessment of safety.** Only in very limited and exceptional circumstances relating to foreseeable health effects **or, where an environmental assessment is required under Union sectoral law, to environmental effects, or where relevant authorities have identified** urgent needs to protect human health, animal health or the environment, **should** such information be disclosed.

- (33) For the purposes of clarity and to increase legal certainty, it is necessary to set out the specific procedural requirements to be followed *by an applicant or by a notifier* in respect of a request for information submitted *to support an application or a notification* under Union  law to be treated in a confidential manner.
- (34) It is also necessary to set out specific requirements with respect to the protection *and confidentiality* of personal data for the purposes of the transparency of the risk assessment process, taking into account Regulations (EU) 2018/1725¹ and (EU) 2016/679² of the European Parliament and of the Council. 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. *In particular, for the purpose of ensuring the transparency and to avoid conflicts of interest, it is necessary to publish the names of the participants and observers in certain meetings of the Authority.*

¹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

² 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).

- (35) For the purpose 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 *should be developed*.
- (36) Having regard to the fact that the Authority would be required to store scientific data, including confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security.
- (37) Furthermore, in order to assess the effectiveness and efficiency of the different legal provisions applicable to the Authority, it is also appropriate to provide for a Commission evaluation of the Authority ■ . That evaluation should, in particular, review the procedures for selecting the members of Scientific Committee and Scientific Panels, for their degree of transparency, cost-effectiveness, and suitability to ensure independence and competence, and to prevent conflicts of interests.

- (38) Studies, including tests, submitted by business operators in support of applications 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, *such as those set by Directive 2004/10/EC of the European Parliament and of the Council¹ or those developed by the International Organization for Standardization*, may arise in some cases and this is why *international and national systems are in place to verify such compliance. It is therefore appropriate for the Commission to carry out fact-finding missions to assess the application by laboratories and other testing facilities of the relevant standards for carrying out tests and studies submitted to the Authority as part of an application. Those fact-finding missions would allow the Commission to identify, and to aim at correcting, possible weaknesses in the systems and non-compliance and to provide an additional level of guarantees to reassure the general public on the quality of studies. Based on the conclusions of such fact-finding missions, the Commission could propose appropriate legislative measures aimed at improving compliance with the relevant standards.*

¹ *Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).*

- (39) In order to ensure consistency with the proposed adaptations in Regulation (EC) No 178/2002, provisions relating to public access and the protection of confidential information in, Regulations (EC) No 1829/2003¹, (EC) No 1831/2003², (EC) No 2065/2003³, (EC) No 1935/2004⁴, (EC) No 1331/2008⁵, (EC) No 1107/2009⁶, (EU) 2015/2283⁷ and in Directive 2001/18/EC⁸ of the European Parliament and of the Council should be amended.

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- ¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
- ² Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).
- ³ Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1).
- ⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).
- ⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).
- ⁶ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).
- ⁷ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).
- ⁸ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

- (40) 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 ■ against the rights of ■ applicants or of notifiers, taking into account the specific objectives of sectoral Union law as well as experience gained. Accordingly, it is necessary to make specific amendments to Regulations (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 1935/2004, **(EC) No 1331/2008**, (EC) No 1107/2009, **(EU) 2015/2283 and** Directive 2001/18/EC in order to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.

- (41) *The rights on access to documents enshrined in Regulation (EC) No 1049/2001 of the European Parliament and of the Council¹ and, where environmental information is concerned, the rights enshrined in Regulation (EC) No 1367/2006² and Directive 2003/4/EC³ of the European Parliament and of the Council are unaffected by this Regulation. The rights provided by those acts should not in any manner be limited by the provisions on proactive dissemination laid down in this Regulation and the relevant assessment of confidentiality request.*
- (42) *In order to ensure uniform conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of a general plan for risk communication and the adoption of standard data formats, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁴.*

¹ *Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).*

² *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).*

³ *Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EE (OJ L 41, 14.2.2003, p. 26).*

⁴ *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).*

- (43) In order to enable *the Commission, Member States*, the Authority and the business operators to adapt to the new requirements set by this Regulation while ensuring that the Authority continues its smooth operation, it is necessary to provide for transitional measures for the application of this Regulation.
- (44) Since the appointment of the members of the Scientific Committee and Scientific Panels depends on the entry in function of the new Management Board, it is necessary to provide for specific transitional provisions allowing a prolongation of the current term of office of the members of the Scientific Committee and Scientific Panels.
- (45) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 of the European Parliament and of the Council¹,

HAVE ADOPTED THIS REGULATION:

¹ 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).

Article 1
Amendments to Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 is amended as follows:

- (1) in Article 6, the following paragraph is added:

"4. Risk communication shall fulfil the objectives and respect the general principles set out in Articles 8a and 8b.";

- (2) in Chapter II, the following Section is inserted:

"SECTION 1a
RISK COMMUNICATION

Article 8a

Objectives of risk communication

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

- (a) ***raise*** awareness and understanding of the specific issues under consideration, ***including in cases of divergences in scientific assessment***, during the entire risk analysis process;

- (b) **ensure** consistency, transparency **and clarity** in formulating risk management recommendations **and decisions**;
- (c) provide a sound basis, **including, where appropriate, a scientific basis**, for understanding risk management decisions;
- (d) **improve the overall effectiveness and efficiency of the risk analysis**;
- (e) foster public understanding of the risk analysis, **including of the respective tasks and responsibilities of risk assessors and risk managers** to enhance confidence in its outcome;
- (f) **ensure** appropriate involvement of **consumers, feed and food businesses, the academic community and all other** interested parties; ■
- (g) ensure appropriate **and transparent** exchange of information with interested parties in relation to risks associated with the ■ food chain;
- (h) **ensure the provision of information to consumers about risk prevention strategies; and**
- (i) **contribute to the fight against the dissemination of false information and the sources thereof.**

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 **and all** appropriate information is exchanged **in an interactive and timely manner 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, **including information on how risk management decisions were reached and which factors were considered**;
- (c) take into account risk perceptions **of all interested parties**;
- (d) facilitate understanding and dialogue amongst all interested parties; and
- (e) be **clear and** accessible, including to those not directly involved in the process **or not having a scientific background, while duly respecting the applicable legal provisions on** confidentiality and protection of personal data.

Article 8c

General plan for risk communication

1. The Commission ***shall adopt, by means of implementing acts,*** a general plan for risk communication ***in order to achieve*** the **■** objectives ***set out in Article 8a, in accordance with the*** general principles set out in ***Article 8b. The Commission shall keep that general plan updated, taking into account technical and scientific progress and experience gained. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2). When preparing those implementing acts, the Commission shall consult the Authority.***
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 communication activities needed;

- (b) identify the *different types and levels of risk communication activities, and the* appropriate main tools and channels to be used for risk communication purposes, taking into account the needs of relevant target audience groups; █
- (c) establish appropriate mechanisms *of coordination and cooperation* in order to strengthen coherence of risk communication amongst risk assessors and risk managers; and
- (d) *establish appropriate mechanisms to ensure an open dialogue amongst consumers, food and feed businesses, the academic community and all other interested parties, and their appropriate involvement.*";

█

(3) *in Article 22(7), the second subparagraph is replaced by the following:*

"It shall act in close cooperation with the competent bodies in the Member States that carry out similar tasks to those of the Authority and, where appropriate, with the relevant Union agencies.";

(4) Article 25 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Each Member State shall nominate a member and an alternate member *as its representatives* to the Management Board. The members and alternate members thus nominated shall be appointed by the Council and have *the right to vote*.";

(b) the following paragraphs are inserted:

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

(a) two members and *two* alternate members appointed by the Commission as its representatives, with the right to vote;

(b) *two members* appointed by the European Parliament, with the right to vote;

- (c) four *members and four alternate* members with the right to vote as representatives of civil society and food chain interests, namely one member and one alternate member from consumer organisations, one member and one alternate member from environmental non-governmental organisations, one member and one alternate member from farmers organisations, and one member and one alternate member from industry organisations.

The members *and alternate members* referred to in point (c) of the first subparagraph shall be appointed by the Council in consultation with the European Parliament on the basis of a list which shall be drawn up by the Commission and sent to the Council. The list shall include more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament by the Council, together with the relevant background documents. As quickly as possible and at the latest within three months of the receipt of that list, the European Parliament may submit its views for consideration to the Council which shall then appoint those members.

- 1b. The members and the alternate members of the Management Board shall be *nominated and appointed on the basis of their relevant experience and expertise in the field of food chain* law and policy, *including risk assessment, whilst ensuring that there is relevant expertise in the fields of managerial, administrative, financial and legal matters within the Management Board.*";
- (c) paragraph 2 is replaced by the following:
- "2. The term of office of members and alternate members shall be four years *and may be renewed*. However, the ■ term of office of the members and alternate members referred to in point (c) of the first subparagraph of paragraph 1a may be *renewed* only once.";
- (d) in paragraph 5, the second subparagraph is replaced by the following:
- "Unless otherwise provided, the Management Board shall act by a majority of its members. Alternate members shall represent the *members* in *their* absence and vote on *their* behalf.";

(5) Article 28 is amended as follows:

(a) paragraph 5 is replaced by the following:

"5. The members of the Scientific Committee who are not members of the Scientific Panels and the ■ members *of the Scientific Panels* shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a five-year term of office, which may be *renewed*, following publication of 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. *The Authority shall publish such a call for expression of interest after having informed the Member States about the necessary criteria and fields of expertise.*

The Member States shall:

- (a) publish the call for expression of interest on the websites of their competent authorities and of their competent bodies which undertake tasks similar to those of the Authority;*
- (b) inform relevant scientific organisations located on their territory;*
- (c) encourage potential candidates to apply; and*
- (d) take any other appropriate measures to support the call for expression of interest.";*

(b) the following paragraphs are inserted:

"5a. The members of the Scientific *Committee who are not members of Scientific Panels and the members of the Scientific* Panels shall be *selected and* appointed ■ in accordance with the following procedure:

- (a) *on the basis of the applications received to a call for expression of interest, the Executive Director shall draw up a draft list of suitable candidates including at least twice the number of candidates necessary to fill the posts in the Scientific Committee and the Scientific Panels and send the draft list to the Management Board, indicating* the specific multidisciplinary expertise needed in each Scientific Panel;
- (b) *on the basis of that draft list, the Management Board shall appoint the members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels and draw up the reserve list of candidates for the scientific Committee and the Scientific Panels;*

■

- (c) the ■ selection *procedure* and the appointments *of the members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels* 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 *implementation of that policy in respect* of the members of the Scientific Panels;
 - (iii) meeting the needs for the specific multi-disciplinary expertise of the Scientific Panel to which they will be appointed and the applicable language regime;
- (d) *where candidates have equivalent scientific expertise, the* Management Board shall ensure that the broadest possible geographical distribution is achieved in the ■ appointments.

- 5b. When the Authority identifies that specific expertise is missing in ***one*** or several Scientific Panels, the Executive Director shall propose ■ to the Management Board, in accordance with the procedure laid down in ***paragraphs 5 and 5a, the appointment of additional members of the relevant Scientific Panels.***
- 5c. 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.
- 5d. ■ Member States ***and employers of*** the members of the Scientific ***Committee and of the Scientific Panels shall refrain from giving those members, or the external experts participating in the working groups of the Scientific Committee or the Scientific Panels, any instruction which is incompatible with the individual tasks of those members and experts, or with the tasks, responsibilities and independence of the Authority.***

- 5e. ■ The Authority shall support the tasks of the *Scientific Committee and Scientific* 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 Article 36, including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Scientific Panels before they adopt them.
- 5f. Each *Scientific* Panel shall include a maximum of 21 members.
- 5g. *Members of Scientific Panels shall have access to comprehensive training on the risk assessment."*
- (c) in paragraph 9, point (b) is replaced by the following:
- "(b) the number of members in each Scientific Panel but no more than the maximum number provided for in paragraph 5f."

(6) the following Articles are inserted:

"Article 32a

Pre-submission advice

1. ***Where Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion, the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on the rules applicable to, and the content required for, the application or notification, prior to its submission. Such advice provided by the staff of the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice.***
2. ***The Authority shall publish general guidance on its website regarding the rules applicable to, and the content required for, applications and notifications, including, where appropriate, general guidance on the design of required studies.***

Article 32b

Notification of studies

1. ***The Authority shall establish and manage a database of studies commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.***
2. ***For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.***
3. ***For the purposes of paragraph 1, laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by business operators and carried out by such laboratories or other testing facilities to support an application or a notification, its starting and planned completion dates, as well as the name of the business operator who commissioned such a study.***

This paragraph shall also apply, mutatis mutandis, to laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49.

4. *An application or notification shall not be considered valid or admissible where it is supported by studies that have not been previously notified in accordance with paragraph 2 or 3, unless the applicant or notifier provides a valid justification for the non-notification of such studies.*

Where studies have not been previously notified in accordance with paragraph 2 or 3, and where a valid justification has not been provided, an application or notification may be re-submitted, provided that the applicant or notifier notifies to the Authority those studies, in particular their title and their scope, the laboratory or testing facility carrying them out as well as their starting and planned completion dates.

The assessment of the validity or the admissibility of such re-submitted application or notification shall commence six months after the notification of the studies pursuant to the second subparagraph.

5. *An application or notification shall not be considered valid or admissible, where studies that have previously been notified in accordance with paragraph 2 or 3 are not included in the application or notification, unless the applicant or notifier provides a valid justification for the non-inclusion of such studies.*

Where the studies which have previously been notified in accordance with paragraph 2 or 3 were not included in the application or notification, and where a valid justification has not been provided, an application or notification may be resubmitted, provided that the applicant or notifier submits all the studies that were notified in accordance with paragraph 2 or 3.

The assessment of the validity or admissibility of such re-submitted application or notification shall commence six months after the submission of the studies pursuant to the second subparagraph.

6. *Where the Authority detects, during its risk assessment, that studies notified in accordance with paragraph 2 or 3 are not included in the corresponding application or notification in full, and in the absence of a valid justification of the applicant or notifier to that effect, the applicable time limits within which the Authority is required to deliver its scientific output shall be suspended. That suspension shall end six months after the submission of all data of those studies.*
7. The Authority shall make public the notified information only in cases where it received a corresponding application or notification and after the Authority has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e.

8. The Authority shall lay down ■ the practical arrangements for implementing the provisions of this Article, including *arrangements for requesting and making public the valid justifications in the cases referred to in paragraphs 4, 5 and 6*. Those arrangements shall ■ be in accordance with this Regulation and other *relevant* Union ■ law.

Article 32c

Consultation of third parties

1. Where the *relevant* Union law provides that an approval or an authorisation, including by means of a notification, may be renewed, the potential applicant or notifier for the renewal shall notify the Authority of the studies it intends to perform for that purpose, *including information on how the various studies are to be carried out to ensure compliance with regulatory requirements*. Following such notification of studies, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal, *including on the proposed design of studies*. *Taking into account the received comments from the* stakeholders and the public *which are relevant for the risk assessment of the intended renewal, the Authority* shall provide advice on the content of the intended renewal application or notification, *as well as on the design of the studies*. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications or notifications for renewal by the Scientific Panels.

2. The Authority shall consult stakeholders and the public *on the basis of the non-confidential version of the application* or notification made public by the Authority in accordance with Articles 38 to 39e, and immediately after such disclosure to the public, in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application or notification. *In duly justified cases, where there is a risk that the results of the public consultation performed in accordance with this paragraph cannot be given proper consideration because of the applicable time limits within which the Authority is required to deliver its scientific output, those time limits may be extended for a maximum period of seven weeks.* This paragraph *is without prejudice to the Authority's obligations under Article 33 and* does not apply to the submission of any supplementary information by the applicants or notifiers during the risk assessment process.
3. The Authority shall lay down ■ the practical arrangements for implementing the procedures referred to in this Article and Article 32a.

■

Article 32d

Verification studies

Without prejudice to the obligation on applicants ■ to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances *of serious controversies or conflicting results*, 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.";

(7) Article 38 is amended as follows:

(a) Paragraph 1 is replaced by the following:

"1. The Authority shall carry out its activities with a high level of transparency. It shall in particular make public:

(a) agendas, *participant lists* and minutes of the *Management Board, the Advisory Forum, the* Scientific Committee and the Scientific Panels and their working groups;

- (b) all its scientific outputs, including the opinions of the Scientific Committee and the Scientific Panels after adoption, minority opinions and results of consultations performed during the risk assessment process always being included;
- (c) scientific data, studies and other information supporting applications ■ , 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 protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;
- (d) the information on which its scientific outputs, including scientific opinions are based, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;

- (e) the annual declarations of interest made by the members of the Management Board, the Executive Director and the members of the Advisory Forum, the Scientific Committee and the Scientific Panels, as well as the members of the working groups, and the declarations of interest made in relation to items on the agendas of meetings;
- (f) its scientific studies in accordance with Articles 32 and 32*d*;
- (g) the annual report of its activities;
- (h) requests from the European Parliament, from the Commission or from a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification ■ ;
- (i) *a summary of the advice* provided ■ to potential applicants at pre-submission phase pursuant to Articles 32a and 32c.

Information referred to in the first subparagraph shall be made public without delay, with the exception of the information referred to in point (c) thereof, as far as applications are concerned, and in point (i) thereof, which shall be made public without delay once an application has been considered valid or admissible.

The information referred to in the second subparagraph shall be made public in a dedicated section of the Authority's website. That dedicated section shall be publicly available and easily accessible. That information shall be available to be downloaded, printed and searched through in an electronic format.";

(b) the following paragraph is inserted:

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

- (a) ■ any *existing rules concerning* intellectual property *rights which set out limitations on certain uses of the disclosed* documents or their content; and
- (b) any provisions set out in Union ■ law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').

The disclosure to the public of the information referred to in point (c) of ***the first subparagraph of*** paragraph 1 shall not be considered to be explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited ***in breach of any intellectual property right or data exclusivity rules***, and the Union shall not be responsible for its use by third parties. ***The Authority shall ensure that clear undertakings or signed statements are given to that effect by those who access the relevant information prior to its disclosure.***";

(c) paragraph 3 is replaced by the following:

"3. The Authority shall lay down ■ the practical arrangements for implementing the transparency rules referred to in paragraphs 1, 1a and 2 of this Article, taking into account Articles 39 to 39g and 41.";

(8) Article 39 is replaced by the following:

"Article 39

Confidentiality

1. By way of derogation from Article 38, the Authority shall not make public any information for which confidential treatment has been requested under the conditions laid down in this Article.
2. *Upon the request of an applicant*, the Authority may **grant** confidential treatment *only with respect to the following items of information where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:*
 - (a) the *manufacturing or production process, including the* method and *innovative aspects thereof, as well as* other technical and industrial specifications *inherent* to that *process or* method, *except for information which is relevant to the assessment of safety;*

- (b) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
 - (c) commercial information revealing sourcing, market shares or business strategy of the applicant; and
 - (d) quantitative composition of the subject matter of the request, *except for information which is relevant to the assessment of safety*.
3. The list of information referred to in paragraph 2 shall be without prejudice to any *sectoral* Union law.
4. Notwithstanding paragraphs 2 and 3:
- (a) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to *in* paragraphs 2 and 3 ;
 - (b) *information* which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable effects *on human health, animal health or the environment, shall nevertheless be made public.*";

(9) the following Articles are inserted:

"Article 39a

Confidentiality request

1. When submitting an application ■, supporting scientific data and other supplementary information in accordance with Union ■ law, the applicant may request certain parts of the information submitted to be treated as confidential in accordance with Article 39(2) and (3). Such request shall be accompanied by verifiable justification that demonstrates how making public the information concerned significantly harms the interests concerned in accordance with Article 39(2) and (3).
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 not include the information the applicant deems confidential *on the basis of* Article 39(2) and (3) *and shall indicate the places where such information has been deleted*. 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.

Article 39b

Decision on confidentiality

1. The Authority shall:

- (a) make public ■ the non-confidential version *of the application* as submitted by the applicant *without delay once that application has been considered valid or admissible*;
- (b) proceed, without delay, to a concrete and individual examination of the confidentiality request in accordance with this Article;
- (c) inform the applicant in writing of its intention to disclose information and the reasons for that, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority, the applicant may state its views or withdraw its application within two weeks of the date on which it was notified of the Authority's position;

- (d) adopt a reasoned decision on the confidentiality request, taking into account the observations of the applicant, within 10 weeks of the date of receipt of the confidentiality request with respect to applications and without delay in the case of supplementary data and information; notify the applicant *of its decision and provide information on the right to submit a confirmatory application in accordance with paragraph 2;* and inform the Commission and the Member States, *where* appropriate, of its decision; and
- (e) make public any additional data and information for which the confidentiality request has not been accepted as justified at the earliest two weeks after the notification of its decision to the applicant has taken place pursuant to point (d).

2. *Within two weeks of the notification of the Authority's decision on the confidentiality request to the applicant pursuant to paragraph 1, the applicant may submit a confirmatory application asking the Authority to reconsider its decision. The confirmatory application shall have suspensive effect. The Authority shall examine the grounds for the confirmatory application and shall adopt a reasoned decision on that confirmatory application. It shall notify the applicant of that decision within three weeks of submitting the confirmatory application and shall include in that notification information on the available remedies, namely an action before the Court of Justice of the European Union (the 'Court of Justice') against the Authority pursuant to paragraph 3. The Authority shall make public any additional data and information for which the confidentiality request has not been accepted by the Authority as justified, at the earliest two weeks after the notification of the Authority's reasoned decision on the confirmatory application to the applicant has taken place pursuant to this paragraph.*
3. Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice, under the conditions laid down in Articles 263 and 278 of the Treaty on the Functioning of the European Union (TFEU) respectively.

Article 39c

Review of confidentiality

Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential may nevertheless be made public in accordance with point (b) of Article 39(4). Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply *mutatis mutandis*.

Article 39d

Obligations with regard to confidentiality

1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application ■ or to a request by the European Parliament, by the Commission or by the Member States for a scientific output, including a scientific opinion, unless otherwise indicated in Union ■ law.

2. The Commission and the Member States shall take the necessary measures so that information received by them under Union ■ 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 final. 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.
3. If an applicant ■ withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of ■ information as ***granted*** by the Authority in accordance with Articles 39 to 39e. The application shall be considered withdrawn as of the moment the written request to that effect is received by the competent body that had received the original application. Where the withdrawal of the application takes place before ***a final decision*** on the ■ confidentiality request ***has been adopted by the Authority pursuant to, where appropriate, Article 39b(1) or (2)***, the Commission, the Member States and the Authority, shall not make public the information for which confidentiality has been requested.

4. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of the obligation of professional secrecy pursuant to Article 339 TFEU.
5. The Authority shall lay down in *consultation with the Commission* the practical arrangements for implementing the confidentiality rules laid down in Articles 39, 39a, 39b, 39e and in this Article, including arrangements concerning the submission and treatment of confidentiality requests with respect to information to be made public under Article 38, and taking into account Articles 39f and 39g. *As regards Article 39b(2), the Authority shall ensure that appropriate separation of tasks is applied for the assessment of confirmatory applications.*

Article 39e

Protection of personal data

1. With respect to requests for scientific outputs, including scientific opinions under Union law, the Authority shall always make public:
 - (a) the name and address of the applicant;
 - (b) the names of authors of published or publicly available studies supporting such requests; and
 - (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 matter*.
2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available *unless otherwise specified in* Regulations (EU) 2016/679¹ and (EU) 2018/1725² of the European Parliament and of the Council.

¹ 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).

² Regulation (EU) 2018/1725 of the European Parliament and of the Council of **23 October 2018** on the protection of *natural persons* with regard to the processing of personal data by the *Union* institutions, bodies, *offices and agencies* and on the free movement of such data, *and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)*.

3. Regulations (EU) 2016/679 and **(EU) 2018/1725** shall apply to the processing of personal data carried out pursuant to this Regulation. Any personal data made public pursuant to Article 38 of this Regulation and this Article shall only be used to ensure the transparency of the risk assessment under this Regulation and shall not be further processed in a manner that is incompatible with these purposes, in accordance with point (b) of Article 5(1) of Regulation (EU) 2016/679 and point (b) of Article 4(1) of Regulation **(EU) 2018/1725**, as the case may be.

Article 39f

Standard data formats

1. For the purposes of point (c) of Article 38(1) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats ■ shall be adopted in accordance with paragraph 2 of this Article to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union ■ law. Those ■ standard data formats ■ shall:
 - (a) not be based on proprietary standards;
 - (b) ensure interoperability with existing data submission approaches to the extent possible;
 - (c) *be user-friendly and adapted for the use by small and medium-sized enterprises.*
2. For the adoption of standard data formats referred to in paragraph 1 ■, the following procedure shall be followed:
 - (a) the Authority shall draw up draft standard data formats ■ for the purposes of the different authorisation procedures ■ and relevant requests for a scientific output by the European Parliament, by the Commission and by the Member States;

- (b) the Commission shall, taking into account the applicable requirements in the different authorisation procedures and other legal frameworks and following any necessary adaptations, adopt, by means of implementing acts, standard data formats [REDACTED]. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2);
- (c) the Authority shall make the standard data formats [REDACTED], as adopted, available on its website;
- (d) where standard data formats [REDACTED] have been adopted pursuant to this Article, applications as well as requests for a scientific output, including a scientific opinion by the European Parliament, by the Commission and by the Member States [REDACTED], shall only be submitted in accordance with *those* standard data formats.

Article 39g

Information systems

The information systems operated by the Authority to store its data, including confidential and personal data shall be designed *in a way that guarantees that any access to it is fully auditable and that the highest standards* of security appropriate to the security risks at stake *are attained*, taking into account Articles 39 to 39f. [REDACTED]";

(10) in Article 40(3), the second subparagraph is replaced by the following:

"The Authority shall make public all scientific outputs including the scientific opinions issued by it and supporting scientific data and other information in accordance with Articles 38 to 39e.";

(11) Article 41 is amended as follows **■** :

(a) paragraph 1 is replaced by the following:

"1. Notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation, Regulation (EC) No 1049/2001 of the European Parliament and of the Council* shall apply to documents held by the Authority.

Where environmental information is concerned, **■** Regulation (EC) No 1367/2006 of the European Parliament and of the Council ****■** *shall also apply. Directive 2003/4/EC of the European Parliament and of the Council*** shall apply to environmental information held by Member States, notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation.*

*** Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).**

**** 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).**

Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).";

(b) paragraph 2 is replaced by the following:

"2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 by ... [six months after the date of entry into force of this amending Regulation], ensuring as wide access as possible to documents in its possession.";

(12) Article 61 is replaced by the following:

"Article 61

Review clause

1. The Commission shall ensure the regular review of the application of this Regulation.

2. By ...[five years after the date *of application of this amending* Regulation], and every five years thereafter, the Commission shall evaluate the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. *That evaluation shall also cover the impact of Article 32a on the functioning of the Authority with particular attention to the relevant workload and mobilisation of staff, and to any shifts in the allocation of the Authority's resources that may have taken place, at the expense of activities of public interest.* That evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.
3. *In the evaluation referred to in paragraph 2, the Commission shall also evaluate whether the organisational framework of the Authority needs to be further updated with regard to decisions on requests for confidentiality and confirmatory applications, namely by setting up a specific Board of Appeal or by other appropriate means.*
4. Where the Commission considers that the **continued operation** 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.

5. The Commission shall report to the European Parliament, to the Council and to the Management Board on the findings of its reviews and evaluations under this Article. Those findings shall be made public.";

(13) the following Article is inserted:

"Article 61a

Fact-finding missions

■ Commission experts shall perform *fact-finding missions in Member States to assess the application, by laboratories and by other testing facilities, of the relevant standards for carrying out tests and studies submitted to the Authority as part of an application, as well as compliance with the notification obligation set out in Article 32b(3), by ...[four years after the date of application of this amending Regulation]. By that date, Commission experts shall also perform fact-finding missions to assess the application of those standards by laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49.*

Non-compliance identified during those fact-finding missions shall be brought to the attention of the Commission, Member States, the Authority as well as the assessed laboratories and other testing facilities. The Commission, the Authority and Member States shall ensure the appropriate follow-up to such identified non-compliance.

The outcome of these fact-finding missions shall be presented in an overview report. On the basis of that report, the Commission shall submit a legislative proposal, if appropriate, as regards, in particular, any necessary control procedures, including audits."

Article 2

Amendments to Regulation (EC) No 1829/2003

Regulation (EC) No 1829/2003 is amended as follows:

(1) in Article 5, paragraph 3 is amended as follows:

(a) the introductory wording is replaced by the following:

"The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall be accompanied by the following:";

(b) point (l) is replaced by the following:

"(l) an identification of the parts of the application and any other supplementary information that the applicant requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 30 of this Regulation and Article 39 of Regulation (EC) No 178/2002;"

(c) the following point is added:

"(m) a summary of the dossier in a standardised form.";

(2) in Article 6, paragraph 7 is replaced by the following:

"7. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 *to 39e* of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.";

(3) in Article 10, paragraph 1 is replaced by the following:

"1. On its own initiative or following a request from the Commission or from a Member State, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) of this Regulation still meets the conditions set out in this Regulation. It shall forthwith transmit that opinion to the Commission, Member States and the authorisation-holder. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with *Articles 39 to 39e* of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.";

(4) in Article 11(2), the introductory wording is replaced by the following:

"2. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following:";

(5) in Article 17, paragraph 3 is amended as follows:

(a) the introductory wording is replaced by the following:

"The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following:";

(b) point (l) is replaced by the following:

"(l) an identification of the parts of the application and any other supplementary information that the applicant requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 30 of this Regulation and Articles 39 to 39e of Regulation (EC) No 178/2002;"

(c) the following point is added:

"(m) a summary of the dossier in a standardised form.";

(6) in Article 18, paragraph 7 is replaced by the following:

"7. The Authority shall, in accordance with Article 38(1) of Regulation (EC) No 178/2002, make its opinion public, after the deletion of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.";

(7) in Article 22, paragraph 1 is replaced by the following:

"1. On its own initiative or following a request from the Commission or from a Member State, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set out in this Regulation. It shall forthwith transmit that opinion to the Commission, Member States and the authorisation-holder. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.";

(8) in Article 23(2), the introductory wording is replaced by the following:

"2. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following:";

(9) in Article 29, paragraphs 1 and 2 are replaced by the following:

"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 Articles 38 to 39e of Regulation (EC) No 178/2002 and taking into account Article 30 of this Regulation.

2. The Authority shall apply Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents* when handling applications for access to documents held by the Authority.

* ***Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43)."***

(10) Article 30 is replaced by the following:

"Article 30

Confidentiality

1. In accordance with the conditions and the procedures laid down in **Articles** 39 to 39e of Regulation (EC) No 178/2002 and this Article:
 - (a) the applicant may submit a request to treat certain ***parts of the*** information submitted under this Regulation as confidential, accompanied by verifiable justification; and
 - (b) the Authority shall assess the confidentiality request submitted by the applicant.
2. In addition to ***the items of information referred to in points (a), (b) and (c) of*** Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also ***grant*** confidential treatment ***with respect*** to the following information, ***where*** the disclosure of ***such information is demonstrated by the applicant to potentially harm its*** interests ***to a significant degree***:
 - (a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and

- (b) breeding patterns and strategies.
- 3. The use of the detection methods and the reproduction of the reference materials, provided under Articles 5(3) and 17(3) for the purpose of applying this Regulation to GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.
- 4. ***This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002."***

Article 3

Amendments to Regulation (EC) **No** 1831/2003

Regulation (EC) No 1831/2003 is amended as follows:

(1) Article 7 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. An application for an authorisation as provided for in Article 4 of this Regulation shall be sent to the Commission, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply mutatis mutandis. The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority (hereinafter referred to as the ‘Authority’).”;

(b) in paragraph 2, point (c) is replaced by the following:

"(c) **make** public ■ the application and any information supplied by the applicant, in accordance with Article 18.";

(2) Article 18 is replaced by the following:

"Article 18

Transparency and confidentiality

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, in accordance with Articles 38 to 39e ■ of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.
2. In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and in this Article, the applicant may submit a request to treat certain ***parts of the*** information submitted under this Regulation as confidential, accompanied by verifiable justification. The Authority shall assess the confidentiality request submitted by the applicant.

3. In addition to *the items of information referred to in* Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also *grant* confidential treatment *with respect* to the following items of information, *where* the disclosure of *such information is demonstrated by the applicant to potentially harm its* interests *to a significant degree*:
- (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) of, 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.
4. *This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002."*

Article 4
Amendments to Regulation (EC) No 2065/2003

Regulation (EC) No 2065/2003 is amended as follows:

(1) Article 7 is amended as follows:

(a) in paragraph 2, point (c) is replaced by the following:

"(c) The Authority shall:

- (i) inform without delay the Commission and the other Member States of the application and shall make the application and any supplementary information supplied by the applicant available to them; and
- (ii) **make public** ■ the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 14 and 15.";

(b) paragraph 4 is replaced by the following:

"4. The Authority shall publish detailed guidance, following the agreement with the Commission, concerning the preparation and the submission of the application, referred to in paragraph 1 of this Article, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002.";

(2) in Article 14, paragraph 1 is replaced by the following:

"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, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.";

(3) Article 15 is replaced by the following:

"Article 15

Confidentiality

1. In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002:

- (a) the applicant may submit a request to treat certain *parts of the* information submitted under this Regulation as confidential, accompanied by verifiable justification; and
- (b) the Authority shall assess the confidentiality request submitted by the applicant.

2. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002."

Article 5
Amendments to Regulation (EC) No 1935/2004

Regulation (EC) No 1935/2004 is amended as follows:

(1) Article 9 is amended as follows:

(a) in paragraph 1, point (c) is replaced by the following:

"(c) the Authority shall without delay:

- (i) inform the Commission and the other Member States of the application and shall make the application and any supplementary information supplied by the applicant available to them; and
- (ii) **make public** ■ the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 19 and 20.";

(b) paragraph 2 is replaced by the following:

"2. The Authority shall publish detailed guidelines, following the agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.";

(2) in Article 19, paragraph 1 is replaced by the following:

"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, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis* and with Article 20 of this Regulation.";

(3) Article 20 is replaced by the following:

"Article 20

Confidentiality

1. In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and in this Article:

- (a) the applicant may submit a request to treat certain *parts of the* information submitted under this Regulation as confidential, accompanied by verifiable justification; and
- (b) the Authority shall assess the confidentiality request submitted by the applicant.

2. In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also **grant** confidential treatment **with respect** to the following items of information, **where** the disclosure of **such information is demonstrated by the applicant to potentially harm its interests to a significant degree**:
- (a) any information provided in detailed descriptions of starting substances and **mixtures** used to manufacture the substance subject to the authorisation, the composition of **mixtures**, materials or articles in which the applicant intends to use that substance, the manufacturing methods of those **mixtures**, materials or articles, impurities, and migration testing results, **except for information which is relevant to the assessment of safety**;
 - (b) the trademark under which the substance shall be marketed as well as the tradename of the **mixtures**, material or articles in which it shall be used, where applicable; and
 - (c) any other information deemed confidential within the specific procedural rules referred to in point (n) of Article 5(1) of this Regulation.
3. ***This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.***

Article 6
Amendments to Regulation (EC) No 1331/2008

Regulation (EC) No 1331/2008 is amended as follows:

- (1) in Article 6, the following paragraph is added:

"5. The Authority shall **make** public ■ the additional information supplied by the applicant in accordance with Articles 11 and 12.";

- (2) Article 11 is replaced by the following:

"Article 11
Transparency

Where the Commission requests the opinion of the Authority in accordance with Article 3(2) of this Regulation, the Authority shall make public **without delay** the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles **38** to 39e ■ of Regulation (EC) No 178/2002. The Authority shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.";

(3) Article 12 is replaced by the following:

"Article 12

Confidentiality

1. The applicant may submit a request to treat certain ***parts of the*** information submitted under this Regulation be as confidential, accompanied by verifiable justification, upon submission of the application.
2. Where an opinion by the Authority is required in accordance with Article 3(2) of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.
3. ***In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:***
 - (a) ***where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety;***

- (b) where applicable, detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety.*
4. Where an opinion by the Authority is not required in accordance with Article 3(2) of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 3 of this Article shall apply mutatis mutandis.
5. *This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002."*

Article 7
Amendments to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended as follows:

(1) Article 7 is amended as follows:

(a) *in* paragraph 1, the first subparagraph is replaced by the following:

"**1** An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State (the ‘rapporteur Member State’), together with a summary and a complete dossier as provided for in Article 8(1) and (2) of this Regulation or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4 of this Regulation. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.";

(b) paragraph 3 is replaced by the following:

"3. When submitting the application, the applicant may submit a request, pursuant to Article 63, to treat certain information, including certain parts of the dossier, to be as confidential and shall physically separate that information.

Member States shall assess the confidentiality requests. *After* consultation with the Authority, the rapporteur Member States shall decide what information is to be treated as confidential, in accordance with Article 63.

The Authority, following consultations with the Member States, shall lay down practical arrangements to ensure the consistency of those assessments."

(2) Article 10 is replaced by the following:

"Article 10

Public access to the dossiers

The Authority shall without delay make the dossiers referred to in Article 8, including any supplementary information supplied by the applicant, available to the public, *with the exception of* any information *to* which *the rapporteur Member State has granted* confidential treatment **■** pursuant to Article 63.";

(3) In Article 15, paragraph 1 is replaced by the following:

"1. The application provided for in Article 14 of this Regulation shall be submitted by a producer of the active substance to a Member State, with a copy to the Commission, to the other Member States and to the Authority, no later than three years before the expiry of the approval. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.";

(4) Article 16 is replaced by the following:

"Article 16

Public access to the information for renewal

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 ***granted*** by the Authority pursuant to Article 63.

The Authority, following consultations with the Member States, shall lay down practical arrangements to ensure the consistency of those assessments.";

(5) in Article 63, paragraphs 1, 2 and 3 are replaced by the following:

"1. *An* applicant may submit a request to treat certain ***parts of the*** information submitted under this Regulation as confidential, accompanied by verifiable justification.

2. ***Confidential*** treatment may be ***granted only*** with respect to the ■ following items of information, ***where*** the disclosure of ***such information is demonstrated by the applicant to potentially harm its*** interests ***to a significant degree***:

(a) ***information referred to in Article 39(2) of Regulation (EC) No 178/2002;***

(b) the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities;

(c) results of production batches of the active substance including impurities; and

(d) information on the complete composition of a plant protection product.

2a. ***Where the Authority assesses confidentiality requests under this Regulation, the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and paragraph 2 of this Article shall apply.***

2b. Where Member States assess confidentiality requests under this Regulation, the following requirements and procedures apply:

- (a) confidentiality treatment may only be granted with respect to information listed in paragraph 2;***
- (b) where the Member State has decided which information is to be treated as confidential, it shall inform the applicant of its decision;***
- (c) Member States, the Commission and the Authority shall take the necessary measures so that information for which confidential treatment has been granted is not made public;***
- (d) Article 39e of Regulation (EC) No 178/2002 shall also apply mutatis mutandis;***
- (e) notwithstanding paragraph 2 and points (c) and (d) of this paragraph:***
 - (i) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Member State may disclose the information referred to in paragraph 2;***

- (ii) *information which forms part of the conclusions of the scientific outputs delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment shall nevertheless be made public. In that case, Article 39c of Regulation (EC) No 178/2002 shall apply;*
- (f) *if the applicant withdraws or has withdrawn an application, Member States, the Commission and the Authority shall respect the confidentiality as granted in accordance with this Article. Where the withdrawal of the application takes place before the Member State has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.*
3. *This Article is without prejudice to Directive 2003/4/EC* and Regulations (EC) No 1049/2001** and (EC) No 1367/2006*** of the European Parliament and of the Council.*

* *Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).*

** *Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).*

*** *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)."*

Article 8
Amendments to Regulation (EU) 2015/2283

Regulation (EU) 2015/2283 is amended as follows:

(1) Article 10 is amended as follows:

(a) paragraph 1 is replaced by the following:

"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. ***The Commission shall make a summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.***";

(b) paragraph 3 is replaced by the following:

"3. Where the Commission requests an opinion from the European Food Safety Authority (the 'Authority'), the Authority shall **make** public ■ the application in accordance with Article 23 and shall give its opinion as to whether the update is liable to have an effect on human health.";

(2) ■ in *Article 15*, paragraph 2 is replaced by the following:

"2. Within four months from the date on which a valid notification is forwarded by the Commission in accordance with paragraph 1 of this Article, a Member State or the Authority may submit to the Commission duly reasoned safety objections to the placing on the market within the Union of the traditional food concerned. Where the Authority submits duly reasoned safety objections, it shall make public, without delay, the notification, pursuant to Article 23, which shall apply mutatis mutandis.";

(3) Article 16 is amended as follows:

(a) in the first paragraph, the following sentence is added :

"The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002.";

(b) in the second paragraph, the following sentence is added:

"The Authority shall *make* public ■ the application, relevant supporting information and any supplementary information supplied by the applicant in accordance with Article 23.";

(4) Article 23 is replaced by the following:

"Article 23

Transparency and confidentiality

1. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, 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, in accordance with Articles 38 to 39e ■ of Regulation (EC) No 178/2002 and with this Article.

2. The applicant may submit a request to treat certain ***parts of the*** information submitted under this Regulation as confidential, accompanied by verifiable justification, upon submission of the application.
3. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.
4. ***In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:***
 - (a) ***where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety;***
 - (b) ***where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety.***

5. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16 of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 4 of this Article shall apply mutatis mutandis.
6. ***This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002."***

Article 9
Amendments to Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

(1) in Article 6, the following paragraph is inserted:

"2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist ***under Union law.***";

(2) in Article 13, the following paragraph is inserted:

"2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist ***under Union law.***";

(3) Article 25 is replaced by the following:

"Article 25

Confidentiality

1. ***The*** notifier ■ may submit a request to ***the*** competent authority to treat certain ***parts of the*** information submitted under this Directive as confidential, accompanied by verifiable justification, ***in accordance with paragraphs 3 and 6.***

■

2. ***The*** competent authority shall assess the confidentiality request submitted by the notifier ■ .

3. *Upon request of a notifier, the competent authority may grant confidential treatment **only** with respect to the ■ following items of information, upon verifiable justification, **where the disclosure of such information is demonstrated by the notifier to potentially harm its interests to a significant degree:***
- (a) *items of **information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;***
 - (b) *DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and*
 - (c) *breeding patterns and strategies.*
4. *The competent authority shall, after consultation with the notifier, decide which information is to be treated as confidential and shall inform the notifier of its decision.*
5. *Member States, the Commission and the relevant Scientific Committee(s) shall take the necessary measures to ensure that confidential information notified or exchanged under this Directive is not made public.*
6. *The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall also apply **mutatis mutandis**.*

7. *Notwithstanding paragraphs 3, 5 and 6 of this Article:*
- (a) *where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the competent authority may disclose the information referred to in paragraph 3; and*
 - (b) *information which forms part of the conclusions of the scientific outputs delivered by the relevant Scientific Committee(s) or the conclusions of the assessment reports and which relate to foreseeable effects on human health, animal health or the environment shall nevertheless be made public. In that case Article 39c of Regulation (EC) No 178/2002 shall apply.*
8. *In the event of a withdrawal of the notification by the notifier, Member States, the Commission and the relevant Scientific Committee(s) shall respect the confidentiality as granted by the competent authority in accordance with this Article. Where the withdrawal of the notification takes place before the competent authority has decided on the relevant confidentiality request, Member States, the Commission and the relevant Scientific Committee(s) shall not make public the information for which confidentiality has been requested.";*

(4) in Article 28, the following paragraph is added:

"4. Where the relevant Scientific Committee is consulted in accordance with paragraph 1 of this Article, it shall make public ***without delay*** the notification █ , relevant supporting information and any supplementary information supplied by the notifier █ , as well as its scientific opinions, ***with the exception of any information to which the competent authority has granted confidential treatment*** in accordance with Article █ 25."

Article 10

Transitional measures

1. This Regulation shall not apply to applications ■ under Union ■ law as well as requests for scientific outputs submitted to the Authority before ... [18 months after the date of entry into force of this Regulation].
2. *The term of office of the members of the Management Board of the Authority (the ‘Management Board’) who are in office on 30 June 2022, shall expire on that date. Notwithstanding the dates of application referred to in Article 11, the procedure for nomination and appointment of members to the Management Board set out in point 4 of Article 1 shall apply for the purposes of allowing the members appointed under those rules to start their term of office on 1 July 2022.*
3. *Notwithstanding the dates of application referred to in Article 11, the term of office of the members of the Scientific Committee and of the Scientific Panels who are in office on 30 June 2021, shall be prolonged until the members of that Scientific Committee and those Scientific Panels appointed according to the selection and appointment procedure laid down in point 5 of Article 1 start their term of office.*

Article 11

Entry into force

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

It shall apply from ... [18 months after the date of entry into force of this Regulation].

However, points 4 and 5 of Article 1 shall apply from 1 July 2022.

■

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

Done at ...,

For the European Parliament

For the Council

The President

The President
