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DRAFT OPINION

of the Committee on Legal Affairs

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur for opinion: Jiří Maštálka

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SHORT JUSTIFICATION

Assessing the proposal

This long awaited European Commission proposal for the disclosure of confidential industry studies used in the European Food Safety Authority's (EFSA) risk assessments contains positive elements but fails to enable meaningful independent scrutiny of the data.

The proposal amends Regulation 178/2002 (hereafter the General Food Law (GFL)) and several related Regulations and Directives. The rapporteur considers that there are some positive changes in the proposal concerning transparency, however, he has also identified a number a provisions that need to be changed or strengthened in order to achieve what the European Commission intends on doing.

To that aim, the rapporteur has adopted a comprehensive stance, building on the Commission's proposal in order to fully implement a much needed reform of the risk assessment process conducted by EFSA, thus allowing the EU as a whole to abide by the Aarhus Convention (Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters).

The two main features of the proposal, automatic and pro-active publication of data in a machine-readable format and the creation of a register of studies aimed at preventing industry cherry-picking of favourable studies, along with some minor changes with regard to risk communication, consultation of third parties, reform of the composition of EFSA's management board are positive steps in the right direction.

The rapporteur considers however, that if the proposed industry authorisation for any publication and use of independent data cross checks is indeed to be mandated, the usefulness of these two provisions will be rather limited. Indeed, the proposal introduces a new provision stating that the disclosure of scientific data and studies regarding applications for authorisations under food law, authorisations for GMOs or additives in food, 'shall be without prejudice to' 'any intellectual property right which may exist over documents or their content'. Furthermore, the proposal introduces a presumption with regard to categories of information that the disclosure of such information 'may be deemed to significantly harm commercial interests'.

The impossibility of re-using the data without permission would compromise the possibility to reduce the overall number of toxicity studies, hinder the public scrutiny of the results, including a better understanding of the potential adverse effects on health and the environment. The peer review process that is essential to ensure the full effectiveness of the risk assessment conducted is essentially at risk.

Notwithstanding the changes with a positive effect on transparency in the proposal, the rapporteur deems necessary to amend the Commission's proposal in order to maintain and expand the current level of transparency under European Union food law with regard to several categories of information, within the several directives that are amended under this proposal.

A real overhaul of the EU's risk assessment in the food chain

The rapporteur does not consider that it is reasonable to "weigh up the relevant rights of the public to transparency in the risk assessment process, including those flowing from the Aarhus Convention, against the rights of commercial applicants" as stated in the European Commission's proposal. Nor that the EU should grant more protection to commercial parties than the Aarhus legislation already provides for (implemented through Regulations 1049/2001 and 1367/2006). He is also firmly opposed to the use of the EU taxpayers money granted to EFSA to give advice to the private companies that are applicants.

The rapporteur aims to make transparency the rule and confidentiality the exception. The exceptions to the principle of transparency must be interpreted strictly to fully guarantee public and independent scrutiny. That translates into several amendments made to the GFL regulation.

Proposed amendments to the proposal within the sectorial regulations targeted are set to close the existing loopholes in the obligation to disclose information gathered when there is an "overriding public interest in disclosure" related to food safety. Then he considers appropriate to lay down in the GFL a horizontal and non-exhaustive list of information items which can never be kept secret.

AMENDMENTS

The Committee on Legal Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Citation 1

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

Or. en

Amendment 2

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) The evaluation of Regulation (EC)	(3) The evaluation of Regulation (EC)

No 178/2002[21] , ("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.	No 178/2002[21] , ("Fitness Check of the General Food Law"), found that risk communication is overall, not considered to be effective enough, which ***can have*** an impact on the outcome of the risk analysis process.
[21] 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.	[21] 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.

Or. en

Amendment 3

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) It is therefore necessary to ensure a comprehensive and continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should be combined with an open dialogue between all interested parties to ensure ***the coherence*** and consistency within the risk analysis process.	(4) It is therefore necessary to ensure a comprehensive and continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should be combined with an open dialogue between all interested parties to ensure ***prevalence of public interest only, accuracy*** and consistency within the risk analysis process.

Or. en

Amendment 4

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Particular emphasis should be placed on explaining in ***a coherent,***	(5) Particular emphasis should be placed on explaining in ***accurate, clear*** and

appropriate and timely manner not only risk assessment findings themselves but also how these are utilized to help inform risk management decisions along with other legitimate factors, where relevant.	timely manner not only risk assessment findings themselves but also how these are utilized to help inform risk management decisions along with other legitimate factors, where relevant.

Or. en

Amendment 5

Proposal for a regulation
Recital 8

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

Or. en

Amendment 6

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) Transparency of the risk assessment process contributes ***to*** the Authority	(9) ***Lack of*** transparency ***and clarity*** of the risk assessment process contributes the

acquiring greater legitimacy ***in the eyes of the consumers and general public*** in pursuing its mission, ***increases their confidence in its work and ensures that*** the Authority ***is*** more accountable to the Union citizens ***in a democratic system***. It is therefore essential to ***maintain*** the confidence of the ***general*** public ***and other interested parties*** in the risk analysis process underpinning Union food law and in particular ***in*** the risk assessment, ***including the organisation and independence of the Authority and transparency***.	Authority ***losing*** legitimacy in pursuing its mission, ***better functioning of a democratic system depends on*** the Authority ***being*** more accountable to the Union citizens . It is therefore essential to ***restore*** the confidence of the public in the risk analysis process underpinning Union food law and in particular ***the independence, transparency and clarity of*** the risk assessment.

Or. en

Amendment 7

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) Experience shows that the ***role*** of the Management Board of the Authority ***is focussed on administrative and financial aspects and does not impact on the independence of the scientific work performed*** by the ***Authority***. It is thus appropriate to ***include*** representatives of ***all*** Member States in the Management Board of the Authority***, while providing that those representatives should have experience in particular on risk assessment***.	(11) Experience shows that the ***level of independence*** of the Management Board of the Authority ***from industry applicants is key to ensure public confidence in the work conducted*** by the ***Agency***. It is thus appropriate to ***exclude*** representatives of Member States in the Management Board of the Authority ***who cannot demonstrate the absence of conflict of interest with the applicants***.

Or. en

Amendment 8

Proposal for a regulation
Recital 12

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

Or. en

Amendment 9

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) To preserve the independence of the risk assessment from risk management and from ***other*** interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels by the Member States, their selection by the Executive Director of the Authority and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to ***defend EFSA's interests*** and in particular the independence of its expertise has a role in ***the selection and appointment of those*** scientific experts***. Further*** measures should ***also*** be put in place to ensure that scientific experts have the means to act independently***.***	(14) To preserve the independence of the risk assessment from risk management and from ***vested private*** interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels by the Member States, their selection by the Executive Director of the Authority and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to ***safeguard EFSA's accountability,*** and in particular the independence of its expertise***,*** has a role in ***excluding*** scientific experts ***who oppose the publication of their name or who have conflicts of interest, from risk assessment. Adequate budgetary*** measures should be put in place to ensure that scientific experts have the means to act independently.

Or. en

Amendment 10

Proposal for a regulation
Recital 15

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

Or. en

Amendment 11

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health ***is*** better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter ***is*** unsafe in	(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health ***and the environment are*** better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a

order to be able to ban it from the market. Moreover, public money should ***not*** be used to ***commission costly*** studies that will in the end help the ***industry*** to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and ***in some cases*** the efficacy of a subject matter.	subject matter unsafe in order to be able to ban it from the market. Moreover, public money should ***never*** be used to ***cover the costs of*** studies that will in the end help the ***private entities*** to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit ***- and cover all the costs relating to -*** relevant studies, including tests, to demonstrate the safety and the efficacy of a subject matter ***where relevant***.

Or. en

Amendment 12

Proposal for a regulation
Recital 17

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

Or. en

Amendment 13

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) The Authority should have knowledge of the subject matter of all studies performed by an applicant with a view to a future application for an authorisation under Union food law. To this end, it is necessary and appropriate that business operators commissioning the studies and laboratories carrying them out notify those studies to the Authority when commissioned. Information about the notified studies should be made public only once a corresponding application for authorisation has been made public in accordance with the applicable rules on transparency.	(18) The Authority should have knowledge of the subject matter of all studies performed by an applicant with a view to a future application for an authorisation under Union food law. To this end, it is necessary and appropriate that business operators commissioning the studies and laboratories carrying them out notify those studies to the Authority when commissioned. Information about the notified studies should be made public only once a corresponding application for authorisation ***or renewal*** has been made public in accordance with the applicable rules on transparency.

Or. en

Amendment 14

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) There are ***certain*** public concerns about the Authority's assessment in the area of authorisation being primarily based on industry studies. The Authority already makes searches in scientific literature to be able to consider other data and studies existing on the subject matter submitted to its assessment. In order to ***provide an additional level of guarantee ensuring*** that the Authority ***can have access to*** all relevant scientific data and studies available on a subject matter of an authorisation procedure, it is appropriate to	(20) There are public concerns about the Authority's assessment in the area of authorisation being primarily based on industry studies. The Authority already makes searches in scientific literature to be able to consider other data and studies existing on the subject matter submitted to its assessment. In order to ***a ensure*** that the Authority ***includes*** all relevant scientific data and studies available on a subject matter of an authorisation procedure, it is appropriate to provide for a ***public*** consultation***, once a corresponding***

provide for a consultation ***of third parties*** in order to identify whether other relevant scientific data or studies are available. ***To increase the effectiveness of the consultation, the consultation should take place when the studies submitted by industry included in an application for authorisation are made public, under the transparency rules of this Regulation.***	***application for authorisation or renewal has been made public,*** in order to identify whether other relevant scientific data or studies are available.

Or. en

Amendment 15

Proposal for a regulation
Recital 21

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

Or. en

Amendment 16

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21 a) Sufficient flexibility must be built into the process so that new insights into serious health adverse effects can be promptly taken into consideration, even when they are not specifically covered by regulatory data requirements.

Or. en

Amendment 17

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) Food safety is a sensitive matter of prime interest for all Union citizens. While maintaining the principle that the burden is on the industry to prove compliance with Union requirements, it is important to establish an additional verification tool to address specific cases of high societal importance where there is a controversy on safety issues, namely the commissioning of additional studies with the objective of verifying evidence used in the context of risk assessment. Considering that it would be financed by the Union budget and that the use of this exceptional verification tool should remain proportionate, the Commission should 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).	***deleted***

Or. en

Amendment 18

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(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 legislative acts covering the agri-food chain***. ***Their interplay can impact on the acceptability of the risk assessment by the general public.***	(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 ***yet*** fully transparent.

Or. en

Amendment 19

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(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 application[23] .	(24) ***As a Party to the Aarhus Convention, the EU has recognized that, in the field of the environment, improved access to information and public participation in decision-making enhance the quality and the implementation of decisions, contribute to public awareness of environmental issues, give the public the opportunity to express its concerns and enable public authorities to take due account of such concerns.*** The European

	Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" further confirmed concerns regarding transparency with respect to studies commissioned by the industry and submitted in authorisation application[23] .
[23] Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.	[23] Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.

Or. en

Amendment 20

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) It is therefore necessary to strengthen the transparency of the risk assessment process in a proactive manner. Public access to all scientific data and information supporting requests for authorisations under Union food law as well as other requests for scientific output should be ensured, as early as possible in the risk assessment process. ***However, this process should be without prejudice to existing intellectual property rights or to any provisions of Union food law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations.***	(25) ***To further the accountability and to regain public support for decisions of the Authority,*** it is therefore necessary to strengthen the transparency ***and clarity*** of the risk assessment process in a proactive manner. ***In order to ensure public scrutiny,*** public access to all scientific data and information supporting requests for authorisations under Union food law as well as other requests for scientific output should be ensured, as early as possible in the risk assessment process.

Or. en

Amendment 21

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) ***To determine what level of disclosure strikes the appropriate balance, the relevant rights of the*** public ***to transparency in the risk assessment process, should be weighted up against the rights of commercial applicants, taking into account the objectives of*** Regulation ***(EC) No 178/2002***.	(27) ***The present Regulation is intended to give the fullest possible effect to the right of*** public ***access to documents of the Authority and must be read in conjunction with*** Regulation ***No 1049/2001 and 1367/2006***.

Or. en

Amendment 22

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) ***Accordingly and with respect to the procedures governing requests for authorisation procedures provided in Union food law, experience gained so far has shown that certain*** information ***items are generally considered sensitive and should remain confidential across the different sectoral authorisation procedures***. It is appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of information items ***whose disclosure may be considered to*** significantly ***harm the*** commercial interests ***concerned and should not therefore be disclosed to the public,*** ("general horizontal list of confidential items"). ***Only in very limited and exceptional circumstances relating to foreseeable health effects and urgent needs to protect human health, animal health or the environment, such*** information ***should be disclosed***.	(28) ***Any*** information ***relating to impacts on health or the environment must therefore always be made public***. It is appropriate to lay down in Regulation (EC) No 178/2002 a horizontal ***exhaustive*** list of information items ***which could be kept confidential on the ground that they would*** significantly ***undermine the protection of commercial interest. However, this information can only be kept secret if the company opposing its dissemination proves, with verifiable justifications, that the dissemination would significantly undermine its*** commercial interests ("general horizontal list of confidential items"). ***The exceptions to the principle of transparency must be interpreted strictly. In any event, even in a case the disclosure of the*** information ***is considered to undermine the commercial interests of an economic operator, if there is an overriding public interest in the***

disclosure, the information cannot be kept secret. It is appropriate to lay down in Regulation (EC)No178/2002 a horizontal non-exhaustive list of information items which can never be kept secret, an overriding public interest in their disclosure being deemed.

Or. en

Amendment 23

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) It is also necessary to ***set out specific requirements with respect*** to the protection of personal data for the purposes of the transparency of the risk assessment process ***taking into account*** Regulation (EC) No 45/2001 of the European Parliament and of the Council[24] and Regulation (EU) 2016/679 of the European Parliament and of the Council[25] . Accordingly, no personal data should be made publicly available under this Regulation, unless it is necessary and proportionate for the purposes of ensuring the transparency, independence and the reliability of the risk assessment process, while preventing conflicts of interests.	(30) It is also necessary to ***refer*** to the protection of personal data for the purposes of the transparency of the risk assessment process ***to*** Regulation (EC) No 45/2001 of the European Parliament and of the Council[24] and Regulation (EU) 2016/679 of the European Parliament and of the Council[25] . 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. ***This Regulation considers necessary and proportionate for the purpose of ensuring the transparency, independence and reliability of the risk assessment process, in particular to avoid conflicts of interest, to publish the names of any individual designated by the Authority to contribute to the Authority's decision making process, including in the context of the adoption of guidance documents.***
[24] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of	[24] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of

personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

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

personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

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

Or. en

Amendment 24

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) To ensure that sectoral specificities with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency in the risk assessment process, including those flowing from the Aarhus Convention[35] , against the rights of commercial applicants, taking into account the specific objectives of sectoral Union legislation as well as experienced gained. Accordingly, it is necessary to amend Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004 and Regulation (EC) No 1107/2009 to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.	***deleted***
[35] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention	

on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p.13).

Or. en

Amendment 25

Proposal for a regulation
Recital 37

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

Or. en

Amendment 26

Proposal for a regulation
Recital 38

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

Or. en

Amendment 27

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8a – point a

Text proposed by the Commission	*Amendment*
(a) promote awareness and understanding of the specific issues under consideration during the entire risk analysis ***process***;	(a) promote ***transparency, clarity,*** awareness and understanding of the specific issues under consideration during the entire risk analysis ***and management processes***;

Or. en

Amendment 28

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8a – point b

Text proposed by the Commission	*Amendment*
(b) promote ***consistency*** and transparency in formulating risk	(b) promote ***a high level of health and environmental protection*** and transparency

management recommendations;	in formulating risk management recommendations;

Or. en

Amendment 29

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8a – point c

Text proposed by the Commission	*Amendment*
(c) provide a ***sound*** basis for ***understanding*** risk management decisions;	(c) provide a ***scientific*** basis for risk management decisions;

Or. en

Amendment 30

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8a – point d

Text proposed by the Commission	*Amendment*
(d) foster public understanding of the risk analysis process so as to enhance ***confidence*** in its outcome;	(d) foster public understanding of the risk analysis process so as to enhance ***accountability*** in its outcome;

Or. en

Amendment 31

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8b – point e

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

Or. en

Amendment 32

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8c – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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:	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 ***accurate*** and systematic manner both at Union and national level***, while acknowledging scientific divergent opinions where they exist***. It shall:

Or. en

Amendment 33

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8c – paragraph 2 – point a

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

Or. en

Amendment 34

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8c – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) establish appropriate mechanisms in order to strengthen coherence of risk communication amongst risk assessors and risk managers and ensure an open dialogue amongst all interested parties.	(c) establish appropriate mechanisms in order to strengthen coherence of risk communication amongst risk assessors and risk managers and ensure an open dialogue amongst all interested parties***, while acknowledging scientific divergent opinions where they exist***.

Or. en

Amendment 35

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b
Regulation (EC) No 178/2002
Article 8c – paragraph 2, point 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***one member*** appointed by the European Parliament, with the right to vote.	(b) ***two members and two alternate members*** appointed by the European Parliament, with the right to vote.

Or. en

Amendment 36

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b
Regulation (EC) No 178/2002
Artilce 8c – paragraph 2 – point 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***four*** members with the right to vote	(c) ***five*** members with the right to vote

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

Or. en

Amendment 37

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point d
Regulation (EC) No 178/2002
Article 8c – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
d) the second subparagraph of paragraph 5 is replaced by the following:	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 member in his absence and vote on his behalf .”;	“Unless otherwise provided, the Management Board shall act by a majority of its members. Alternate members shall represent the member in ***her or*** his absence and vote on ***her or*** his behalf .”;

Or. en

Amendment 38

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point b
Regulation (EC) No 178/2002
Article 8c – paragraph 3 – point c

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

Or. en

Amendment 39

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32 a

Text proposed by the Commission	*Amendment*
Article 32a	***Deleted***
General advice	
At the request of a potential applicant for a food law authorisation, the staff of the Authority shall advise on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.	

Or. en

Amendment 40

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32b – paragraph 1

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

Or. en

Amendment 41

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32b – paragraph 3

Text proposed by the Commission	*Amendment*
3. The notified information shall be made public only in case a corresponding application for authorisation 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.***	3. The notified information shall be made public only in case a corresponding application for authorisation has been received.

Or. en

Amendment 42

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32b – point 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. Data from a test from applicant that is not registered prior to the initiation of the experimental work shall not be used in a risk assessment.

Or. en

Amendment 43

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32b – point 3 b (new)

Text proposed by the Commission	*Amendment*
	3 b. The subject matter shall not be authorised unless all data from all registered studies are submitted.

Or. en

Amendment 44

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32c – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority	1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority

shall launch a consultation of stakeholders and the public on the intended studies for renewal and shall ***provide advice on the content of the intended renewal application taking into account*** the received comments. ***The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.***	shall launch a consultation of stakeholders and the public on the intended studies for renewal and shall ***publish*** the received comments.

Or. en

Amendment 45

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32c – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Authority shall consult stakeholders and the public regarding the studies supporting applications for authorisation once they are made public by the Authority in accordance with Article 38 and Articles 39 to 39f in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application for authorisation. ***This provision does not apply to the submission of any supplementary information by the applicants during the risk assessment process.***	2. The Authority shall consult stakeholders and the public regarding the studies supporting applications for authorisation once they are made public by the Authority in accordance with Article 38 and Articles 39 to 39f in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application for authorisation.

Or. en

Amendment 46

Proposal for a regulation
Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002
Article 32e

Text proposed by the Commission	*Amendment*
Article 32e	***deleted***
Verification studies	
Without prejudice to the obligation of applicants for authorisations under food law to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification;	

Or. en

Amendment 47

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:	The Authority shall carry out its activities with a high level of transparency ***in line with a high level of transparency in line with the Aarhus Convention and Regulation 1367/2006 and without prejudice to Regulation 1049/2001 as well as with directive 2003/4, providing for an active and systematic dissemination to the public of environmental information***. It shall in particular make public without delay:

Or. en

Amendment 48

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) agendas and minutes of the Scientific Committee and the Scientific Panels and their Working Groups;	(a) agendas***, participants lists,*** and minutes of the Scientific Committee and the Scientific Panels and their Working Groups;

Or. en

Amendment 49

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point c

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

Or. en

Amendment 50

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point d

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

Or. en

Amendment 51

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point i

Text proposed by the Commission	*Amendment*
	The authority shall publish the non-confidential information specified under subparagraphs (c) and (d) immediately upon receipt of the application. It shall publish any data and information for which the confidentiality request has not been accepted no later than four weeks after the notification of its decision to the applicant pursuant to Article 39(1) subparagraph (d).",

Or. en

Amendment 52

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point b

Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point b – paragraph 1a – point a

Text proposed by the Commission	*Amendment*
(a) to any intellectual property right which may exist over documents or their content; and,	***deleted***

Or. en

Amendment 53

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point b
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point b – paragraph 1a – point b

Text proposed by the Commission	*Amendment*
(b) any provisions set out in Union food law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').	***deleted***

Or. en

Amendment 54

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point b
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – point b – paragraph 2

Text proposed by the Commission	*Amendment*
The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third	The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be ***commercially*** used, reproduced, or otherwise exploited ***for***

parties shall not engage the responsibility of the European Union.	***commercial purposes. For the avoidance of doubt, the information published can be used for the purpose of public scrutiny of the results, including abetter understanding of the potential adverse effects on health and the environment*** and its use by third parties ***for that purpose*** shall not engage the responsibility of the European Union.***"***

Or. en

Amendment 55

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – title

Text proposed by the Commission	*Amendment*
Confidentiality	***Limitations to transparency***

Or. en

Amendment 56

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. By way of derogation from Article 38 ***and without prejudice to Regulation 1049/2001 and Directive 2003/4***, the Authority shall not make public information for which confidential treatment has been requested ***and granted in application of*** the conditions laid down in this Article.

Or. en

Amendment 57

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The Authority may ***only*** accept to provide confidential treatment in relation to the following information, ***the disclosure of which may be deemed, upon*** verifiable ***justification, to*** significantly ***harm the interests concerned***:	2. ***Unless there is an overriding public interest in disclosure,*** the Authority may accept to provide confidential treatment in relation to the following information, ***and provided the request for confidential treatment demonstrates, with adequate and*** verifiable ***evidence , that disclosure would*** significantly***, specifically and actually, harm its commercial interest***:

Or. en

Amendment 58

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 2 – point 1

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

Or. en

Amendment 59

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

Regulation (EC) No 178/2002
Article 39 – paragraph 2 – point 4

Text proposed by the Commission	*Amendment*
(4) quantitative composition of the subject matter of the request for a scientific output, including a scientific opinion.	***deleted***

Or. en

Amendment 60

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. Notwithstanding paragraphs 2 and 3, the following information shall ***nevertheless*** be made public:	4. Notwithstanding paragraphs 2 and 3, the following information shall ***always*** be made ***publicly available in a readily and easily searchable form to allow independent scrutiny, and overriding*** public ***interest in disclosure being deemed to exist***:

Or. en

Amendment 61

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) ***Where urgent action is essential to protect public health, animal health or*** the environment***, such as in emergency situations, the Authority may disclose the information referred to paragraphs 2 and***	(a) ***Information relating to emissions into*** the environment ***within the meaning of Regulation 1367/2006;***

3; and,

Or. en

Amendment 62

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 4 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) full study reports, including test methods, results, and discussion, from studies used in the regulatory assessment;

Or. en

Amendment 63

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 4 – point a b (new)

Text proposed by the Commission	*Amendment*
	(ab) Information relating to human health, animal health or state of environment, including (but not limited) to emergency situations;

Or. en

Amendment 64

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 4 – point b

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

Or. en

Amendment 65

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. This Article is without prejudice to Regulations 1049/2001 and 1367/2006

Or. en

Justification

This formulation is necessary for the benefit of transparency

Amendment 66

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. When submitting an application for an authorisation, supporting scientific data and other supplementary information in accordance with Union food 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	1. When submitting an application for an authorisation, supporting scientific data and other supplementary information in accordance with Union food 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.	accompanied by verifiable justification demonstrating how making public the information concerned significantly harms ***its competitive position*** in accordance with paragraphs 2 and 3 of Article 39.

Or. en

Amendment 67

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39a – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall ***be without*** the information the applicant ***deems*** confidential in accordance with paragraphs 2 and 3 of ***Article 39***. The confidential version shall contain all information submitted, including ***information*** the applicant ***deems*** confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the ***grounds*** on the basis of which confidentiality is requested for the different pieces of information.	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 ***redact with black bars*** the information the applicant ***requests the*** confidential ***treatment of*** in accordance with paragraphs 2 and 3 of ***Article39***. The confidential version shall contain all information submitted, including ***in formation*** the applicant ***considers*** confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the ***verifiable justifications*** on the basis of which confidentiality is requested for ***each of*** the different pieces of information.

Or. en

Amendment 68

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

Regulation (EC) No 178/2002
Article 39b – paragraph 1 – point c)

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

Or. en

Amendment 69

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39b – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(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).	(e) make public any additional data and information for which the confidentiality request has not been accepted as justified not earlier than two weeks ***and no later than four weeks*** after the notification of its decision to the applicant has taken place, pursuant to point (d).

Or. en

Amendment 70

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39b – subparagraph 2

Text proposed by the Commission	*Amendment*
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***.	***Where it is clear that applicant made abusive confidentiality claims,*** the Authority ***may charge a fine for the unnecessary administrative burden created thereby. The fine should be effective, proportionate and dissuasive***.

Or. en

Amendment 71

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39d – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application for an authorisation 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 food law***.	1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application for an authorisation or to a request by the European Parliament, the Commission or the Member States for a scientific output, including a scientific opinion.

Or. en

Amendment 72

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39e – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. With respect to requests for scientific outputs, including scientific	1. With respect to requests for scientific outputs, including scientific

opinions under Union food law, the Authority shall always make public:	opinions under Union food law, ***or comments on draft guidance documents,*** the Authority shall always make public:

Or. en

Amendment 73

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39e – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the names of authors ***of published, or publicly available***, studies ***supporting such requests;*** and	(b) the names of authors, studies and ***any output sent to the Authority;***

Or. en

Amendment 74

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39e – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the names of all participants in meetings of the Scientific Committee and the Scientific Panels ***and*** their Working Groups.	(c) the names of all participants ***and observers*** in meetings of the Scientific Committee and the Scientific Panels **,** their Working Groups ***or any other ad hoc group created to contribute to the Authority's duties***.

Or. en

Amendment 75

Proposal for a regulation
Article 2 – paragraph 1 – point 3 – introductory part

Text proposed by the Commission	*Amendment*
(3) Article 25 ***is*** replaced by ***the*** following:	(3) ***In*** Article 25***, paragraph 1,2,and 5 are*** replaced by following :

Or. en

Amendment 76

Proposal for a regulation
Article 2 – paragraph 1 – point 3
Directive (EC) No 2001/18/EC
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, which shall apply mutatis mutandis, confidential treatment may be accepted with respect to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(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.;	

Or. en

Amendment 77

Proposal for a regulation
Article 3 – paragraph 1 – point 10 – introductory part

Text proposed by the Commission	*Amendment*
(10) Article 30 is replaced by the following:	(10) ***In*** Article 30 ***paragraph 1*** is replaced by the following:

Or. en

Amendment 78

Proposal for a regulation
Article 3 – paragraph 1 – point 10
Regulation (EC) No 1829/2003
Article 30 – paragraph 2

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

Or. en

Amendment 79

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – introductory part

Text proposed by the Commission	*Amendment*
(2) Article 18 ***is*** replaced by the following:	(2) ***In*** Article 18 ***paragraphs 1 and 2 are*** replaced by the following:

Or. en

Amendment 80

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EC) No 1831/2003
Article 18 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(a) the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) and Annex I to this Regulation; and,	
(b) specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.	

Or. en

Amendment 81

Proposal for a regulation
Article 5 – paragraph 1 – point 3 – introductory part

Text proposed by the Commission	*Amendment*
(3) Article 15 ***is*** replaced by the following:	(3) ***In*** Article 15 ***paragraphs 1 and 2 are*** replaced by the following:

Or. en

Amendment 82

Proposal for a regulation
Article 6 – paragraph 1 – point 3 – introductory part

Text proposed by the Commission	*Amendment*
(3) Article 20 ***is*** replaced by the following:	(3) ***In*** Article 20 ***paragraphs A and 3 are*** replaced by the following:

Or. en

Amendment 83

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2003
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
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 accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(a) any information provided in detailed descriptions of starting substances and preparations used to manufacture the substance subject to the authorisation, the composition of preparations, materials or articles in which the applicant intends to use this substance, the manufacturing methods of these preparations, materials or articles, impurities, and migration testing results;	
(b) the trademark under which the substance, shall be marketed as well as the tradename of the preparations, material or articles in which it shall be used, where applicable; and,	
(c) any other information deemed	

confidential within the specific procedural rules referred to in Article 5(1)(n) of this Regulation.

Or. en

Amendment 84

Proposal for a regulation
Article 7 – paragraph 1 – point 3 – introductory part

Text proposed by the Commission	*Amendment*
(3) Article 12 ***is*** replaced by the following:	(3) ***In*** Article 12***, the first subparagraph of paragraph 1, paragraphs 2, 3 and 4 are*** replaced by the following:

Or. en

Amendment 85

Proposal for a regulation
Article 8 – paragraph 1 – point 5
Regulation (EC) No 1107/2009
Article 16 – paragraph 5 – point 1

Text proposed by the Commission	*Amendment*
1. In accordance with the conditions and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this article, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification**.**	1. In accordance with the conditions and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this article, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification***, except information that is considered toxicologically, ecotoxicologically or environmentally relevant.***

Or. en

Amendment 86

Proposal for a regulation
Article 8 – paragraph 1 – point 5
Regulation (EC) No 178/2002
Article 16 – paragraph.2

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3), confidential treatment may be accepted with respect to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(a) 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;	
(b) results of production batches of the active substance including impurities; and,	
(c) information on the complete composition of a plant protection product;	

Or. en

Amendment 87

Proposal for a regulation
Article 9 – paragraph 1 – point 4 – introductory part

Text proposed by the Commission	*Amendment*
(4) Article 23 ***is*** replaced by the following:	(4) ***In*** Article 23 ***paragraphs 1 to 3 and first subparagraph of paragraph 4 are*** replaced by the following :

Or. en