European Parliament
2014-2019

Committee on Legal Affairs

2018/0088(COD)

7.9.2018

AMENDMENTS
88 - 269

Draft opinion
Jiří Maštálka
(PE625.400v01-00)

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

Proposal for a regulation
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

AM_Com_LegOpinion

Amendment 88
Enrico Gasbarra

Proposal for a regulation
Citation 1

Text proposed by the Commission	*Amendment*
having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, ***and*** 168(4)(b) thereof,	having regard to the Treaty on the Functioning of the European Union, and in particular Articles ***6,*** 43, 114, 168(4)(b)***, 169 and 191*** thereof,

Or. it

Amendment 89
Daniel Buda

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.***

Or. ro

Amendment 90
Enrico Gasbarra

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) The evaluation of Regulation (EC) No 178/2002, ("Fitness Check of the General Food Law")[21], 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, ("Fitness Check of the General Food Law")[21], found that risk communication is overall, not considered to be effective enough, which has ***a negative*** impact on consumers' confidence on the outcome of the risk analysis process.
[21] Commission Staff Working Document, "The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002)", SWD(2018)38 final, dated 15.1.2018.	[21] Commission Staff Working Document, "The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002)", SWD(2018)38 final, dated 15.1.2018.

Or. it

Amendment 91
Emil Radev

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 has ***a direct*** impact on consumers' confidence on the outcome of the risk analysis process.
[21] Commission Staff Working Document,	[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.	"The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002)", SWD(2018)38 final, dated 15.1.2018.

Or. bg

Amendment 92
Enrico Gasbarra

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 the coherence***,*** ***comprehensiveness*** and consistency ***of*** the risk analysis process.

Or. it

Amendment 93
Emil Radev

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***	(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

coherence ***and*** consistency within the risk analysis process.	coherence***,*** consistency ***and transparency*** within the risk analysis process.

Or. bg

Amendment 94
Daniel Buda

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***.

Or. ro

Amendment 95
Emil Radev

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 ***and the need to ensure their independence***.

Or. bg

Amendment 96
Emil Radev

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 holding of the*** relevant public consultations.

Or. bg

Amendment 97
Enrico Gasbarra

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 risk, the nature of the risk and its potential ***environmental and*** public health impact, who and what are directly or indirectly affected by the risk, the levels of risk exposure, the ability to control risk***, the ways of managing it*** 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 ***which is constantly updated, clear and easy to access, and which also includes specifically dedicated instruments in order more easily to highlight alert information and to provide responses to the public concerning public***

health risks.

Or. it

Amendment 98
Emil Radev

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 risk, the nature of the risk and its potential public health ***and environmental*** 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 ***and timely*** mechanisms to ensure coherent risk communication.

Or. bg

Amendment 99
Daniel Buda

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	(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.	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***, comprehensive and prompt*** risk communication.
	Or. ro

Amendment 100
Emil Radev

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 of this***.
[22] https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.	[22] https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.
	Or. bg

Amendment 101
Daniel Buda

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 on risk assessment ***and have no conflict of interest with the applicants***.

Or. ro

Amendment 102
Emil Radev

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 in the Management Board of the Authority, while providing that those representatives should have ***considerable*** experience in particular on risk assessment***, after they have made a declaration of an absence of conflict of interests***.

Or. bg

Amendment 103
Răzvan Popa

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 ***but also representatives of the industry*** in the Management Board of the Authority, while providing that those representatives should have experience in particular on risk assessment.

Or. en

Amendment 104
Enrico Gasbarra

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 in the Management Board of the Authority, while providing that those representatives should have experience in particular on ***assessing and managing***

risks and problems.

Or. it

Amendment 105
Enrico Gasbarra

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.

Or. it

Amendment 106
Daniel Buda

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) The Fitness Check of the General	(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.	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***, with two-thirds of the experts of the scientific groups coming from six Member States in this instance.*** 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.
	Or. ro

Amendment 107
Răzvan Popa

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. The system has thus to be strengthened and Member States should take a more ***transparent and*** 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.
	Or. en

Amendment 108
Răzvan Popa

Proposal for a regulation
Recital 14

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

Or. en

Amendment 109
Emil Radev

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	(14) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the nomination of the

members of the Scientific Panels by the Member States, their selection by the Executive Director of the Authority and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to defend EFSA's interests and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures should also be put in place to ensure that scientific experts have the means to act independently.

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 defend EFSA's interests and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures should also be put in place to ensure that scientific experts have the means to act independently ***of the Member States by whom they are appointed***.

Or. bg

Amendment 110
Răzvan Popa

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	(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 is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission

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.	costly studies that will in the end help the ***players in 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.

Or. en

Amendment 111
Emil Radev

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	(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

and in some cases the efficacy of a subject matter.	demonstrate the safety and in some cases the efficacy of a subject matter.

Or. bg

Amendment 112
Daniel Buda

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.

Or. ro

Amendment 113
Emil Radev

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.

Or. bg

Amendment 114
Enrico Gasbarra

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	(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.	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.

Or. it

Amendment 115
Emil Radev

Proposal for a regulation
Recital 18

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

Or. bg

Amendment 116
Daniel Buda

Proposal for a regulation

Recital 18

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

Or. ro

Amendment 117
Emil Radev

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	(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 ***non-interested*** third parties in order to identify whether other relevant scientific data or

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.	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.

Or. bg

Amendment 118
Răzvan Popa

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 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.

Or. en

Amendment 119

Emil Radev

Proposal for a regulation
Recital 21

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

Or. bg

Amendment 120
Răzvan Popa

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Studies, including tests, submitted by business operators in support of applications for authorisations under Union sectoral food law usually comply with internationally recognised principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, ***issues***	(21) Studies, including tests, submitted by business operators in support of applications for authorisations under Union sectoral food law usually comply with internationally recognised principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, ***non-***

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.

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.

Or. en

Amendment 121
Emil Radev

Proposal for a regulation
Recital 22

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

Or. bg

Amendment 122
Enrico Gasbarra

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 EU has promoted many 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*** perceived as fully transparent.

Or. it

Amendment 123
Răzvan Popa

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	(23) The Fitness Check of the General Food Law demonstrated that although the Authority has made considerable progress in terms of transparency, the risk assessment process, especially in the context of authorisation procedures covering the agri-food chain, is not ***yet*** fully transparent. This is also partly due to

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.	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.

Or. en

Amendment 124
Heidi Hautala
on behalf of the Verts/ALE Group

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.

Or. en

Amendment 125
Emil Radev

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) It is therefore necessary to	(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.

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. 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.

Or. bg

Amendment 126
Răzvan Popa

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) It is therefore necessary to strengthen the transparency of the risk assessment process in a proactive manner ***in order to ensure the liability of the Authority***. 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. 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.

Or. en

Amendment 127
Răzvan Popa

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Where the opinion of the Authority is requested in relation to authorisation procedures under Union food law and having regard to its obligation to ensure public access to all supporting information with respect to the provision of its scientific outputs, the Authority ***should*** have responsibility for assessing confidentiality requests.	(26) Where the opinion of the Authority is requested in relation to authorisation procedures under Union food law and having regard to its obligation to ensure public access to all supporting information with respect to the provision of its scientific outputs, the Authority ***must*** have responsibility for assessing confidentiality requests.

Or. en

Amendment 128
Enrico Gasbarra

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) To determine what level of disclosure strikes the appropriate balance, the relevant rights of the public to transparency ***of information*** 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.

Or. it

Amendment 129
Heidi Hautala
on behalf of the Verts/ALE Group

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

Or. en

Amendment 130
Heidi Hautala
on behalf of the Verts/ALE Group

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 intended to limit in any manner the scope of the rights given by Regulation 1049/2001 and 1367/2006.

Or. en

Amendment 131
Enrico Gasbarra

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	(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.

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 ***an exhaustive*** 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"). ***In all circumstances that could give rise to an alert about potential risks to public health and/or clearly established problems which are indicative of an*** urgent ***need*** to protect human health, animal health or the environment, such information should be disclosed***, as the interests of public health should always prevail over commercial interests***.

Or. it

Amendment 132
Heidi Hautala
on behalf of the Verts/ALE Group

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***	(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 ***exhaustive*** list of information items ***which could be kept confidential on the grounds that their*** disclosure ***would*** significantly

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***.

undermine the protection of commercial interests (“general horizontal list of confidential items”). ***To request confidentiality, the company in question must prove, with justification, that the proactive disclosure of the information item would significantly undermine its commercial interests. However, where disclosure of the*** information ***is of overriding public interest, confidentiality cannot be granted***.

Or. en

Amendment 133
Răzvan Popa

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) 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 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.

Or. en

Amendment 134
Răzvan Popa

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 set out specific requirements with respect to the protection ***and the confidentiality*** of personal data for the purposes of the transparency of the risk assessment process taking into account Regulation (EC) No 45/2001 of the European Parliament and of the 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.
[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).

Or. en

Amendment 135
Enrico Gasbarra

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 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***, suitability*** and reliability of the risk assessment process, while preventing conflicts of interests.
[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).

Or. it

Amendment 136
Enrico Gasbarra

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***, 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).

Or. it

Amendment 137
Emil Radev

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 accordance with a high level of security ***and in full compliance with the Data Protection Regulation***.

Or. bg

Amendment 138
Enrico Gasbarra

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 such a way as to ensure complete*** security.

Or. it

Amendment 139
Enrico Gasbarra

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	(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.

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.

Or. it

Amendment 140
Emil Radev

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.

Or. bg

Amendment 141
Heidi Hautala
on behalf of the Verts/ALE Group

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	***deleted***

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.

_____

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

Or. en

Amendment 142
Enrico Gasbarra

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	(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.	the specific objectives of sectoral Union legislation as well as experienced gained***, always, however, bearing in mind that, where there are specific grounds for concern about public welfare and public health, the public interest must prevail 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).

Or. it

Amendment 143
Enrico Gasbarra

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) In order to further strengthen the link between risk assessors and risk managers at Union and national levels as well as the coherence and consistency of risk communication, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to adopt a general plan on risk communication on matters covering the	(37) In order to further strengthen the link between risk assessors and risk managers at Union and national levels as well as the coherence***, comprehensiveness, reliability*** and consistency of risk communication, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to adopt a general plan on risk

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.

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

Or. it

Amendment 144
Daniel Buda

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*** and the business operators to adapt to the new requirements ***and to ensure a balance between, on the one hand, benefits for citizens, Member States and interested parties and, on the other hand, an negligible impact on innovation and industry as a whole,*** while ensuring that the Authority continues its smooth operation, it is necessary to provide for transitional measures for the application of this Regulation.

Or. ro

Amendment 145

Daniel Buda

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

Text proposed by the Commission	*Amendment*
(b) promote consistency and transparency in formulating risk management recommendations;	(b) promote consistency, transparency ***and measures to ensure a high level of health protection*** in formulating risk management recommendations;
	(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Or. ro

Amendment 146
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
b) promote consistency and transparency in formulating risk management recommendations;	b) promote consistency***, maximum reliability*** and transparency in formulating risk management recommendations;

Or. it

Amendment 147
Enrico Gasbarra

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

Regulation (EC) No 178/2002
Chapter II, SECTION 1a – Article 8a – point c

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

Or. it

Amendment 148
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
d) foster public understanding of the risk analysis process so as to enhance confidence in its outcome;	d) foster public understanding of the risk analysis process so as to enhance confidence in its outcome ***and restore consumers' trust in the EU and its institutions***;

Or. it

Amendment 149
Daniel Buda

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

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.)

Or. ro

Amendment 150
Emil Radev

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/202
Article 8a – point fa (new)

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

Or. bg

Amendment 151
Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Chapter II, SECTION 1a – Article 8b – 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 to the provision of risk assessment and the adoption of risk management decisions;	b) ***constantly*** provide ***up-to-date and*** transparent information at each stage of the risk analysis process from the framing of requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions;

Or. it

Amendment 152
Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Chapter II, SECTION 1a – Article 8b – 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;

Or. it

Amendment 153
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
d) facilitate understanding and dialogue amongst all interested parties; and,	d) facilitate understanding and dialogue 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,

Or. it

Amendment 154
Emil Radev

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

Text proposed by the Commission	*Amendment*
r) facilitate understanding ***and*** dialogue amongst all interested parties; and	d) facilitate understanding***,*** dialogue ***and cooperation*** amongst all interested parties; and

Or. bg

Amendment 155
Daniel Buda

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Chapter II – SECTION 1a – Article 8b(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 ***respecting*** confidentiality and protection of personal data. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. ro

Amendment 156
Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Chapter II, SECTION 1a – Article 8c – 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 ***(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 for situations in which any emergencies are managed that might arise in the field of food or the environment, which presupposes an increase in dedicated communication tools and measures (helplines, a suitably identified section of the EFSA website, apps and specific information campaigns)***; and,

Or. it

Amendment 157
Enrico Gasbarra

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

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.

Or. it

Amendment 158
Emil Radev

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	b) ***two members and their substitutes*** appointed by the European Parliament,

vote.

with the right to vote.

Or. bg

Amendment 159
Enrico Gasbarra

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*** appointed by the European Parliament, with the right to vote.

Or. it

Amendment 160
Emil Radev

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,	c) ***five*** members with the right to vote representing civil society and food chain interests namely, one from consumers organisations, one from environmental non-governmental organisations, one from farmers organisations and one from ***the agrochemical industry and one from the food industry***. 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

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.	European Parliament, together with the relevant background documents. As quickly as possible and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint those members.

Or. bg

Amendment 161
Enrico Gasbarra

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

Or. it

Amendment 162
Daniel Buda

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

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.”,

Or. ro

Justification

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

Amendment 163
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
2. The term of office of members and alternate members shall be four years**.** ***However, the term of office of the members referred to in paragraph 1a(a) and (b) shall not be limited in duration***. The term of office of the members referred to in paragraph 1a(c) may be renewable only once.,	2. The term of office of members and alternate members shall be four years ***(2012 revision of the rules governing the decentralised agencies of the Union - Joint Declaration).*** The term of office of the members referred to in paragraph 1a(c) may be renewable only once.,

Or. it

Amendment 164
Emil Radev

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

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

Or. bg

Amendment 165
Emil Radev

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***	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

nominate at least 12 scientific experts. Member States may nominate nationals of other Member States.

nationals of other Member States.

Or. bg

Amendment 166
Emil Radev

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 ***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 him, given the criteria for selection set up in point d) of this paragraph, to draw up a larger list. The Executive Director shall submit the list to the Management Board for appointment.

Or. bg

Amendment 167
Enrico Gasbarra

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	e) The Management Board shall ensure that the broadest***, most***

geographical distribution is achieved in the final appointments.	***comprehensive and most participatory*** possible geographical distribution is achieved in the final appointments.

Or. it

Amendment 168
Enrico Gasbarra

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

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

Or. it

Amendment 169
Emil Radev

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

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.

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.

Or. bg

Amendment 170
Enrico Gasbarra

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*
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.	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 ***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 ***conceived*** as a priority task for the protection of the safety of the food chain.

Or. it

Amendment 171
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
At the request of a potential applicant for a food law authorisation, the staff of the Authority ***shall*** advise on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.	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 paragraph 1 shall not be involved in any scientific work, including within the meaning of Article 28 (5f), that is directly or indirectly relevant to the application that is the subject of the advice. The*** advice provided by the staff of the Authority ***shall be documented and be published on the Authority's website immediately after it has been provided. It shall contribute to the development of a Frequently Asked Questions document, in order to develop more comprehensive guidelines for applicants and reduce 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.***

Or. en

Amendment 172
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
At the request of a potential applicant for a food law authorisation, the staff of the Authority shall advise on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.	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. ***For the purpose of avoiding any conflict of interest among the parties concerned, it is desirable and recommended that the staff assigned this task of assistance during the preparatory stage of applications for authorisation should not be the same who subsequently take part in assessing them.*** The advice provided by the staff of the Authority shall ***above all*** be without prejudice***, influence or discrimination*** and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

Or. it

Amendment 173
Daniel Buda

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***	***With a view to ensuring transparency and facilitating access for those concerned,***

Authority shall advise on the relevant provisions and the ***required*** content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.	***the Authority shall publish a guide setting out the requirements and the details to be included in the application for authorisation.*** At the request of a potential applicant for a food law authorisation, the Authority shall advise on the relevant provisions, ***giving details of*** the required content of the application for authorisation ***and the accompanying studies or documentation***. 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. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. ro

Amendment 174
Emil Radev

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 326 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. Any studies commissioned shall take account of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Or. bg

Amendment 175
Emil Radev

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

Text proposed by the Commission	*Amendment*
3. The notified information shall be made public only in case a corresponding application for authorisation has been received and after the Authority has decided on the disclosure of the accompanying studies in accordance with Article 38 and Articles 39 to 39f.	3. The notified information shall be made public only in case a corresponding application for authorisation has been received 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.

Or. bg

Amendment 176
Enrico Gasbarra

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 in accordance with Article 38 and Articles 39 to 39f.

Or. it

Amendment 177
Emil Radev

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

Text proposed by the Commission	*Amendment*

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

Or. bg

Amendment 178
Enrico Gasbarra

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

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.

Or. it

Amendment 179
Emil Radev

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

Text proposed by the Commission	*Amendment*
The Commission experts shall perform controls, including audits, to obtain assurance that testing facilities comply	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.	with relevant ***EU and external*** 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 ***and/or of the third countries concerned***.

Or. bg

Amendment 180
Heidi Hautala
on behalf of the Verts/ALE Group

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

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 Commission ***and the Parliament***, 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. ***Verification studies shall be funded via the contributions of applicants to a common fund. The Commission shall adopt a delegated act in accordance with Article 32f to determine the modalities of this fund.***

Or. en

Amendment 181

Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regolamento (CE) n. 178/2002
Article 32e

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 Commission, in exceptional circumstances, may request the Authority to 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.;

Or. it

Amendment 182
Emil Radev

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*
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	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 the scientific data and findings conflict with one another,*** 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.

subject to verification.

Or. bg

Amendment 183
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(4a) The following Article 32f is inserted:
	Article 32f
	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
	2. The power to adopt delegated acts referred to in Article 32e shall be conferred on the Commission for a period five years from... [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
	3. The delegation of power referred to in Article 32e may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date

specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 32e 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 to 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 European Parliament or of the Council.

Or. en

Amendment 184
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
The Authority shall ***carry out its activities with*** a high level of transparency. It shall in particular make public without delay:	The Authority shall ***ensure*** a high level of transparency***, in line with the Aarhus Convention and Regulation 1367/2006, providing for an active and systematic***

	dissemination to the public of environmental information. It shall in particular make public without delay:

Or. en

Amendment 185
Enrico Gasbarra

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

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 ***must*** carry out its activities with ***the maximum*** transparency. It shall in particular make public without delay:

Or. it

Amendment 186
Emil Radev

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

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

with Articles 39 to 39f.

Or. bg

Amendment 187
Emil Radev

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

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

Or. bg

Amendment 188
Emil Radev

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

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

Or. bg

Amendment 189
Emil Radev

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) The following paragraph 1 -a shall be added:
	(1-a) 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 a scientific opinion, taking into account protection of confidential information and 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 protection of confidential data and 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.

Or. bg

Amendment 190
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
The disclosure of the information mentioned in paragraph (1)(c) to the public ***shall*** be without prejudice:	The disclosure of the information mentioned in paragraph (1)(c) to the public ***must*** be without prejudice:

Or. it

Amendment 191
Heidi Hautala
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 192
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(b) any provisions set out in Union food law ***protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations*** (‘data exclusivity rules’).	(b) any provisions set out in Union food law ***giving the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant*** (‘data exclusivity rules’).

Or. en

Amendment 193
Heidi Hautala
on behalf of the Verts/ALE Group

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

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 used, reproduced, or otherwise exploited ***for commercial purposes*** and its use by third parties shall not engage the responsibility of the European Union.

Or. en

Amendment 194
Heidi Hautala
on behalf of the Verts/ALE Group

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 justification and to Regulation 1049/2001 and Regulation 1367/2006.

Or. en

Amendment 195
Enrico Gasbarra

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, the Authority shall not make public information for which confidential treatment has been requested under the conditions laid down in this Article ***(without prejudice to the principle that the interests of public health must always prevail over private interests)***.

Or. it

Amendment 196
Heidi Hautala
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 197
Daniel Buda

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.)*

Or. ro

Amendment 198
Emil Radev

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, market shares***, innovative product ideas*** or business strategy of the applicant; and

Or. bg

Amendment 199
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
	(3a) innovative commercial elements and models, formulae and products covered by patents whose protection 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

Or. it

Amendment 200
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
4. Notwithstanding paragraphs 2 and 3, the following information ***shall*** nevertheless be made public:	4. Notwithstanding paragraphs 2 and 3, the following information ***must*** nevertheless be made public:

Or. it

Amendment 201
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 202
Enrico Gasbarra

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

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***.;

Or. it

Amendment 203
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(ba) Where an overriding public interest in disclosure exists.

Or. en

Amendment 204
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	4a. This provision is without prejudice to Directive 2003/4 and Regulations 1049/2001 and 1367/2006.

Or. en

Amendment 205
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39 a – 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	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 ***requests*** confidential ***treatment for*** in accordance with paragraphs 2 and 3 of Article 39***. This information shall be garbled by black bars***. The confidential version shall contain all information submitted, including information the applicant ***considers*** confidential. Information requested to be treated as

applicant shall clearly indicate the ***grounds*** on the basis of which confidentiality is requested for the different pieces of information.

confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the ***verifiable justifications*** on the basis of which confidentiality is requested for ***each of*** the different pieces of information.

Or. en

Amendment 206
Emil Radev

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

Text proposed by the Commission	*Amendment*
(a) make public, without delay, the non-confidential version, as submitted by the applicant;	***deleted***

Or. bg

Amendment 207
Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39b – point 1 – subpoint 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	(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,	the Member States, ***in every case***, of its decision; and,

Or. it

Amendment 208
Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39b – point 1 – subpoint 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 of its decision; and,

Or. it

Amendment 209
Emil Radev

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***	e) publish ***non-confidential*** data and information ***relating to the application only once a final decision has been taken in respect of*** the confidentiality request pursuant to ***this Article and the Authority***

to the applicant has taken place, pursuant to ***point (d)***.	***has published its scientific opinion. Where an applicant withdraws the application pursuant to Article 39(c) because the applicant deems the publication of the information planned by the Authority to be too comprehensive, the Authority, the Commission and the Member States shall refrain from publishing any information on the application for authorisation***.

Or. bg

Amendment 210
Emil Radev

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

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

Or. bg

Amendment 211
Emil Radev

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.

Or. bg

Amendment 212
Emil Radev

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 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***.	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 ***any information relating to the planned application***.

Or. bg

Amendment 213
Daniel Buda

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

Text proposed by the Commission	*Amendment*
3. If an applicant in the context of an authorisation procedure withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 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*****.**	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 ***any*** information ***relating to the planned application***. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. ro

Amendment 214
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*

(a) the name ***and address*** of the applicant;	(a) the name of the applicant;

Or. it

Amendment 215
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
(b) the names of authors of published, or publicly available, ***studies*** supporting such requests; and	(b) the names of authors of ***studies*** published***, conducted by research and analysis firms*** or publicly available, supporting such requests; and

Or. it

Amendment 216
Enrico Gasbarra

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

Or. it

Amendment 217
Emil Radev

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39e (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 and shall not be made publicly available.

Or. bg

Amendment 218
Enrico Gasbarra

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

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	The information systems operated by the Authority to store its data, including confidential and personal data shall be designed ***in such a way as to provide 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

auditable.;	security. The system shall ensure that any access to it is fully auditable.;

Or. it

Amendment 219
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(9) in Article 41, the following ***sentence is added at the end of paragraph 1***:	(9) in Article 41, ***paragraph 1 is replaced by*** the following***:***:

Or. en

Amendment 220
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EC) No 178/2002
Article 41 – paragraph 1

Text proposed by the Commission	*Amendment*
Where environmental information is concerned, Articles 6 and Article 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council***[39]*** shall ***also*** apply.***;***	***1. The Authority shall ensure wide access upon demand to the documents which it possesses. Regulation 1049/2001 of the European Parliament and the Council and 1367/2006*** of the European Parliament and of the Council shall apply.

[39] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation

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

Or. en

Amendment 221
Enrico Gasbarra

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 178/2002
Article 57a – point 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 European Parliament or of the Council.;	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.;

Or. it

Amendment 222
Enrico Gasbarra

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

Text proposed by the Commission	*Amendment*
2. Not later than five years after the	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.	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, it would be desirable to increase investment in order to secure more ambitious results.***
	Or. it

Amendment 223
Heidi Hautala
on behalf of the Verts/ALE Group

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

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 ***Authority jointly with the*** Commission shall ***commission an independent external evaluation of its achievements and*** performance in relation to its objectives, ***mandates***, tasks, procedures and ***locations***. The evaluation shall ***be based on the terms of reference issued by the Management Board in agreement with the Commission, and will assess the working practices and the impact*** of the Authority***. The evaluation shall take into account the views of all stakeholders, at both***

Community and national level.

Or. en

Amendment 224
Heidi Hautala
on behalf of the Verts/ALE Group

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

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***

Or. en

Amendment 225
Heidi Hautala
on behalf of the Verts/ALE Group

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

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*** be made public.

Or. en

Amendment 226
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(2a) In Article24, the following paragraph (3a) is inserted:"3a. The obligation to proactively disseminate informationset out in paragraph 1 of this Article, including Article 25 below, andArticles 38 and 39 of Regulation 178/2002, is without prejudice to the right ofany natural or legal person to access document upon request as set byRegulation 1049/2001 and Regulation 1367/2006."

Or. en

Amendment 227
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 2 – paragraph 1 – point 3
Directive 2001/18/EC
article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In ***addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, which shall apply mutatis mutandis, confidential treatment may be accepted with respect to*** the following information***, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the***	2. In ***no case may*** the following information ***when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept confidential:***

interests concerned:

— general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— environmental risk assessment.:

Or. en

Amendment 228
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 2 – paragraph 1 – point 3
Directive 2001/18/EC
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
(a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,	***deleted***

Or. en

Amendment 229
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 2 – paragraph 1 – point 3
Directive 2001/18/EC
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
(b) breeding patterns and strategies.;	***deleted***

Or. en

Justification

Paragraph 2 simply reinstates the current wording of Directive 2001/18/EC. 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 230
Emil Radev

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 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.”.	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, ***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.

Or. bg

Amendment 231
Emil Radev

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	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.

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..

Or. bg

Amendment 232
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, including Article 30 below, and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation 1367/2006.

Or. en

Amendment 233
Heidi Hautala
on behalf of the Verts/ALE Group

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

Article 30

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) 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) 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.***

Or. en

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 234
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,	***deleted***

Or. en

Amendment 235
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(b) breeding patterns and strategies.	***deleted***

Or. en

Amendment 236
Emil Radev

Proposal for a regulation
Article 4 – paragraph 1 – point 6
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, ***at the same time as to its scientific opinion,*** in accordance with Article 18”;

Or. bg

Amendment 237
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(1a) In Article17, the following paragraph (2a) is inserted:“2a. The obligation to proactively disseminate information set out in this Article and Articles 38 and 39 of Regulation178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation1367/2006.”

Or. en

Amendment 238
Emil Radev

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.

Or. bg

Amendment 239
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
3. ***In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment to*** the following information***, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:***	3. The following information ***shall not be considered confidential:***
	(a) name and composition of the feed additive and, where appropriate, indication of the production strain;
	(b) physico-chemical and biological characteristics of the feed additive;
	(c) the conclusions of the study results on effects of the feed additive on human and

animal health and on the environment;

(d) the conclusions of the study results on effects of the feed additive on the characteristics of animal products and its nutritional properties;

(e) methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

Or. en

Justification

Paragraph 3 simply reinstates the current wording of Regulation 1831/2003. 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. Likewise, paragraphs 4 and 5 simply keep the current text of Regulation 1831/2003.

Amendment 240
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(a) the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) and Annex I to this Regulation; and,	***deleted***

Or. en

Amendment 241
Heidi Hautala
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 242
Heidi Hautala
on behalf of the Verts/ALE Group

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

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.

Or. en

Amendment 243
Heidi Hautala
on behalf of the Verts/ALE Group

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

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."

Or. en

Amendment 244
Emil Radev

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.

Or. bg

Amendment 245
Emil Radev

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 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.;	1. The Authority shall make public***, at the same time as its scientific opinion,*** 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.;

Or. bg

Amendment 246
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(2a) In Article14, the following paragraph (1a) is inserted:
	"1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation 1367/2006."

Or. en

Amendment 247
Enrico Gasbarra

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

Or. it

Amendment 248
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 5 – paragraph 1 – point 3
Regulation (EC) No 2065/2003
Article 15 – second paragraph (new)

Text proposed by the Commission	*Amendment*
	Without prejudice to Article 39(3) of Regulation (EC) No 178/2002, information relating to the following shall not be considered confidential:
	(a) the name and address of the applicant and the name of the product;
	(b) in the case of an opinion in favour of authorising the evaluated product, the particulars mentioned in Article 6(2);
	(c) information of direct relevance to the assessment of the safety of the product;
	(d) the analytical method referred to in point 4 of Annex II."

Or. en

Amendment 249
Emil Radev

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.

Or. bg

Amendment 250
Emil Radev

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.”;

Or. bg

Amendment 251
Heidi Hautala
on behalf of the Verts/ALE Group

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 document upon request as set by Regulation 1049/2001 and Regulation 1367/2006."

Or. en

Amendment 252
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20

Text proposed by the Commission	*Amendment*
2. ***In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment*** to the following information***, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:***	2. ***Information relating*** to the following ***shall not be considered confidential:***
	(a) the name and address of the applicant and the chemical name of the substance;

(b) information ***of direct relevance to the assessment of the safety of the substance;***

(c) the analytical method or methods.

Or. en

Amendment 253
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20

Text proposed by the Commission	*Amendment*
(a) any information provided in detailed descriptions of starting substances and preparations used to manufacture the substance subject to the authorisation, the composition of preparations, materials or articles in which the applicant intends to use this substance, the manufacturing methods of these preparations, materials or articles, impurities, and migration testing results;	***deleted***

Or. en

Amendment 254
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20

Text proposed by the Commission	*Amendment*
(b) the trademark under which the substance, shall be marketed as well as the tradename of the preparations,	***deleted***

material or articles in which it shall be used, where applicable; and,

Or. en

Amendment 255
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20

Text proposed by the Commission	*Amendment*
(c) any other information deemed confidential within the specific procedural rules referred to in Article 5(1)(n) of this Regulation..	***deleted***

Or. en

Amendment 256
Emil Radev

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

Text proposed by the Commission	*Amendment*
"Where the Commission requests its opinion in accordance with Article 3(2) 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 39to 39f and Article 40 of Regulation (EC) No 178/2002. It shall also make public any request for its opinion as well as any	Where the Commission requests its opinion in accordance with Article 3(2) of this Regulation, 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 it publishes*** its scientific ***opinion***, in accordance with Article 38, Articles 39to 39f and Article 40 of Regulation (EC) No 178/2002. It shall also make public any request for its

extension of period pursuant to Article 6(1) of this Regulation.”;	opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.”;

Or. bg

Amendment 257
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	The obligation to proactively disseminate information set out in paragraph 1 of this Article, including Article 12 below and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation 1367/2006.

Or. en

Amendment 258
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	3a. Information relating to the following shall not, in any circumstances, be regarded as confidential:

(a) the name and address of the applicant;

(b) the name and a clear description of the substance;

(c) the justification for the use of the substance in or on specific foodstuffs or food categories;

(d) information that is relevant to the assessment of the safety of the substance;

(e) where applicable, the analysis method(s).

Or. en

Amendment 259
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	3b. 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.

Or. en

Amendment 260
Heidi Hautala
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 8 – paragraph 1 – point 5
Regulation (EC) No 1107/2009
Article 63

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3), confidential treatment may be accepted with respect to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(a) the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically a) or environmentally relevant and the related methods of analysis for these impurities;	
(b) results of production batches of the active substance including impurities; and,	
(c) information on the complete composition of a plant protection product.;	

Or. en

Amendment 261
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(a) the specification of impurity of the active substance and the related methods of analysis for impurities in the active	***deleted***

substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for these impurities;

Or. en

Amendment 262
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(b) results of production batches of the active substance including impurities; and,	***deleted***

Or. en

Amendment 263
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(c) information on the complete composition of a plant protection product.;	***deleted***

Or. en

Amendment 264
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(5a) in Article 63, paragraph 3 is replaced by the following:
	3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and to Regulation 1049/2001 and Regulation 1367/2006.

Or. en

Amendment 265
Emil Radev

Proposal for a regulation
Article 9 – paragraph 1 – point 1 – point б
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.”;

Or. bg

Amendment 266
Emil Radev

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

Text proposed by the Commission	*Amendment*
The Authority shall ensure public access to the application, ***relevant supporting information and any supplementary information supplied by the applicant*** in accordance with Article 23.;	The Authority shall ensure public access to ***the non-confidential elements of*** the application***, and to the notification concerning safety concerns under Article 15, at the same time as it publishes its scientific opinion*** in accordance with Article 23.”;

Or. bg

Amendment 267
Emil Radev

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***.

Or. bg

Amendment 268
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	4a. Confidentiality shall not apply to the following information:
	(a) the name and address of the applicant;
	(b) the name and description of the novel food;
	(c) the proposed conditions of use of the novel food;
	(d) a summary of the studies submitted by the applicant;
	(e) the results of the studies carried out to demonstrate the safety of the food;
	(f) where appropriate, the analysis method(s);
	(g) any prohibition or restriction imposed in respect of the food by a third country."

Or. en

Amendment 269
Heidi Hautala
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(4a) In Article25, the following paragraph (1a) is inserted:

"1a. The obligation to proactively disseminate information set out in this Regulation and Articles 38 and 39 of Regulation178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation1367/2006."

Or. en