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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: Pavel Svoboda

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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
Recital 2

Text proposed by the Commission	*Amendment*
(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. Risk communication is an essential part of the risk analysis process.	(2) Regulation (EC) No 178/2002 defines "risk analysis" as a process consisting of three ***distinct but*** 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. Risk communication is an essential part of the risk analysis process and ***presupposes the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions amongst risk assessors,***

	risk managers, consumers, feed and food businesses, the academic community, including the explanation of risk assessment findings and the basis of risk management decisions.

Amendment 2

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(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.	(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 ***can have a negative*** 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.

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, ***transparent, independent*** and continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should be ***capable of contributing to a participatory*** and open dialogue between all interested parties to ensure ***prevalence of public interest only, accuracy, comprehensiveness, transparency*** and consistency of the risk

analysis process.

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

Amendment 5

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) To this effect, it is necessary to establish general objectives and principles of risk communication, taking into account the respective roles of risk assessors and managers.	(6) To this effect, it is necessary to establish general objectives and principles of risk communication, taking into account the respective roles of risk assessors and managers, ***while guaranteeing their independence***.

Amendment 6

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Based on these general 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.	(7) Based on these general objectives and principles, a general plan on risk communication ***in real time*** should be established in close cooperation with the Authority and the Member States, and following ***the organisation of the*** relevant public consultations.

Amendment 7

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 ***environmental and*** 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, the ways of managing it 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, ***exhaustive and expeditious*** mechanisms to ensure ***accurate*** risk communication.

Amendment 8

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) It is appropriate to align the composition of the Management Board of the Authority to the Common Approach on decentralised agencies, in accordance with the Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies of 2012[22].	(10) It is appropriate to align the composition of the Management Board of the Authority to the Common Approach on decentralised agencies, in accordance with the Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies of 2012[22], ***while also taking into account the withdrawal of the United Kingdom from the EU and the legal effects resulting therefrom***.
[22] https://europa.eu/european-	[22] https://europa.eu/european-

union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

Amendment 9

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 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***, including representatives of civil society and industry,*** in the Management Board of the Authority, while providing that those representatives should have experience in particular in ***assessing and managing risks and problems and that they have no conflict of interest with the applicants***.

Amendment 10

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 the protection*** of health and the environment and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

Amendment 11

Proposal for a regulation

Recital 13

Text proposed by the Commission	*Amendment*
(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.	(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. ***In order to tackle this phenomenon more effectively,*** the system has thus to be strengthened ***and promoted,*** and Member States should take a more active role to ensure that a sufficient pool of experts is available, ***by undertaking support actions and using incentives and rewards to increase the level of participation and the degree of interest in seeking to engage in it,*** to meet the needs of the Union risk assessment system in terms of high level of scientific expertise, independence and multidisciplinary expertise.

Amendment 12

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	(14) 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, ***transparent*** 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

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***.***	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. ***To this effect, it is necessary to implement new and adequate budgetary measures.***

Amendment 13

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 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.	(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 subject matter unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.

Amendment 14

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 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 ***and provide wide and non-discriminatory access to information***, the advice of the Authority should be made public.

Amendment 15

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	(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***.	authorisation ***or renewal*** has been ***submitted and the Authority has published its official scientific opinion***.

Amendment 16

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 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.***	(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 ***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 application for authorisation or renewal has been made public,*** in order to identify whether other relevant scientific data or studies are available.

Amendment 17

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	(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, ***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.

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 are to*** be verified by the Commission.

Amendment 18

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.

Amendment 19

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	(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).	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 ***Authority*** should be responsible for triggering the commissioning of such verification studies. Account should be taken of the fact that in some specific cases the studies commissioned may need to have a wider scope than the evidence at stake (for example new scientific developments becoming available).

Amendment 20

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 ***the Union has promoted a considerable number of measures to protect the quality and safety of food and products (Regulation (EC) No 2073/2005; Regulation (EC) No 853/2004; Regulation (EC) No 854/2004; and in particular Recital 12 of Directive 2009/128/EC) and,*** 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.

Amendment 21

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) The Aarhus Convention establishes a number of rights of the public with regard to the environment.

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

Amendment 22

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 Union 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.

Amendment 23

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 and in order to ensure the liability 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.

Amendment 24

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 intends to ensure transparency in the risk assessment process and give the fullest possible effect to the right of the*** public ***to transparency of information and access to documents of the Authority and is to be read in conjunction with Regulation No 1049/2001 and 1367/2006.***

Amendment 25

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27a) The provisions on active dissemination laid down in this Regulation are not meant to limit, in any manner, the scope of the rights provided

for by Regulation (EC) No 1049/2001 and (EC) No 1367/2006.

Amendment 26

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 ***having a direct impact on health or the environment should therefore always be made public***. It is appropriate to lay down, in Regulation (EC) No 178/2002, an ***exhaustive*** horizontal list of information items ***which may be kept confidential as they would*** significantly ***undermine the protection of commercial interest. However, it should only be possible for this information to be kept secret if the company opposing its dissemination can verifiably prove that the proactive disclosure of the information item would significantly undermine its*** commercial interests ("general horizontal list of confidential items"). ***The exceptions to the principle of transparency must be interpreted strictly. However, even if the disclosure of the information is considered to undermine the commercial interests of an economic operator, the information should, in case there is an overriding public interest in the disclosure, not be kept confidential as the interests of public health prevail over commercial interests. It is appropriate to lay down, in Regulation (EC)No178/2002, a horizontal exhaustive list of information items for which it should not be possible to keep them confidential, since they relate to circumstances where an overriding public interest in their disclosure is deemed to exist.***

Amendment 27

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, for*** the protection and ***confidentiality*** of personal data for the purposes of the transparency of the risk assessment process, ***to*** regulation (EC) No 45/2001 of the European Parliament and of the Council 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. ***For the purpose of ensuring the transparency, independence, sustainability and reliability of the risk assessment process, in particular to avoid conflicts of interest, it is considered necessary and proportionate to publish the names of any individual designated by the Authority to contribute to the Authority's decision making process, including in the context of the adoption of guidance documents.***
[24] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).	[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).	[25] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Amendment 28

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) For the purposes of increased transparency and in order to ensure that requests for scientific outputs received by the Authority are processed in an effective manner, standard data formats and software packages should be developed. In order to ensure uniform conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of standard data formats and software packages, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[26].	(31) For the purposes of increased transparency and in order to ensure that requests for scientific outputs received by the Authority are processed in an effective manner, standard data formats and software packages should be developed. In order to ensure uniform ***and harmonised*** conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of standard data formats and software packages, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[26].
[26] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	[26] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment 29

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(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.	(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 a way that ensures complete*** security.

Amendment 30

Proposal for a regulation
Recital 33

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

Amendment 31

Proposal for a regulation
Recital 35

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

Amendment 32

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.	(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***, while, however, bearing in mind that, where there are specific grounds for concern about public welfare and public health, public interest prevails over commercial interests***. 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.
[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).	[35] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p.13).

Amendment 33

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	(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

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

Amendment 34

Proposal for a regulation
Recital 38

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

Amendment 35

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

Amendment 36

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

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

Amendment 37

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

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

Amendment 38

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

Text proposed by the Commission	*Amendment*
(d) foster public understanding of the	(d) foster public understanding of the

risk analysis process so as to enhance ***confidence*** in its outcome;	risk analysis process so as to enhance ***accountability*** in its outcome, ***and restore consumer trust in the Union and its institutions***;

Amendment 39

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

Text proposed by the Commission	*Amendment*
(f) ensure appropriate exchange of information with interested parties in relation to risks associated with the agri-food chain.	(f) ensure appropriate exchange of information with interested parties in relation to risks associated with the agri-food chain ***and strategies to avoid them.*** *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Amendment 40

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

Text proposed by the Commission	*Amendment*
	(fa) combat sources and dissemination of false and misleading information;

Amendment 41

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

Text proposed by the Commission	*Amendment*
b) provide transparent information at each stage of the risk analysis process from the framing of requests for scientific advice	b) ***constantly*** provide ***up-to-date and*** transparent information at each stage of the risk analysis process from the framing of

to the provision of risk assessment and the adoption of risk management decisions;	requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions;

Amendment 42

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

Text proposed by the Commission	*Amendment*
c) take into account risk perceptions;	c) take into account ***the level of risk, its possible consequences and*** risk perceptions;

Amendment 43

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

Text proposed by the Commission	*Amendment*
d) facilitate understanding and dialogue amongst all interested parties; and,	d) facilitate understanding, dialogue ***and cooperation*** amongst all interested parties***, such as consumers and consumer associations, environmental groups, animal welfare organisations, health organisations, citizens' associations, scientific research centres, trade unions and also cooperatives, associations of producers and farmers, representatives of small and medium-sized enterprises, and the research and innovation sectors***; and,

Amendment 44

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 8b – paragraph 1 – 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 the protection of personal data.

Amendment 45

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 an ***accurate*** and systematic manner both at Union and national level***, while acknowledging diverging scientific opinions where they exist***. It shall:

Amendment 46

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;

Amendment 47

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

Article 8c – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
b) identify the appropriate main tools and channels to be used for risk communication purposes, taking into account the needs of relevant target audience groups; and,	b) identify the appropriate main tools and channels ***(a clear, effective and accessible website)*** to be used for risk communication purposes, taking into account the ***specific*** needs of relevant target audience groups ***and in particular arranging for specific communication in situations in which emergencies are managed that might arise in the field of food or the environment, which presuppose an increase in dedicated communication tools and measures (helplines, a suitably identified section of the EFSA website, apps and specific information campaigns)***; and,

Amendment 48

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 ***and constant interaction*** amongst all interested parties***, while acknowledging scientific divergent opinions where they exist***.

Amendment 49

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b
Regulation (EC) No 178/2002
Article 25 – paragraph 1a – 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.

Amendment 50

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b
Regulation (EC) No 178/2002
Article 25 – paragraph 1a – point c

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

Amendment 51

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b
Regulation (EC) No 178/2002
Article 25 – paragraph1b

Text proposed by the Commission	*Amendment*
1b. The members of the Management Board and where relevant, the alternate members shall be appointed taking into account high competence in the area of food safety risk assessment as well as competences in the food chain safety legislation and policy, and relevant managerial, administrative and budgetary/financial skills.,	1b. The members of the Management Board and where relevant, the alternate members shall be appointed taking into account high competence in the area of food safety risk assessment as well as competences in the food chain safety legislation and policy, and relevant managerial, administrative and budgetary/financial skills.”,

Justification

Alternate members are empowered to vote in place of full members, which means that they must have the same qualifications.

Amendment 52

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point d
Regulation (EC) No 178/2002
Article 25 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
“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 .”;

Amendment 53

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point b
Regulation (EC) No 178/2002
Article 28 – paragraph 5a – point b

Text proposed by the Commission	*Amendment*
b) Member States ***shall*** nominate experts ***with a view to collectively reach the number indicated by the Executive Director***. ***Each Member State shall nominate at least 12 scientific experts.***	b) Member States ***may*** nominate experts ***for the fields indicated on the basis of a call for expressions of interest***. Member States may ***also*** nominate nationals of other Member States.

Member States may nominate nationals of other Member States.

Amendment 54

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point b
Regulation (EC) No 178/2002
Article 28 – paragraph 5a – 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 ***on the basis of the expressions of interest***, 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.

Amendment 55

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point b
Regulation (EC) No 178/2002
Article 28 – paragraph 5a – point e

Text proposed by the Commission	*Amendment*
e) The Management Board shall ensure that the broadest possible geographical distribution is achieved in the final appointments.	e) The Management Board shall ensure that the broadest***, most comprehensive and most participatory*** possible geographical distribution is achieved in the final appointments.

Amendment 56

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point b

Regulation (EC) No 178/2002
Article 28 – paragraph 5d

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

Amendment 57

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

Text proposed by the Commission	*Amendment*
At the request of a potential applicant for a food law authorisation, the staff of the Authority ***shall*** advise on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.	At the request of a potential applicant for a food law authorisation, the staff of the Authority ***may, in written form,*** advise on the relevant provisions and the required content of the application for authorisation. The ***staff of the Authority providing the advice referred to in the first sentence shall not be involved in any scientific work, including within the meaning of paragraph 5f of Article 28, that is directly or indirectly relevant to the application which is the subject of the advice. The*** advice provided by the staff of the

	Authority ***shall immediately be documented and published on the Authority's website. It shall contribute to the development of a Frequently Asked Questions document with the purpose of developing more comprehensive guidelines for applicants and reducing the need for individual correspondence.***
	The advice provided shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels. ***Within [36 months after the entry into force of this regulation], the Commission shall assess the impact of this article on the functioning of the Authority. Particular attention shall be paid to the additional workload and mobilisation of staff, and whether it has led to any shift in the allocation of the Autority's resources at the expense of activities of public interest.***

Amendment 58

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32b – paragraph 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 ***if*** a corresponding application for authorisation has been received and after the Authority has decided on the disclosure of the accompanying studies ***and its scientific opinion*** in accordance with Article 38 and Articles 39 to 39f.

Amendment 59

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.

Amendment 60

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

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

Amendment 61

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

Article 32e – paragraph 1

Text proposed by the Commission	*Amendment*
Without prejudice to the obligation of applicants for authorisations under food law to demonstrate the safety of a subject matter submitted to a system of authorisation, ***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.;	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 ***Authority may, where scientific data and findings are in conflict with each other,*** commission scientific studies with the objective of verifying evidence used in its risk assessment process***, with the aim of obtaining greater assurance about food or feed safety***. The studies commissioned may have a wider scope than the evidence subject to verification.;

Amendment 62

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

Text proposed by the Commission	*Amendment*
	Any studies commissioned shall take into account Directive 2010/63/EU on the protection of animals used for scientific purposes.

Amendment 63

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – subparagraph 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 ***ensure*** a high level of transparency, ***in line with the Aarhus Convention and Regulation (EC) No 1367/2006, without prejudice to Regulation (EC) No 1049/2001, as well as***

	in line with with Directive 2003/4/EC, providing for an active and systematic dissemination to the public of environmental information. It shall in particular make public without delay:

Amendment 64

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

Amendment 65

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

Amendment 66

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a
Regulation (EC) No 178/2002
Article 38 – paragraph 1 – subparagraph 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;	***deleted***

Amendment 67

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

Text proposed by the Commission	*Amendment*
i) advice provided by the Authority to potential applicants at pre-submission phase pursuant to Article 32a and 32c.	***deleted***

Amendment 68

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

Text proposed by the Commission	*Amendment*
	(aa) The following paragraph -1a is inserted:
	(-1a) At the time of publication of its scientific opinion, the Authority shall also make the following public:
	(a) 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, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39f.
	b) the information on which its scientific outputs, including scientific opinions, are based, taking into account the protection of confidential data and the protection of personal data in accordance with Articles 39 to 39f;
	c) information concerning the consultation sessions with applicants conducted by the Authority pursuant to Article 32a and 32c prior to their applications.

Amendment 69

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

Text proposed by the Commission	*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 parties shall not engage the responsibility of the European Union.	The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be ***commercially*** used, reproduced, or otherwise exploited ***for commercial purposes. For the avoidance of doubt, the information published may be used for the purpose of public scrutiny of the results, including a better 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.”

Amendment 70

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point c a (new)
Regulation (EC) No 178/2002
Article 38 – paragraph 3a

Text proposed by the Commission	*Amendment*
	(ca) the following paragraph 3a is inserted:
	3a. 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, to Regulation (EC) No 1049/2001 and to Regulation (EC) No 1367/2006.

Amendment 71

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 (EC) No 1049/2001 and Directive 2003/4/EC and the general principle that the interests of public health always prevail over private interests,*** the Authority shall not make public information for which confidential treatment has been requested ***and granted in application of*** the conditions laid down in this Article.

Amendment 72

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

Text proposed by the Commission	*Amendment*

	(2a) innovative commercial elements and models, formulae and products covered by patents the protection of which might be threatened by any failure to maintain confidentiality during the initial study request procedure, thus exposing the requester to damage and risks of market distortion and unfair competition

Amendment 73

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 2 – point 3

Text proposed by the Commission	*Amendment*
(3) commercial information revealing sourcing, market shares or business strategy of the applicant; ***and***	(3) commercial information revealing sourcing, ***innovative ideas for the product/substance,*** market shares or business strategy of the applicant; *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Amendment 74

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 ***which indicate risks of possible effects on, and threats to, public and animal*** health ***or the environment***.;

Amendment 75

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

Text proposed by the Commission	*Amendment*
	4a. This Article is without prejudice to Directive 2003/4/EC and Regulations (EC) No 1049/2001 and 1367/2006

Justification

This formulation is necessary for the benefit of transparency

Amendment 76

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 ***edit, with black bars,*** the information for which the applicant ***request***s confidential ***treatment*** in accordance with paragraphs 2 and 3 of ***Article 39***. The confidential version shall contain all information submitted, including information 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.

Amendment 77

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.

Amendment 78

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

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

Amendment 79

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).

Amendment 80

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

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

Amendment 81

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39d – paragraph 3

Text proposed by the Commission	*Amendment*
3. If an applicant in the context of an authorisation procedure withdraws or has	3. If an applicant in the context of an authorisation procedure withdraws or has

withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39to 39f. The application shall be considered withdrawn as of the moment the written request is received by the competent body that had received the original application. Where the withdrawal of the application takes place before the Authority has decided on the relevant confidentiality request, the Authority, the Commission and the Member States shall not make public ***the information for which confidentiality has been requested***.

withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39to 39f. The application shall be considered withdrawn as of the moment the written request is received by the competent body that had received the original application. Where the withdrawal of the application takes place before the Authority has decided on the relevant confidentiality request, the Authority, the Commission and the Member States shall not make public ***any information relating to the planned application***.

Amendment 82

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

Text proposed by the Commission	*Amendment*
(a) the name ***and address*** of the applicant;	(a) the name of the applicant;

Amendment 83

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

Text proposed by the Commission	*Amendment*
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 there is an overriding public interest.	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***, constituting a threat to their independence and autonomous judgement,*** and shall not

be made publicly available, unless there is an overriding public interest.

Amendment 84

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

Text proposed by the Commission	*Amendment*
The information systems operated by the Authority to store its data, including confidential and personal data shall be designed ***to a high level*** of security appropriate to the security risks at stake, taking into account Articles 39 to 39f of this Regulation. Access shall be based at the minimum on a system requiring two factor authentication or providing an equivalent level of security. The system shall ensure that any access to it is fully auditable.;	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 the highest standards*** of security appropriate to the security risks at stake ***will be attained***, taking into account Articles 39 to 39f of this Regulation. Access shall be based at the minimum on a system requiring two factor authentication or providing an equivalent level of security. The system shall ensure that any access to it is fully auditable.;

Amendment 85

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 178/2002
Article 57a – paragraph 6

Text proposed by the Commission	*Amendment*
6. A delegated act adopted pursuant to Article 8(c) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period ***shall*** be extended by two months at the initiative of the	6. A delegated act adopted pursuant to Article 8(c) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period ***may*** be extended by two months at the initiative of the

European Parliament or of the Council.;	European Parliament or of the Council.;

Amendment 86

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 178/2002
Article 61 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall assess the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.	2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall assess the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification. ***Conversely, if the evaluation shows that the set objectives are being attained and the tasks assigned are being performed, the possibility to increase investment in order to secure more ambitious results shall be explored.***

Amendment 87

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 178/2002
Article 61 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendment 88

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 178/2002
Article 61 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ***Commission*** shall ***report to*** the European Parliament, ***the Council and the Management Board on the evaluation findings. The findings of the evaluation shall*** be made public.	4. The ***evaluations and recommendations referred to in paragraphs 1 and 2*** shall ***be forwarded to the Council and*** the European Parliament, ***and*** shall be made public.

Amendment 89

Proposal for a regulation
Article 2 – paragraph 1 – point 2 a (new)
Directive 2001/18/EC
Article 24 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	(2a) In Article 24, the following paragraph 3a is inserted:
	"3a. The obligation to proactively disseminate the information set out in paragraph 1 of this Article, in line with Article 25, and in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006."

Amendment 90

Proposal for a regulation
Article 2 – paragraph 1 – point 4
Directive 2001/18/EC
Article 28 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the relevant Scientific	4. Where the relevant Scientific

Committee is consulted under paragraph 1, it shall make public the notification/application, relevant supporting information and any supplementary information supplied by the notifier/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 25 of this Directive.”.	Committee is consulted under paragraph 1, it shall make public the notification/application, relevant supporting information and any supplementary information supplied by the notifier/applicant, ***at the same time*** as its scientific ***opinion***, in accordance with Article 38 and Articles 39 to 39f of Regulation (EC) No 178/2002, which shall apply mutatis mutandis, and Article 25 of this Directive.

Amendment 91

Proposal for a regulation
Article 3 – paragraph 1 – point 9
Regulation (EC) No 1829/2003
Article 29 – paragraph 1

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

Amendment 92

Proposal for a regulation
Article 3 – paragraph 1 – point 9
Regulation (EC) No 1829/2003
Article 29 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The obligation to proactively disseminate the information set out in paragraph 1 of this Article, in line with Article 30, and in line with Articles 38 and

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

Amendment 93

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:***	2. ***Information relating*** to the following ***shall not be considered confidential:***
(a) ***DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,***	(a) ***name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;***
(b) ***breeding patterns and strategies.***	(b) ***general description of the GMO and the name and address of the authorisation-holder;***
	(c) physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);
	(d) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on human and animal health and on the environment;
	(e) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;
	(f) methods for detection, including sampling and identification of the

transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3(1) and 15(1);

(g) information on waste treatment and emergency response.

Justification

Paragraph 2 simply reinstates the current wording of Regulation 1829/2003. If the aim of the proposal is to strengthen transparency, then, instead of enlarging the list of information which can be kept confidential, the current provisions relating to information that can never be kept confidential must be kept.

Amendment 94

Proposal for a regulation
Article 4 – paragraph 1 – point 1 – point b
Regulation (EC) No 1831/2003
Article 7 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
c) ensure public access to the application and any information supplied by the applicant, in accordance with Article 18.”;	c) ensure public access to the application and any information supplied by the applicant, and ***at the same time to its scientific opinion,*** in accordance with Article 18”;

Amendment 95

Proposal for a regulation
Article 4 – paragraph 1 – point 1 a (new)
Regulation (EC) No 1831/2003
Article 17 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In Article 17, the following paragraph 2a is inserted:
	“2a. The obligation to proactively disseminate information set out in this Article and in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any

natural or legal person to access documents upon request as set out in Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006."

Amendment 96

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

Text proposed by the Commission	*Amendment*
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, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.	1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, ***at the same time as its scientific opinion***, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.

Amendment 97

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

Text proposed by the Commission	*Amendment*
	3a. The Authority shall apply the principles of Regulation (EC) No 1049/2001 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.

Amendment 98

Proposal for a regulation

Article 4 – paragraph 1 – point 2
Regulation (EC) No 1831/2003
Article 18 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001."

Amendment 99

Proposal for a regulation
Article 5 – paragraph 1 – point 1 – point a
Regulation (EC) No 2065/2003
Article 7 – paragraph 2 – point c – point ii

Text proposed by the Commission	*Amendment*
ii) ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 14 and 15.”;	(ii) ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant, ***when it publishes its scientific opinion,*** in accordance with Articles 14 and 15.

Amendment 100

Proposal for a regulation
Article 5 – paragraph 1 – point 2
Regulation (EC) No 2065/2003
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Authority shall make public the application for authorisation, relevant supporting information and any	1. The Authority shall make public***, at the same time as its scientific opinion,*** the application for authorisation, relevant

supplementary information supplied by the applicant as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002.;	supporting information and any supplementary information supplied by the applicant as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002.;

Amendment 101

Proposal for a regulation
Article 5 – paragraph 1 – point 2 a (new)
Regulation (EC) No 2065/2003
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(2a) In Article 14, the following paragraph 1a is inserted:
	"1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006."

Amendment 102

Proposal for a regulation
Article 5 – paragraph 1 – point 3
Regulation (EC) No 178/2002
Article 15 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) and, the Authority shall assess the confidentiality request submitted by the applicant.	(b) and, the Authority shall assess the confidentiality request submitted by the applicant ***and shall be required to respond - and provide the necessary justification - within two months of receipt of the application***.

Amendment 103

Proposal for a regulation
Article 6 – paragraph 1 – point 1 – point a
Regulation (EC) No 1935/2004
Article 9 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 19 and 20;	ii) ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant, ***at the same time as to its scientific opinion,*** in accordance with Articles 19 and 20.

Amendment 104

Proposal for a regulation
Article 6 – paragraph 1 – point 2
Regulation (EC) No 1935/2004
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
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, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and Article 20 of this Regulation.”;	1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, ***at the same time*** as its scientific ***opinion***, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and Article 20 of this Regulation.”;

Amendment 105

Proposal for a regulation
Article 6 – paragraph 1 – point 2 a (new)
Regulation (EC) No 1935/2004
Article 19 – paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	(2a) in Article 19, the following paragraph 2a is inserted:
	“2a. The obligation to proactively disseminate information set out in

paragraph 1 is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006."

Amendment 106

Proposal for a regulation
Article 7 – paragraph 1 – point 2
Regulation (EC) No 1331/2008
Article 11 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The obligation to proactively disseminate information set out in paragraph 1 of this Article, in line with Article 12 and in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006.

Amendment 107

Proposal for a regulation
Article 7 – paragraph 1 – point 3
Regulation (EC) No 1331/2008
Article 12 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

Amendment 108

Proposal for a regulation
Article 8 – paragraph 1 – point 5 a (new)
Regulation (EC) No 1107/2009
Article 63 – paragraph 3

Present text	*Amendment*
	(5a) in Article 63, paragraph 3 is replaced by the following:
3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information	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 Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006.***

Amendment 109

Proposal for a regulation
Article 9 – paragraph 1 – point 1 – point b
Regulation (EC) No 2015/2283
Article 10 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Commission requests an opinion from**,** the European Food Safety Authority ('the Authority'), the Authority shall ensure public access to 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.";	3. Where the Commission requests an opinion from the European Food Safety Authority ('the Authority'), the Authority shall ensure public access to the application in accordance with Article 23 ***when it publishes its opinion*** as to ***the question of*** whether the update is liable to have an effect on human health.";

Amendment 110

Proposal for a regulation
Article 9 – paragraph 1 – point 3 – point b
Regulation (EC) No 2015/2283
Article 16 – paragraph 2 – last sentence

Text proposed by the Commission	*Amendment*
The Authority shall ensure public access to the application, ***relevant supporting information and any supplementary***	The Authority shall ensure public access to ***the non-confidential elements of*** the application***, and to the notification***

information supplied by the applicant in accordance with Article 23.;	***concerning safety concerns under Article 15, at the same time as it publishes its scientific opinion*** in accordance with Article 23.”;

Amendment 111

Proposal for a regulation
Article 9 – paragraph 1 – point 4
Regulation (EC) No 2015/2283
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
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, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article.	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, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article***, at the same time as it publishes its opinion concerning the application***.

Amendment 112

Proposal for a regulation
Article 9 – paragraph 1 – point 4 a (new)
Regulation (EU) No 2015/2283
Article 25 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(4a) In Article 25, the following paragraph 1a is inserted:
	“1a. The obligation to proactively disseminate the information set out in this Regulation, in line with Articles 38 and 39 of Regulation (EC) No 178/2002, is without prejudice to the right of any natural or legal person to access documents upon request as set out in Regulation (EC) No 1049/2001 and

Regulation (EC) No 1367/2006.”

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Transparency and sustainability of the EU risk assessment in the food chain
References	COM(2018)0179 – C8-0144/2018 – 2018/0088(COD)
Committee responsible Date announced in plenary	ENVI 28.5.2018
Opinion by Date announced in plenary	JURI 28.5.2018
Rapporteur Date appointed	Jiří Maštálka 23.4.2018
Discussed in committee	3.9.2018
Date adopted	10.10.2018
Result of final vote	+: 12 –: 5 0: 6
Members present for the final vote	Max Andersson, Joëlle Bergeron, Jean-Marie Cavada, Kostas Chrysogonos, Mady Delvaux, Rosa Estaràs Ferragut, Enrico Gasbarra, Lidia Joanna Geringer de Oedenberg, Heidi Hautala, Sajjad Karim, Sylvia-Yvonne Kaufmann, Gilles Lebreton, António Marinho e Pinto, Pavel Svoboda, József Szájer, Axel Voss, Francis Zammit Dimech, Tadeusz Zwiefka
Substitutes present for the final vote	Geoffroy Didier, Pascal Durand, Angel Dzhambazki, Angelika Niebler, Virginie Rozière, Tiemo Wölken

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

12	+
ALDE	António Marinho e Pinto
ECR	Angel Dzhambazki, Sajjad Karim
PPE	Geoffroy Didier, Rosa Estaràs Ferragut, Angelika Niebler, József Szájer, Axel Voss, Francis Zammit Dimech, Tadeusz Zwiefka
S&D	Enrico Gasbarra, Virginie Rozière

5	-
GUE/NGL	Kostas Chrysogonos
S&D	Lidia Joanna Geringer de Oedenberg
VERTS/ALE	Max Andersson, Pascal Durand, Heidi Hautala

6	0
ALDE	Jean-Marie Cavada
EFDD	Joëlle Bergeron
ENF	Gilles Lebreton
S&D	Mady Delvaux, Sylvia-Yvonne Kaufmann, Tiemo Wölken

Key to symbols:
+ : in favour
- : against
0 : abstention