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From: General Secretariat of the Council
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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]
- Analysis of the final compromise text with a view to agreement

Delegations will find in Annex to this document the compromise text as provisionally agreed with the European Parliament at the trilogue on 11 February 2019

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]

(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 Articles 43(2), 114, and 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 procedure,

Whereas:

¹ OJ C , , p. .

² OJ C , , p. .

(1) Regulation (EC) No 178/2002 of the European Parliament and of the Council³ lays down the general principles and requirements of food law, so as to form a common basis for measures governing food law both at Union and Member State level. It provides, amongst others, that food law must 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 [...].

(3) ***Risk communication is an essential part of the risk analysis process.*** The evaluation of Regulation (EC) No 178/2002⁴, (“Fitness Check of the General Food Law”), found that risk communication is overall, not considered to be effective enough, which has an impact on consumers’ confidence on the outcome of the risk analysis process.

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

³ 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).

⁴ Commission Staff Working Document, “The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002)”, SWD(2018)38 final, dated 15.1.2018.

(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 these are utilised 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 these factors were weighted up against each other.***

(5a) Given the ambiguity in the public perception of the difference between hazard and risk, risk communication should endeavour to clarify this distinction and thereby ensure that this is better understood by the general public

(5b) Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health due to a non-compliance resulting from intentional violations of applicable Union legislation perpetrated through fraudulent or deceptive practices, public authorities should inform the public accordingly as soon as possible, identifying to the fullest extent possible the concerned products and the risk that they may present.

(6) 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.***

(7) Based on these objectives and principles, a general plan on risk communication should be established in close cooperation with the Authority and the Member States, and following relevant public consultations. ***The general plan should promote an integrated risk communication framework for all risk assessors and risk managers at national and Union level on all matters relating to the food chain. It should also allow for the necessary flexibility and not deal with situations specifically covered by the general plan for crisis management.***

(8) The general plan should identify the key factors to be taken into account when **considering the type and level of** risk communications' activities **needed**, such as the different levels of risk, the nature of the risk and its potential impact **on public 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 [...] legislative framework and relevant market context.

(8a) The general plan 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 national and Union 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**.

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

(10) 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**.

(11) Experience shows that the role of the Management Board of the Authority is focussed on administrative and financial aspects and does not impact on the independence of the scientific work performed by the Authority. It is thus appropriate to include representatives of all Member States, ***the Commission, the European Parliament, as well as civil society and industry associations*** in the Management Board of the Authority while providing that those representatives should have experience [...] ***and expertise not only in the fields of food chain legislation and policy, including risk assessment, but also in those of general, financial and legal matters and ensuring that they act independently in the public interest.***

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

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

(14) 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 Executive Director and the appointment by the Management Board of the Authority of the members of the Scientific Committee and of the Scientific Panels*** [...] are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to defend [...] ***the Authority's*** interests and in particular the independence of its expertise has a role in the selection [...] of those scientific experts. ***The Management Board should endeavour to ensure, to the largest extent possible, that experts appointed in 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.

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

(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an [...] **application or notification** complies with Union requirements given the scientific knowledge in its possession. This principle is based on the premise that public health **and, where relevant, the environment** is better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter is unsafe in order to be able to ban it from the market. [...] According to this principle and in accordance with 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.

(17) Provisions exist on the content of applications [...] **or notifications**. It is essential that the application [...] **or notification**-submitted to the Authority for its risk assessment meets the applicable specifications to ensure the best quality scientific assessment by the Authority. Applicants and in particular small- and medium-sized enterprises do not always have a clear understanding of these specifications. It **is** thus appropriate that, **where the Authority may be requested to provide a scientific output, it should** provide advice to a potential applicant, upon request. **This advice upon request should be** on the applicable rules and the required content of an application [...] **or a notification**, before an application **or notification** is formally submitted, while not entering into the design of the studies to be submitted that remain the applicant's responsibility [...].

(18) *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 support an [...] application [...] under Union [...] law. To this end, it is necessary and appropriate that when business operators commission or carry-out studies with a view to submit an application [...] they notify those studies to the Authority [...]. The notification obligation should also apply to the laboratories and other testing facilities carrying-out the studies.* 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, it is appropriate to provide for certain procedural consequences in case of non-compliance in the context of the notification obligations. The Authority should lay down practical arrangements to implement the notification obligations, including procedures for requesting and making public the justifications for their non-compliance.*

(18a) In accordance with Directive 2010/63/EU of the European Parliament and of the Council, 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.

(19) In the case of applications to request the renewal of an authorisation, the authorised substance or product has already been on the market for several years. Therefore experience and knowledge exist on this substance or product. *Where the Authority may be requested to provide a scientific output, it is appropriate that the studies planned for supporting requests for renewals, including information on the proposed design, notified by the applicant to the Authority are submitted to a consultation of third parties [...]. The Authority should systematically provide advice to the applicants on the content of the intended renewal application, as well as on the design of studies, taking into account the received comments.*

(20) There are certain public concerns about the Authority's assessment in the area of authorisations being primarily based on industry studies. ***It is of utmost importance that the Authority carries 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 ensuring that the Authority can have access to all relevant scientific data and studies available on a subject matter of an ***application for an authorisation or a renewal of an*** authorisation [...], it is appropriate to provide for a consultation of third parties in order to identify whether other relevant scientific data or studies are available. To increase the effectiveness of the consultation, the consultation should take place ***immediately after*** the studies submitted by industry included in an application [...] ***have been*** made public, under the ***applicable*** transparency rules [...]. ***Where there is a risk that the results of a public consultation cannot be given due consideration due to the applicable deadlines, it is appropriate to provide for a limited extension of these deadlines.***

(21) 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 Directive 2004/10/EC of the European Parliament and of the Council on the inspection and verification of good laboratory practice⁵ or standards 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 that the Commission carries 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. This would allow to identify possible weaknesses in the systems and non compliance, to aim at correcting those and to provide an additional level of guarantees to reassure the general public on the quality of studies. [...] Based on the conclusions of these fact finding missions, the Commission could propose appropriate legislative measures aiming at improving the compliance with these standards.*

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

⁵ *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. 44-59)*

(23) 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 agri-food chain, is not always perceived as fully transparent. This is also partly due to the different transparency and confidentiality rules that are laid down not only in Regulation (EC) No 178/2002 but also in other Union *sectoral* legislative acts [...]. Their interplay can impact on the acceptability of the risk assessment by the general public.

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

(25) It is therefore necessary to strengthen the transparency of the risk assessment process in a proactive manner. *All scientific data and information supporting requests for authorisations under Union law as well as other requests for scientific output should be made publicly available proactively and be easily accessible* as early as possible in the risk assessment process. However, this process 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 [...]. *It should be ensured that public disclosure is not considered as a permission for further uses or exploitation, without however jeopardising the proactive character of public disclosure and the easy access to the disclosed data and information*

(25a) To ensure the transparency of this process, 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.

(26) Where the opinion of the Authority is requested in relation to [...] **applications 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.

(27) To determine what level of **proactive** disclosure strikes the appropriate balance, the relevant rights of the public to transparency in the risk assessment process, should be weighted up against the rights of [...] applicants, taking into account the objectives of Regulation (EC) No 178/2002.

(28) Accordingly and with respect to the **application** procedures [...] provided in Union law, experience gained so far has shown that certain information items are generally considered sensitive and should remain confidential across the different sectoral procedures. It is appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of information items whose disclosure [...] **is demonstrated by the applicant** to [...] **potentially** harm the commercial interests concerned **to a significant degree** and should not therefore be disclosed to the public; (“general horizontal list of confidential items”). **These items should amongst others comprise 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 except for information which is relevant to the assessment of the safety.** Only in very limited and exceptional circumstances relating to foreseeable health **effects or, where an environmental assessment is required under Union sectoral legislation, environmental** effects, or **where relevant authorities have identified** urgent needs to protect human health, animal health or the environment, such information should be disclosed.

(29) 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* in respect of a request for information submitted [...] *to support an application* under Union [...] law to be treated in a confidential manner.

(30) 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 Regulation (EC) No 45/2001 of the European Parliament and of the Council⁶ and Regulation (EU) 2016/679 of the European Parliament and of the Council⁷. 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. *Nevertheless, 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.*

(31) For the purposes of increased transparency and in order to ensure that requests for scientific outputs received by the Authority are processed in an effective manner, standard data formats [...] should be developed [...].

(32) 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.

⁶ 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).

⁷ 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).

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

(34) 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 Directive 2001/18/EC of the European Parliament and of the Council⁸, Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁹, in Regulation (EC) No 1831/2003 of the European Parliament and of the Council¹⁰, in Regulation (EC) No 2065/2003 of the European Parliament and of the Council¹¹, in Regulation (EC) No 1935/2004 of the European Parliament and of the Council¹², in Regulation (EC) No 1331/2008 of the European Parliament and of the Council¹³, in Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹⁴ and in Regulation (EU) 2015/2283 of the European Parliament and of the Council¹⁵ should be amended.

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).

⁹ 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).

¹⁰ 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).

¹¹ 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).

¹² 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).

¹³ 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).

¹⁴ 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).

¹⁵ 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).

[...]

(35) 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, taking into account the specific objectives of sectoral Union legislation as well as experienced gained. Accordingly, it is *in particular* necessary to amend Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004, **Regulation (EC) No 1331/2008**, Regulation (EC) No 1107/2009 **and Regulation (EU) No 2015/2283** to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.

(35a) The rights on access to documents enshrined in Regulation (EC) No 1049/2001 of the European Parliament and of the Council¹⁶ and, where environmental information is concerned, the rights enshrined in Regulation (EC) No 1367/2006 of the European Parliament and of the Council¹⁷ and Directive 2003/4/EC of the European Parliament and of the Council¹⁸ are unaffected. The provisions on proactive dissemination laid down in this Regulation and the relevant assessment of confidentiality request should not in any manner limit the rights provided by those acts.

¹⁶ *Regulation (EC) No 1049/2001 of the European Parliament and of the Council on public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).*

¹⁷ *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).*

¹⁸ *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).*

(36)[...] 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 Council¹⁹.

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

(38) The appointment of the Scientific Committee and Scientific Panels' members being dependent of 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 members.

(39) 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 Council²⁰ and delivered an opinion on [...],

¹⁹ 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).

²⁰ 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).

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 178/2002

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

(1) in Chapter II the following SECTION 1a is inserted:

"SECTION 1a

RISK COMMUNICATION

Article 8a

Objectives of risk communication

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

- (a) [...] **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;
- (ca) improve the overall effectiveness and efficiency of the risk analysis process;***

- (d) foster public understanding of the risk analysis process, ***including of the respective tasks and responsibilities of risk assessors and risk managers***, so as to enhance confidence in its outcome;
- (e) [...] ***ensure*** appropriate involvement of [...] ***consumers, feed and food businesses, the academic community and all other interested parties***; [...]
- (f) ensure appropriate ***and transparent*** exchange of information with interested parties in relation to risks associated with the [...] food chain;
 - (fa) ensure information to consumers about risk prevention strategies; and***
 - (fb) 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). In preparation of 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 communications' 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.

[...]

(1c) 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 carrying out similar tasks to these of the Authority and, where appropriate, with the relevant Union agencies.

(2) 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 1a and 1b 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 and representing the Commission, 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 representing civil society and food chain interests namely, one from consumers organisations, one from environmental non-governmental organisations, one from farmers organisations and one from industry organisations. Those members **and alternate members** shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint those members.

1b. The members of the Management Board and [...] the alternate members shall be **nominated and appointed [...] on the basis of their relevant experience and expertise in the field of food chain legislation and policy, including risk assessment, whilst ensuring there is relevant expertise in the fields of general, financial and legal matters.**”

(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 referred to in paragraph 1a(c) may be **renewed** only once.”,

(d) the second subparagraph of paragraph 5 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.”;

(3) 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 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 in the *Official Journal of the European Union*, in relevant leading scientific publications and on the Authority’s website of a call for expressions of interest. **The Authority shall publish the call after having informed the Member States on the criteria and areas of expertise.**

The Member States shall:

(a) **publish the call 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.”**

(e) The following paragraphs 5a to 5g 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 expressions 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 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 the [...] *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 determine 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 *its implementation in respect [...]* of the Scientific Panels' members;

(iii) Meeting the needs for the specific multi-disciplinary expertise of the Panel to which they will be appointed and the applicable language regime.

(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* Panel or several 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 Panel(s) [...].

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 of the present Article.

5d. [...] *Member States [...] and employers of the members of the Scientific Committee and of the Scientific Panels shall refrain from giving the members of the Scientific Committee and Scientific Panels, or the external experts participating in their working groups, any instruction which is incompatible with the individual tasks of those persons, 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 the Article 36 including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Panels before they adopt them.

5f. Each *Scientific* Panel shall include a maximum of 21 members.”,

5fa. *Members of Scientific Panels shall have access to comprehensive training on the risk assessment process.*

(c) paragraph 9(b) is replaced by the following:

“The number of members in each Scientific Panel within the maximum provided for in paragraph 5f.”;

(4) the following Articles 32a, 32b, 32c, 32d and 32e are inserted:

“Article 32a

Pre-submission [...] advice

1. [...] *Where Union law makes 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 relevant provisions and the required content of 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 web-site regarding applicable rules and required content of applications and notifications, including general guidance on the design of required studies where appropriate.*

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 makes provisions for the Authority to provide a scientific output, including a scientific opinion [...].*

1a. For the purposes of paragraph 1, business operators shall notify, without delay, to the Authority the [...] title and the scope of the study, the laboratory or testing facility carrying out the study, and the starting and planned completion dates of any study commissioned or carried out by them to support an [...] application or a notification [...].

2. The notification obligation under paragraph 1a shall also apply to [...] laboratories and other testing facilities located in the Union carrying out those studies.

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

2a. 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 paragraphs 1a and 2, unless the applicant or notifier provides a valid justification for the non-notification of such studies.

An application or notification may be re-submitted, provided that the applicant or notifier notifies to the Authority the studies that have not been previously notified in accordance with paragraphs 1a and 2 and, in particular, the title, the scope, the laboratory or the testing facility carrying out the study as well as the starting and end-date thereof.

The assessment of the validity or the admissibility of the new application or notification shall commence 6 months after the notification of the studies pursuant to the previous subparagraph.

2b. An application or notification shall not be considered valid or admissible, where studies that have previously been notified in accordance with paragraphs 1a and 2 are not included in the application or notification, unless the applicant or notifier provides a valid justification for the non-inclusion of such studies.

An application or notification may be re-submitted, provided that the applicant or notifier submits all the studies that were notified in accordance with paragraphs 1a and 2.

The assessment of the validity or admissibility of the new application or notification shall commence 6 months after the submission of the studies pursuant to the previous subparagraph.

2c. Where the Authority detects, during its risk assessment, that studies notified in accordance with paragraphs 1a and 2 are not included in the corresponding application or notification in full, and in the absence of a valid justification to that effect, the applicable time limits within which the Authority is required to deliver its scientific output shall be suspended. This suspension shall be terminated 6 months after the submission of all data of the relevant studies.

3. The notified information shall be made public only in case a corresponding application [...] has been received and after the Authority has decided on the disclosure of the accompanying studies in accordance with Article 38 and Articles 39 to 39f.

4. The Authority shall lay down [...] the practical arrangements for implementing the notification obligations laid down in paragraphs 1a and 2, including [...] **arrangements for requesting and publishing the valid justifications in cases referred to in paragraphs 2a, 2b and 2c.** Those arrangements shall [...] be in accordance with the present Regulation and other **relevant** Union [...] law.

Article 32c

Consultation of third parties

1. Where **relevant** Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose, **including information on how the various studies are to be carried out to ensure compliance with regulatory requirements**. Following this notification, 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 which are relevant for the risk assessment of the intended renewal, the Authority** shall provide advice on the content of the intended renewal application, **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 for renewal of authorisation by the Scientific Panels.

2. The Authority shall consult stakeholders and the public **on the basis of the non-confidential version of the application** made public by the Authority in accordance with Article 38 and Articles 39 to 39f in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application [...] **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 due consideration due to the applicable time limits within which the Authority is required to deliver its scientific output, these applicable time limits may be extended for a maximum period of seven weeks**. This provision **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 during the risk assessment process.

3. The Authority shall lay down [...] the practical arrangement for implementing the procedures referred to in Articles 32a and this Article.

[...] Fact-finding missions

Commission experts shall perform *fact finding missions in Member States 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 [...], as well as the compliance with the notification obligation set out in paragraph 2 of Article 32b, within 4 years after the date of application of Regulation xxx/xxxx²². Within the same timeline, Commission experts shall also perform fact finding missions to assess the application of these standards by laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements, including as referred to in Article 49.*

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

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.

²¹ This Article will be moved and be the new Article 61a.

²² *OJ: please insert the serial number of this amending Regulation*

Article 32d

Verification studies

Without prejudice to the obligation of 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.”;

(5) 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, *participants 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 protection of confidential information and protection of personal data in accordance with Articles 39 to 39f.

- (d) the information on which its scientific outputs, including scientific opinions are based, taking into account protection of confidential data and protection of personal data in accordance with Articles 39 to 39f;
- (e) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee, Scientific Panels and of their Working Groups, as well as 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, the Commission or 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*** advices provided [...] to potential applicants at pre-submission phase pursuant to Article 32a and 32c.

2. Items referred to the first paragraph shall be made public without undue delay, with the exception of the items referred to in points (c), as far as applications are concerned, and (i), which shall be made public without delay once an application has been considered valid or admissible.

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

- (b) the following paragraph 1a is inserted:

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

- (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 mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited *in breach of any intellectual property right or data exclusivity rules* and its use by third parties shall not engage the responsibility of the European Union. *The Authority shall ensure that clear undertakings or signed statements are given to that effect by those accessing the relevant documents, prior to their 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 Article 41.";

(6) Article 39 is replaced by the following:

Confidentiality

1. By way of derogation from Article 38, the Authority shall not make public information for which confidential treatment has been requested under the conditions laid down in this Article.
2. The Authority may [...] **grant** confidential treatment [...] **only with respect to the information items listed in this paragraph upon request of an applicant, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree [...].**

Those information items are:

- (1) **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 the safety;**
 - (2) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
 - (3) commercial information revealing sourcing, market shares or business strategy of the applicant; and,
 - (4) quantitative composition of the subject matter of the request [...], **except for information which is relevant to the assessment of the 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 public health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to *in those* paragraphs [...].

(b) ~~I~~nformation which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable *effects on public health, animal health or the environment, shall nevertheless be made public.*”;

(7) the following Articles 39a to 39g are inserted:

“Article 39a

Request for confidentiality

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 kept confidential in accordance with paragraphs 2 and 3 of Article 39. This request shall be accompanied by verifiable justification demonstrating how making public the information concerned significantly harms the interests concerned in accordance with paragraphs 2 and 3 of Article 39.

2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall be without the information the applicant deems confidential *on the basis of* paragraphs 2 and 3 of Article 39 *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 it, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority it may state its views or withdraw its application within two weeks from the date on which it was notified of the Authority's position;
 - (d) adopt a reasoned decision on the confidentiality request taking into account the observations of the applicant within ten weeks from the date of receipt of the confidentiality request with respect to applications for authorisation and without undue delay in the case of supplementary data and information, [...] notify the applicant ***of its decision and provide information on the right to make a confirmatory application in accordance with paragraph 2 of this Article***, 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 not earlier than two weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).

2. Within two weeks from the notification of the Authority's decision on the confidentiality request to the applicant pursuant to paragraph 1, the applicant may make a confirmatory application asking the Authority to reconsider its decision. The confirmatory application shall have suspensive effect. The Authority shall examine the grounds of the confirmatory application and shall adopt a reasoned decision on that confirmatory application. It shall notify the applicant of that decision within three weeks after lodging the confirmatory application and inform the applicant of the available remedies, namely instituting court proceedings 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 not earlier than 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 of the European Union, under the conditions laid down in Articles 263 and 278 of the Treaty 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 paragraph 4(b) of Article 39. 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, the Commission or the Member States for a scientific output, including a scientific opinion, unless otherwise indicated in specific 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 definitive. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public.
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 39f. The application shall be considered withdrawn as of the moment the written request is received by the competent body that had received the original application. Where the withdrawal of the application takes place before ***a final decision on the confidentiality request has been adopted by the Authority pursuant to, where appropriate, paragraphs 1 or 2 of Article 39b***, the Authority, the Commission and the Member States 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 confidentiality pursuant to Article 339 of the Treaty.

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 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*.

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 the legislative acts referred to in paragraph 3.*

3. Regulation (EU) 2016/679 of the European Parliament and of the Council²³ and [...] ***Regulation (EU) 2018/1725 of the European Parliament and of the Council***²⁴ shall apply to the processing of personal data carried out pursuant to this Regulation. Any personal data made public pursuant to Article 38 and this article shall only be used to ensure the transparency of risk assessment process under this Regulation and not be further processed in a manner that is incompatible with these purposes, in the meaning of Article 5(1)(b) of Regulation (EU) 2016/679 and Article 4(1)(b) of [...] ***Regulation (EU) 2018/1725***, as the case may be.

Article 39f

Standard data formats

1. For the purposes of Article 38(1)(c) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats [...] shall be adopted to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union [...] law. These [...] standard data formats [...] shall:

(a) not be based on proprietary standards; [...]

²³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, p. 1).

²⁴ ***Regulation (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).***

- (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 [...] 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, the Commission and the Member States.

(b) Taking into account the applicable requirements in the different authorisation procedures and other legislative frameworks and following any necessary adaptations, the Commission shall adopt standard data formats [...] by means of implementing acts. Those implementing acts shall be adopted in accordance with Article 58(2).

(c) The Authority shall make the standard data formats [...], as adopted, available on its website.

(d) Where standard data formats [...] have been adopted pursuant to this article, applications as well as requests for a scientific output, including a scientific opinion by the European Parliament, the Commission and the Member States [...], 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 *will be attained*, taking into account Articles 39 to 39f of this Regulation [...].

(8) in Article 40, the second subparagraph of paragraph 3 is replaced by the following:

“The Authority shall publish all scientific outputs including the scientific opinions issued by it and supporting scientific data and other information in accordance with Article 38 and Articles 39 a to 39f.”;

(9) in Article 41 [...]:

(a) paragraph 1 is replaced by the following:

"1. Notwithstanding the rules on confidentiality provided for in Articles 39 to 39d, 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 Council²⁵ 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."***

(b) paragraph 2 is replaced by the following:

²⁵ ~~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).~~

"2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 of the European Parliament and of the Council and Articles 6 and 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council, within six months after the date referred to in Article 11(a) of Regulation (EU) xxxx/xxxx²⁶, ensuring as wide access as possible to documents in its possession."

[...]

(10) 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. Not later than five years after the date [...] *of application of Regulation (EU) xxxx/xxxx²⁷[...]*, and every five years thereafter, the Commission shall assess the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. ***The evaluation shall include 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.*** The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.

2a. In that review, the Commission shall assess in particular whether the organisational framework of the Authority should 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.

²⁶ ***OJ: please insert the serial number of this amending Regulation.***

²⁷ ***OJ: please insert the serial number of this amending Regulation.***

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

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

Article 2

Amendments to Directive (EC) 2001/18/EC on the deliberate release into the environment of genetically modified organisms

Directive (EC) No 2001/18/EC is amended as follows:

(1) In Article 6, the following paragraph 2a 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 2a 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 request certain parts of the information submitted under this Directive to be kept confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6 of this Article.*

2. The competent authority shall assess the confidentiality request submitted by the notifier [...].
[...]

3. *The competent authority may grant confidential treatment only with respect to the information items listed in this paragraph, upon verifiable justification, where the disclosure of such information is demonstrated by the notifier to potentially harm its interests to a significant degree:*

(a) information referred to in points (1), (2) and (3) 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 kept 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 so that confidential information notified or exchanged under this Directive is not made public.*

6. *The relevant provisions of Article 39e on protection of personal data and Article 41, on access to documents, of Regulation (EC) No 178/2002 shall also apply mutatis mutandis.*

7. *Notwithstanding paragraphs 3, 5 and 6:*

(a) where urgent action is essential to protect public 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 this 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 4 is added:

“4. Where the relevant Scientific Committee is consulted under paragraph 1, 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 of this Directive.”

Article 3

Amendments to Regulation (EC) No 1829/2003 on genetically modified food and feed

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

(1) Article 5 is amended as follows:

(a) in paragraph 3 the introductory sentence 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) in paragraph 3 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 kept confidential, accompanied by verifiable justification, pursuant to Articles 30 of this Regulation and Article 39 of Regulation (EC) No 178/2002; ”;

(c) in paragraph 3 the following point (m) 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 conformity 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 39f* of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.”;

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

“1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity 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* 39f of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.”;

(4) in Article 11(2), the introductory sentence 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) Article 17 is amended as follows:

(a) in paragraph 3 the introductory sentence 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) in paragraph 3 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 kept confidential, accompanied by verifiable justification, pursuant to Article 30 of this Regulation and Articles 39 to 39f of Regulation (EC) No 178/2002;”;

(c) in paragraph 3 the following point (m) 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, in conformity 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 39f of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.”;

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

“1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity 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 Article 39 to 39f of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.”;

(8) in Article 23, the introductory sentence of paragraph 2 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 Article 38 *and* Articles 39 to 39f [...] 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.”;

(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 39f of Regulation (EC) No 178/2002 and this article,

(a) the applicant may request certain *parts of the* information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,

(b) the Authority shall assess the confidentiality request submitted by the applicant.

2. In addition to *the information referred to in points (1), (2) and (3) of* Article 39(2) and pursuant to Article 39(3) of Regulation (EC) No 178/2002, 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 Article 5(3) and 17(3) for the purpose of applying this Regulation to the 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 4

Amendments to Regulation No (EC) 1831/2003 on feed additives

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 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:

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 Article 38 **and** Articles 39 to 39f [...] 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 39f of Regulation (EC) No 178/2002 and this Article, the applicant may request certain **parts of the** information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and, the Authority shall assess the confidentiality request submitted by the applicant.
3. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also **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) the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) and Annex I to this Regulation; and,
 - (b) specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.
4. ***This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.***

Article 5

Amendments to Regulation (EC) No 2065/2003 on smoke flavourings

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 other Member States and the Commission 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:

“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), 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 Article 38 **and** Articles 39 to 39f [...] 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 39f of Regulation (EC) No 178/2002,

- (a) the applicant may request certain *parts of the* information submitted under this Regulation to be kept 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 6

Amendments to Regulation (EC) No 1935/2004 on Food Contact Materials

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 other Member States and the Commission 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 issue and publish detailed guidelines, following 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 Article 38 **and** Articles 39 to 39f [...] of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis* and 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 39f of Regulation (EC) No 178/2002 and this article:

(a) the applicant may request certain ***parts of the*** information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,

(b) the Authority shall assess the confidentiality request submitted by the applicant.

2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also ***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) 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 this substance, the manufacturing methods of these *mixtures* [...], materials or articles, impurities, and migration testing results, *except for information which is relevant to the assessment of the 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 Article 5(1)(n) of this Regulation.

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

Article 7

Amendments to Regulation (EC) No 1331/2008 on the common authorisation procedure for food additives, food enzymes and food flavourings

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

- (1) in Article 6, the following paragraph 5 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:

“Where the Commission requests its opinion 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 Article 38 ***and*** Articles 39 to 39f [...] of Regulation (EC) No 178/2002. It 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 request certain ***parts of the*** information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.

1a. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also 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) 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/substances in which the applicant intends to use this substance, except for information which is relevant to the assessment of the safety;

b) where applicable, detailed analytical information on the variability and stability of individual production batches of the substance, except for information which is relevant to the assessment of the safety.

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 39f of Regulation (EC) No 178/2002.

3. 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 to 39f of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.

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

Article 8

Amendments to Regulation (EC) No 1107/2009 on plant protection products

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

(1) Article 7 is amended as follows:

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

“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 pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept 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 kept 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 of this Regulation 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 of this Regulation.”;

(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 other Member States, the Commission and 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:

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 38 [...] of Regulation (EC) No 178/2002 [...] **and** Article 63 of this Regulation.

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 and 2 are replaced by the following:

“1. [...] **An** applicant may request certain **parts of the** information submitted under this Regulation to be kept confidential, accompanied by verifiable justification.

2. [...] **Confidential treatment may be granted only with respect to the information items listed in this paragraph, 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 these 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 39f 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 shall be kept confidential, it shall inform the applicant of its decision;

c) The 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) The relevant provisions of Article 39e of Regulation (EC) No 178/2002 on protection of personal data 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 public 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 animal health, human health or the environment shall nevertheless be made public. In this case, Article 39c of Regulation (EC) No 178/2002 shall apply;

f) If the applicant withdraws or has withdrawn an application, the 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, the Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

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

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

Article 9

Amendments to Regulation (EU) No 2015/2283 on novel foods

Regulation (EU) No 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 the 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) [...] ***paragraph 2 of Article 15 is amended as follows:***

"2. Within four months from the date on which a valid notification is forwarded by the Commission in accordance with paragraph 1, 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) the following sentence is added at the end of the first paragraph:

“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) the following sentence is added at the end of the second paragraph:

“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 its opinion in accordance with Articles 10(3) and 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 Article 38 **and** Articles 39 to 39f [...] of Regulation (EC) No 178/2002 and with this Article.

2. The applicant may request certain **parts of the** information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.

2a. In addition to 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) 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 substances in which the applicant intends to use this novel food, except for information which is relevant to the assessment of the safety;

b) where applicable, detailed information on the variability and stability of individual production batches, except for information which is relevant to the assessment of the safety.

3. Where the Commission requests its opinion in accordance with Articles 10(3) and 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. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16, the Commission shall assess the confidentiality request submitted by the applicant. Article 39 and 39a of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.

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

Article 10

Transitional measures

1. The provisions of this Regulation shall not apply to applications [...] under Union [...] law as well as requests for scientific outputs submitted to the Authority prior to [*general date of entry of application: 18 months after its entry into force*].

2. ***The term of office of the members of the Management Board of the Authority who are in office on 30 June 2022, shall expire on that date. Notwithstanding the dates of application referred to in Article 11 of this Regulation, the procedure for nomination and appointment of members to the Management Board set out in Article 1(2) of this Regulation, shall apply for the purposes of allowing the members appointed under these rules to start their term of office on [date of application in Article 11(2): 1 July 2022].***

3. Notwithstanding the dates of application referred to in Article 11 of this Regulation, 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 Committee and those Panels appointed according to the selection and appointment procedure in Article 1(3) of this Regulation 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 its entry into force*], except for [...] Article 1(2) **and (3) of this Regulation which** shall apply from 1st July 2022.

[...]

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

Done at Brussels,

For the European Parliament

For the Council

The President

The President