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AMENDMENTS
53 - 226

Draft opinion
Karin Kadenbach
(PE625.353v02-00)

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 53
Maria Gabriela Zoană

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 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 ***the safety and security of food for human consumption and animal*** feed. Risk communication is an essential part of the risk analysis process.

Or. ro

Amendment 54
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

Proposal for a regulation
Recital 4

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

Or. en

Amendment 55
Maria Lidia Senra Rodríguez

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) It is therefore necessary to ensure a comprehensive and continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should be combined with an open dialogue between all interested parties to ensure ***the*** coherence and consistency within the risk analysis process.	(4) It is therefore necessary to ensure a comprehensive and continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should be combined with an open dialogue between all interested parties to ensure coherence and consistency within the risk analysis process ***as well as to ensure that the precautionary principle is applied***.

Or. es

Amendment 56
Maria Gabriela Zoană

Proposal for a regulation
Recital 4

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

Or. ro

Amendment 57
Maria Gabriela Zoană

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Particular emphasis should be placed on explaining in a coherent, appropriate and timely manner not only risk assessment findings themselves but also how these are utilized to help inform risk management decisions along with other legitimate factors, where relevant.	(5) Particular emphasis should be placed on explaining in a coherent, appropriate and timely manner not only risk assessment findings themselves but also how these ***findings*** are utilized to help inform risk management decisions along with other legitimate factors, where relevant.

Or. ro

Amendment 58
Georgios Epitideios

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 ***at both Union and national level***.

Or. el

Amendment 59
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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	(8) The general plan should identify the key factors to be taken into account when risk communications' activities are considered, such as the different levels of ***hazard and*** risk, the nature of the ***hazard and*** risk and its potential public health ***and environmental*** impact, who and what ***can be*** directly or indirectly affected by the

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 levels of risk exposure, the ability to control ***exposure and*** risk and other factors that influence risk ***understanding*** including the level of urgency as well as the applicable legislative framework and relevant market context. The general plan should also identify the tools and channels to be used and should establish appropriate mechanisms to ensure ***accurate*** risk communication.

Or. en

Amendment 60
Maria Lidia Senra Rodríguez

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) Transparency of the risk assessment process contributes to the Authority acquiring greater legitimacy in the eyes of ***the*** consumers and general public in pursuing its mission, increases their confidence in its work and ensures that the Authority is more accountable to the Union citizens in a democratic system. It is therefore essential to maintain the confidence of the general public and other interested parties in the risk analysis process underpinning Union food law and in particular in ***the*** risk assessment, including the organisation ***and independence*** of the Authority ***and transparency.***	(9) Transparency of the risk assessment process contributes to the Authority acquiring greater legitimacy in the eyes of consumers and ***the*** general public in pursuing its mission, increases their confidence in its work and ensures that the Authority is more accountable to the Union citizens in a democratic system. It is therefore essential to maintain the confidence of the general public and other interested parties in the risk analysis process underpinning Union food law***,*** and in particular in risk assessment, including the organisation***, independence and transparency*** of the Authority***, which have been called into question in the wake of a number of complaints about conflicts of interest involving many of the Authority's experts and the scandal surrounding the renewal of the authorisation for glyphosate, when the Authority took over the opinions provided by Monsanto;***

Or. es

Amendment 61

Michela Giuffrida

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) A lack of transparency and the difficulty in accessing documents processed by EU agencies were the second most common reason for complaints being filed with the European Ombudsman in 2017. It should also be stressed in this regard that the European Ombudsman, after requests for clarification had been made to the Authority in a number of cases, called on EFSA in her 2017 annual report to publish additional information on the authorisations granted on the basis of the risk assessments it conducted, especially when specifically requested to do so by members of the public.

Or. it

Justification

The amendment seeks to underscore the importance of transparency in relations with the public, as evidenced in the latest annual report by the Ombudsman, which explicitly mentions relations with EFSA and the assessments it conducts.

Amendment 62
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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	(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.	representatives should have experience in particular on risk assessment ***and are able to demonstrate the absence of conflict of interest with the applicants***.

Or. en

Amendment 63
Nicola Caputo

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 ***as well as 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.

Or. en

Amendment 64
Maria Lidia Senra Rodríguez

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	(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***, perhaps because developments in the Authority's***

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.

work may have led to an emphasis being placed on criteria other than purely scientific ones. 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. es

Amendment 65
Marco Zullo, Rosa D'Amato, Ignazio Corrao

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Since the Authority is responsible for assessing products in a variety of fields such as agriculture, food and health, it is vital to ensure that the members of the expert groups have the appropriate expertise to make a satisfactory assessment of the effectiveness and security of the product being analysed. In particular, the assessment should cover the specific characteristics of the substance being analysed and establish an appropriate methodology for its correct assessment, taking the approach best suited to that type of substance, and one which should therefore vary depending on whether it is a complex natural substance or a substance obtained through chemical synthesis.

Or. it

Amendment 66
Herbert Dorfmann

Proposal for a regulation

Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14 a) Furthermore, as the Authority is responsible for the assessment of products in different sectors, namely agriculture, food and health, it is important that the Members of the relevant Panel have the adequate expertise to evaluate the safety and efficacy of a particular subject matter. In particular, the assessment should consider the specific characteristics of the given substance and establish a proper methodology for a correct assessment, applying the most appropriate approach according to the kind of substance, that shall be different if it is isolated compounds obtained by chemical synthesis or natural complex substances.

Or. en

Amendment 67
Georgios Epitideios

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	(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health is better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a

product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.

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. ***At this point it should be stressed that the Authority is required to establish strict criteria for the assessment of products imported from third countries where health checks on the safety of product ingredients are not always reliable.***

Or. el

Amendment 68
Maria Lidia Senra Rodríguez

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,	(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 ***(a principle threatened by the free trade agreements that the Union itself is promoting)***. 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

including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.	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. es

Amendment 69
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health ***is*** better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.	(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health ***and the environment are*** better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.

Or. en

Amendment 70
Annie Schreijer-Pierik

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. nl

Justification

Publishing details of interviews prior to the application could give competitors access to sensitive information on business strategies and product ideas. Information as to the design of the studies considered useful or necessary by EFSA could be particularly useful for SMEs with insufficient experience, which require assistance.

Amendment 71
Franc Bogovič

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	(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.***	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. en

Justification

Publishing details of interviews prior to the application could give competitors access to sensitive information on business strategies and product ideas. Information as to the design of the studies considered useful or necessary by EFSA would be particularly useful for SMEs with insufficient experience.

Amendment 72
Michela Giuffrida

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	(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.	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 ***and the reasoning behind its scientific assessments*** should be made public***, as was indicated by the Ombudsman in her 2017 annual report***.

Or. it

Justification

Amendment referencing the latest annual report by the Ombudsman, in which EFSA is called on to ensure greater transparency as regards assessments and to publish its reasoning.

Amendment 73
Karin Kadenbach

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***, private and public institutes and unversities*** 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.

Or. en

Amendment 74
Annie Schreijer-Pierik

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 ***publicly submitted and the Authority has published its scientific opinion***.

Or. nl

Justification

Scientific data and studies and any other information in support of applications for authorisation should be publicly released only once the Authority publishes its scientific results. If that is done earlier, there is a risk that competitors may gain access to information about innovative product ideas or production processes. Moreover, there would otherwise be a real risk of undesirable political interference in the risk assessment process.

Amendment 75
Franc Bogovič

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	(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***.	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. en

Justification

Scientific data and studies and any other information supporting applications should be made public only once the Authority publishes its scientific results. Otherwise, there is a risk that competitors gain access to information about innovative product ideas or manufacturing processes. Moreover, there would otherwise be the danger of political interference in the risk assessment process.

Amendment 76
Jan Huitema

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. ***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. en

Amendment 77
Maria Lidia Senra Rodríguez

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

Or. es

Amendment 78
Philippe Loiseau, Jacques Colombier

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) Food safety is a sensitive matter of	(22) Food safety is a sensitive matter of

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

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***, the European Parliament or the Council*** 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. fr

Amendment 79
Peter Jahr

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	(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***

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).	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. de

Amendment 80
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) The Fitness Check of the General Food Law demonstrated that although the Authority has made considerable progress in terms of transparency, the risk assessment process, especially in the context of authorisation procedures covering the agri-food chain, is not ***always perceived as*** fully transparent. ***This is also partly due to the different transparency and confidentiality rules that are laid down not only in Regulation (EC) No 178/2002 but also in other Union legislative acts covering the agri-food chain. Their interplay can impact on the acceptability of the risk assessment by the general public.***	(23) The Fitness Check of the General Food Law demonstrated that although the Authority has made considerable progress in terms of transparency, the risk assessment process, especially in the context of authorisation procedures covering the agri-food chain, is not ***yet*** fully transparent.

Or. en

Amendment 81
Anthea McIntyre, James Nicholson

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) The European Citizens' Initiative	***deleted***

"Ban glyphosate and protect people and the environment from toxic pesticides" further confirmed concerns regarding transparency with respect to studies commissioned by the industry and submitted in authorisation application[23] .

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[23] Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.

Or. en

Amendment 82
Michela Giuffrida

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) The setting up by Parliament of the Special Committee on Pesticides is in itself a response to the concerns raised over the system for assessing risks in connection with the herbicidal substance glyphosate and over the studies and assessments relating to it.

Or. it

Amendment 83
James Nicholson, Anthea McIntyre

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	(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.

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. ***Directive (EU) 2016/943 should be fully taken into account.***

Or. en

Amendment 84
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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 ***and clarity*** of the risk assessment process in a proactive manner. ***In order to ensure public scrutiny,*** public access to all scientific data and information supporting requests for authorisations under Union food law as well as other requests for scientific output should be ensured, as early as possible in the risk assessment process. 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 85
James Nicholson, Anthea McIntyre

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 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***, the principle of proportionality and the TRIPS Agreement and Directive (EU) 2016/943***.

Or. en

Amendment 86
Anthea McIntyre, James Nicholson

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***, in line with the current provisions governing the protection*** of confidential ***information***. 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.

Or. en

Amendment 87
Molly Scott Cato
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 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 ***exhaustive*** list of information items ***which could be kept confidential on the grounds that their*** disclosure ***would*** significantly ***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 88
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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	(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.

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"). ***These exceptions to the principle of transparency must be interpreted strictly. 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 89
Annie Schreijer-Pierik

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	(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 ***when there is an*** urgent ***need*** to protect human health, animal health or the environment, such information should be disclosed.

information should be disclosed.

Or. nl

Amendment 90
Philippe Loiseau, Jacques Colombier

Proposal for a regulation
Recital 33

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

Or. fr

Amendment 91
Norbert Erdős, Momchil Nekov, Mireille D'Ornano, Vladimir Urutchev, Marijana Petir, Franc Bogovič, Othmar Karas, Eric Andrieu

Proposal for a regulation
Recital 34 a (new)

Text proposed by the Commission	*Amendment*
	(34 a) whereas the second paragraph of point (a) of Article 2(4) of the Directive 2001/110/EC on honey provides that, where honey originates from more than one Member State or third country, the mandatory indication of the countries of origin may be replaced by one of the

following, as appropriate: 'blend of EU honeys', 'blend of non-EU honeys' or 'blend of EU and non-EU honeys'; whereas the indication 'blend of EU and non-EU honeys' is not informative enough for the consumer;

Or. en

Amendment 92
Norbert Erdős, Momchil Nekov, Mireille D'Ornano, Vladimir Urutchev, Marijana Petir, Franc Bogovič, Othmar Karas, Eric Andrieu

Proposal for a regulation
Recital 34 b (new)

Text proposed by the Commission	*Amendment*
	(34 b) whereas many honey packagers and traders now abuse this way of indicating origin in order to conceal the real country of origin, as well as the proportion of honey from the different countries concerned, as purchasers are becoming more knowledgeable and are distrustful of foodstuffs from certain countries;

Or. en

Amendment 93
Norbert Erdős, Momchil Nekov, Mireille D'Ornano, Vladimir Urutchev, Marijana Petir, Franc Bogovič, Othmar Karas, Eric Andrieu

Proposal for a regulation
Recital 34 c (new)

Text proposed by the Commission	*Amendment*
	(34 c) whereas the resolution of the European Parliament at 1 March 2018 on prospects and challenges for the EU apiculture sector "considers … that labelling such as 'blend of EU honeys', 'blend of non-EU honeys', and especially 'blend of EU and non-EU honeys', completely conceals the origin of the

honey from the consumer and consequently fails to fulfil the principles of EU consumer protection law (paragraph 58)" and, therefore, "Asks for the 'blend of EU and non-EU honeys' descriptor on labels to be replaced by an indication of exactly which country or countries the honey used in the final product come from, and that these be listed in the order which corresponds to the percentage proportions used in the final product … (paragraph 59)

Or. en

Amendment 94
Norbert Erdős, Momchil Nekov, Mireille D'Ornano, Peter Jahr, Eric Andrieu, Vladimir Urutchev, Marijana Petir, Franc Bogovič, Othmar Karas

Proposal for a regulation
Recital 34 d (new)

Text proposed by the Commission	*Amendment*
	(34 d) whereas the situation on the EU internal honey market has been worsened due to the continuous import of adultered honey according to representatives of European and national beekeeper organisations; whereas the EU is not supposed to tolerate this situation anymore and it should take the right step forward which is the correction of the labelling section of the Directive 2001/110/EC on honey;

Or. en

Amendment 95
Norbert Erdős, Momchil Nekov, Mireille D'Ornano, Peter Jahr, Eric Andrieu, Vladimir Urutchev, Marijana Petir, Franc Bogovič, Othmar Karas

Proposal for a regulation
Recital 34 e (new)

Text proposed by the Commission	*Amendment*

(34 e) whereas current rules do not take account of fraudulent practices affecting processed products such as biscuits, breakfast cereals, confectionery, etc.; whereas the label 'honey' can mislead consumers in regard to the real content of the given product, as it is often used when much less than 50 % of the sugar content of the product originates from honey; whereas the food labelling rules has to be corrected also in this field;

Or. en

Amendment 96
James Nicholson, Anthea McIntyre

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) To ensure that sectoral specificities with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency in the risk assessment process, including those flowing from the Aarhus Convention[35] , against the rights of commercial applicants, taking into account the specific objectives of sectoral Union legislation as well as experienced gained. Accordingly, it is necessary to amend Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004 and Regulation (EC) No 1107/2009 to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.	(36) To ensure that sectoral specificities with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency in the risk assessment process, including those flowing from the Aarhus Convention[35] , against the rights of commercial applicants, taking into account ***Directive(EU) 2016/943,*** 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	[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).	in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p.13).

Or. en

Amendment 97
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

Proposal for a regulation
Recital 37

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

Or. en

Amendment 98
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

Proposal for a regulation

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

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

Or. en

Amendment 99
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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

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

Or. en

Amendment 100
Michel Dantin

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

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

Or. fr

Amendment 101
Clara Eugenia Aguilera García, Paolo De Castro, Ricardo Serrão Santos

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

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

Or. es

Amendment 102
Michel Dantin

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

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

Or. fr

Amendment 103
Philippe Loiseau, Jacques Colombier

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

Text proposed by the Commission	*Amendment*
	(fa) restore a climate of trust between European agricultural producers and consumers.

Or. fr

Amendment 104
Annie Schreijer-Pierik

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

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

Or. nl

Justification

The Commission must be able to issue fact checks and corrective statements on line and in print in order to respond to misleading reports in the media or inaccurate or disproportionate communication by the media or national authorities. This is important due to the internal market in the Union. The communication during the Fipronil crisis in 2017 made it clear that the Union's risk communication in the field of food safety is not optimal and it is not carried out in a proportionate manner in all Member States.

Amendment 105
Nicola Caputo

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

Text proposed by the Commission	*Amendment*
	(f a) inform consumers about risk prevention strategies;

Or. en

Amendment 106
Philippe Loiseau, Jacques Colombier

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

Article 8 a – point f b (new)

Text proposed by the Commission	*Amendment*
	(fb) highlight the fact that European agricultural production has the highest environmental and health standards on the global market, which means that the risk to the consumer is as low as possible.

Or. fr

Amendment 107
Franc Bogovič

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

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

Or. en

Justification

Confidentiality and protection of personal data should also include the protection of know-how and business information to protect innovation.

Amendment 108
Philippe Loiseau, Jacques Colombier

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

Text proposed by the Commission	*Amendment*
	(ea) be completely transparent when it comes to the independence of assessors

and the absence of conflicts of interest.

Or. fr

Amendment 109
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
	Rule 8ca
	Transparency of risk communication
	1. The European Commission, the Authority and the Member States shall carry out their tasks as regards risk communication in relation to food law with a high level of transparency. When preparing their approaches and measures to ensure transparency of risk communication, they shall take into account the general principles of risk communication laid down in Article 8b of this Regulation and shall consult in advance with all relevant stakeholders, where applicable including the primary producers within the chain. In order to comply with the requirements set out in paragraph 1, the European Commission and the Authority must adopt relevant guidelines.

Or. nl

Justification

The obligation to adopt more stringent transparency rules should also apply to all risk communication by national authorities, the Authority and the Commission itself. The Fipronil crisis in 2017 showed that risk communication in Member States is not harmonised and does not comply with European guidelines and European risk assessments. Moreover, at that time the national authorities in one or more Member State(s) issued disproportionate communications.

Amendment 110
Nicola Caputo

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

Text proposed by the Commission	*Amendment*
	Article 8c a
	Transparency of risk communication
	(1) The European Commission, the Authority and the Member States shall carry out their tasks as regards risk communication in relation to food law with a high level of transparency.Their approaches and measures to ensure the transparency of risk communication shall be formulated taking account of the general principles of risk communication under Article 8b of this Regulation and after consultation of interested parties.
	(2) The European Commission and the Authority may issue appropriate guidelines in order to comply with paragraph 1.

Or. en

Justification

The requirement for more stringent transparency rules should also apply in the area of risk communication.

Amendment 111
Maria Lidia Senra Rodríguez

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

Text proposed by the Commission	*Amendment*
(b) one member ***appointed by*** the European Parliament, with the right to vote.	(b) one member ***from each political group represented in*** the European Parliament, with the right to vote.

Or. es

Amendment 112
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Amendment 113
Clara Eugenia Aguilera García, Paolo De Castro, Ricardo Serrão Santos

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b
Regulation (EC) No 178/2002
Article 25 – paragraph 1 a – 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	(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, one from aquaculture products*** 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

for consideration to the Council, which shall then appoint those members.	European Parliament may submit its views for consideration to the Council, which shall then appoint those members.

Or. es

Amendment 114
Peter Jahr

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

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

Amendment 115
Paolo De Castro, Clara Eugenia Aguilera García, Ricardo Serrão Santos

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

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

Or. en

Amendment 116
Annie Schreijer-Pierik

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

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.

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. nl

Justification

The interests of producers in the field of GMOs and plant protection products, on the one hand, and those of producers of foodstuffs and additives, on the other, are very different. The Board should therefore also include two representatives of industry.

Amendment 117
Maria Lidia Senra Rodríguez

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

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

Amendment 118
Molly Scott Cato
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 119
Eric Andrieu, Karine Gloanec Maurin

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

Text proposed by the Commission	*Amendment*
(ii) Independence and absence of	(ii) Independence and absence of

conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members;	conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members; ***the fact that each expert is independent and has no conflicts of interest must be certified by the competent national court in the expert's place of residence, and the expert concerned will have to swear an oath before that court.***

Or. fr

Amendment 120
Maria Lidia Senra Rodríguez

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

Text proposed by the Commission	*Amendment*
(ii) Independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members;	(ii) ***Verified*** independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members;

Or. es

Amendment 121
Marco Zullo, Rosa D'Amato, Ignazio Corrao

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

Text proposed by the Commission	*Amendment*
	(iiia) Correspondence between the expertise available within the group responsible for a given assessment and the expertise required for that assessment, so as to ensure satisfactory understanding

of the field in question and appropriate choice of methodology, depending on whether the substance is a complex natural substance or a product obtained through chemical synthesis.

Or. it

Amendment 122
Paolo De Castro

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

Text proposed by the Commission	*Amendment*
	(iii a) Ensuring the expertise of a Panel responsible for a given assessment matches the competences required for such evaluation, proving understanding of a particular subject matter, and adopting the most appropriate methodology depending on the nature of the different chemical compounds.

Or. en

Amendment 123
Marco Zullo, Rosa D'Amato, Ignazio Corrao

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

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 ***Management Board*** 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.

Or. it

Amendment 124
Maria Lidia Senra Rodríguez

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

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

Or. es

Amendment 125
Nicola Caputo

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

Text proposed by the Commission	*Amendment*
	5f a. The Authority shall offer members of Panels comprehensive training on the

risk assessment process.

Or. en

Justification

Not all scientific experts are familiar with the processes of risk assessment.

Amendment 126
Maria Lidia Senra Rodríguez

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

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.	***deleted***

Or. es

Amendment 127
Peter Jahr

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

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	***The Authority shall publish a guidance document including a list of questions and answers regarding the administrative and scientific requirements of an application for authorisation.*** At the request of a potential applicant for a food

be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

law authorisation, the ***Authority shall also offer consultation sessions to explain what information is required and how the various tests and studies necessary to prove the quality, safety and efficacy*** of the ***planned product are to be carried out. The information*** 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 ensure that those staff members who handle and provide information to an applicant are not be members of the team or the Scientific Panel assessing the application for authorisation for which they have provided information. In order to ensure the objectives are adhered to internally, the Authority shall register each request and the content of the information provided by the Authority in response thereto.***

Or. de

Amendment 128
Annie Schreijer-Pierik

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

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.	***The Authority shall publish a guidance document, including a list of questions and answers, regarding all the administrative and scientific requirements applicable to an application for authorisation.*** At the request of a potential applicant for a food law authorisation, the ***Authority shall also offer consultation sessions to explain what information is required and how the various tests and studies necessary to prove the quality, safety and efficacy*** of the ***planned product are to be carried out***. The advice provided

by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

Or. nl

Justification

As indicated during the exchange of views, it is desirable to alter the structure and formulation of the consultation process at EMA.

Amendment 129
Anthea McIntyre, James Nicholson

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

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 ***during a pre-submission meeting***. 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***, and should ensure the protection of any confidential business information and any personal data it contains***.

Or. en

Amendment 130
Paolo De Castro, Clara Eugenia Aguilera García, Ricardo Serrão Santos

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

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. The advice ***would facilitate the understanding on the requirements*** of the ***studies to be conducted and serve to establish guidelines on criteria to apply in the studies where international protocols are missing or not suitable for the specific case***.

Or. en

Amendment 131
Maria Gabriela Zoană

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

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 ***or of an applicant for renewal of an authorisation***, the staff of the Authority shall advise on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

Or. ro

Amendment 132
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Regulation (EC) No 178/2002
Article 32 a

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 ***provide written advice*** on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

Or. en

Amendment 133
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	All correspondence between potential applicants for a food law authorisation and the staff of the Authority shall be publicly available on the EFSA website immediately, and before the publication of the relevant EFSA decision, and 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

Or. en

Amendment 134
Marco Zullo

Proposal for a regulation

Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32 a – subparagraph 1a (new)

Text proposed by the Commission	*Amendment*
	The advice provided should enable the applicant to understand easily the requirements of the studies to be conducted and give guidelines for any studies for which there are no international protocols or for which these cannot be used.

Or. it

Amendment 135
Jan Huitema, Fredrick Federley

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

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

Or. en

Amendment 136
Maria Gabriela Zoană

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

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

Or. ro

Amendment 137
Annie Schreijer-Pierik

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 178/2002
Article 32 b – 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 in accordance with Article 38 and Articles 39 to 39f ***and has published its scientific opinion***.

Or. nl

Justification

Scientific data and studies and any other information in support of applications for authorisation should be publicly released only once the Authority publishes its scientific results. If that is done earlier, there is a risk that competitors may gain access to information about innovative product ideas or production processes. Moreover, there would otherwise be a real risk of undesirable political interference in the risk assessment process.

Amendment 138
Franc Bogovič

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

Justification

Scientific data and studies and any other information supporting applications should be made public only once the Authority publishes its scientific results. Otherwise, there is a risk that competitors gain access to information about innovative product ideas or manufacturing processes. Moreover, there would otherwise be the danger of political interference in the risk assessment process.

Amendment 139
Maria Lidia Senra Rodríguez

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

Text proposed by the Commission	*Amendment*
1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal ***and shall provide advice on the content of the intended renewal application taking into account the received comments. The advice provided by the Authority shall be without***	1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal.

prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.

Or. es

Amendment 140
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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

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

Or. en

Amendment 141
Jan Huitema, Fredrick Federley

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

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 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. ***These controls shall be coordinated with OECD Good Laboratory Practices (GLP) auditing programmes, which currently audit each Member State monitoring authority every 10 years.***

Or. en

Amendment 142
Michel Dantin

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

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 ***established in the Union or in a third country*** 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. ***Those*** controls shall be organised in cooperation with the competent authorities of the Member States ***and the third countries in which the facilities concerned are established***.

Or. fr

Justification

The purpose of this amendment is to provide the legal bases necessary to allow the Commission to check laboratories located in third countries that are carrying out studies submitted in support of authorisation applications. If no checks were carried out in third countries, laboratories located in the EU would not be treated in the same way as those located elsewhere, meaning that the laboratories could not provide a uniform level of guarantee. This would be unacceptable for the European public.

Amendment 143
Nicola Caputo

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

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's Food and Veterinary Office (FVO)*** experts shall perform controls, including audits, to obtain assurance that testing facilities ***in the EU and in third countries*** 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 of the third countries concerned***.

Or. en

Justification

The Food and Veterinary Office works to assure effective control systems and to evaluate compliance with EU standards within the EU, and in third countries exporting to the EU. This is done mainly through inspections carried out by the Food and Veterinary Office in the Member States and in third countries exporting to the EU.

Amendment 144
Eric Andrieu, Karine Gloanec Maurin

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

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	The Commission experts shall perform controls, including audits, to obtain assurance that testing facilities ***located in the Union and in third countries*** comply with relevant standards for carrying out

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.

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. fr

Amendment 145
Maria Lidia Senra Rodríguez

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

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 ***regular*** 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.

Or. es

Amendment 146
Molly Scott Cato
on behalf of the Verts/ALE Group

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

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	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.;	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 modalities of which shall be determined via delegated act***;

Or. en

Amendment 147
Maria Gabriela Zoană

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

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. The studies commissioned may have a wider scope than the evidence subject to verification; ***the studies commissioned must not create any delay in the risk assessment process.***

Or. ro

Amendment 148
Philippe Loiseau, Jacques Colombier

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

Regulation (EC) No 178/2002
Article 32 e

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, ***the European Parliament or the Council,*** in exceptional circumstances, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Or. fr

Amendment 149
Jan Huitema

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

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

Or. en

Amendment 150

Nicola Caputo

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

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 ***may, in the event of conflicting scientific findings,*** request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Or. en

Justification

The wording "exceptional circumstances" leaves too much room for manoeuvre.

Amendment 151
Clara Eugenia Aguilera García, Paolo De Castro, Ricardo Serrão Santos

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

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 Commission may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies ***requested may be as thoroughgoing as necessary in each case to ensure proper*** verification.

subject to verification.***;***

Or. es

Amendment 152
Maria Lidia Senra Rodríguez

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

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, ***the European Parliament or a Member State shall*** request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Or. es

Amendment 153
Maria Lidia Senra Rodríguez

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

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	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 ***shall*** request the Authority to commission scientific studies with the objective of verifying evidence used in its risk

evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.***;***	assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Or. es

Amendment 154
Peter Jahr

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

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 ***EU*** food law to demonstrate the safety of a subject matter submitted to a system of authorisation, the ***Authority may, in the event of conflicting scientific findings,*** commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Or. de

Amendment 155
Molly Scott Cato
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 sentence

Text proposed by the Commission	*Amendment*
The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:	The Authority shall carry out its activities with a high level of transparency***, proactively disseminating the information it possesses***. It shall in particular make

public without delay:

Or. en

Amendment 156
James Nicholson, Anthea McIntyre

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

Text proposed by the Commission	*Amendment*
The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:	The Authority shall carry out its activities with a high level of transparency***, without prejudice to Directive (EU) 2016/943***. It shall in particular make public without delay:

Or. en

Amendment 157
Annie Schreijer-Pierik

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

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

Or. nl

Justification

The article needs to be structured better. It is therefore necessary to distinguish between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by EFSA.

Amendment 158
Annie Schreijer-Pierik

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. nl

Justification

The article needs to be structured better. It is therefore necessary to distinguish between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by EFSA.

Amendment 159
Annie Schreijer-Pierik

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. nl

Justification

The article needs to be structured better. It is therefore necessary to distinguish between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by EFSA.

Amendment 160
Anthea McIntyre, James Nicholson

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

Text proposed by the Commission	*Amendment*
	Member States shall put in place all necessary measures to prevent any breach of the undertakings given by those accessing the dedicated section of the Authority's website. Measures and penalties shall be effective, proportionate and dissuasive against any non-permitted use.

Or. en

Amendment 161
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
	(aa) The following paragraph 1a shall be added:
	"1a.At the time of publication of its scientific opinion, the Authority shall also make the following public:
	(a) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other

scientific data and information supporting requests from the European Parliament, the Commission and the Member States for 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 potential applicants conducted by the Authority pursuant to Article 32a and 32c prior to their applications.";

Or. nl

Justification

This improves the structure of this article. It is therefore necessary to distinguish between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by EFSA. Scientific data and studies and any other information in support of applications for authorisation should be publicly released only once the Authority publishes its scientific results.

Amendment 162
Molly Scott Cato
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 – paragraph 1a

Text proposed by the Commission	*Amendment*
1a. The disclosure of the information mentioned in paragraph (1)(c) to the public shall be without prejudice:	***deleted***
(a) to any intellectual property right which may exist over documents or their content; and,	
(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').

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.

Or. en

Amendment 163
Clara Eugenia Aguilera García, Paolo De Castro, Ricardo Serrão Santos

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

Text proposed by the Commission	*Amendment*
The disclosure of the information mentioned in paragraph (1)(c) to the public shall be without prejudice:	***Except in cases which require exceptional treatment in the general interest,*** the disclosure of the information mentioned in paragraph (1)(c) to the public shall be without prejudice:

Or. es

Amendment 164
James Nicholson, Anthea McIntyre

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

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

content; and,	content***, in accordance with the TRIPS Agreement***; and,

Or. en

Amendment 165
James Nicholson, Anthea McIntyre

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

Text proposed by the Commission	*Amendment*
(b) any provisions set out in Union food law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').	(b) any provisions set out in Union food law protecting the investment made by innovators in gathering the information***, in line with Directive (EU) 2016/943*** and data supporting relevant applications for authorisations ('data exclusivity rules').

Or. en

Amendment 166
Anthea McIntyre, James Nicholson

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

Text proposed by the Commission	*Amendment*
	This article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council on public access to environmental information, 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, and 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.

Or. en

Amendment 167
Molly Scott Cato
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 – introductory sentence

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, ***provided that the request for confidential treatment demonstrates, with adequate and*** verifiable justification, ***that the disclosure would*** significantly***, specifically and actually*** harm the ***commercial*** interests ***of the applicant***:

Or. en

Amendment 168
Anthea McIntyre, James Nicholson

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

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 ***shall not divulge to third parties confidential information that it receives for which*** confidential treatment ***has been requested and justified, except for*** information which ***must be made public if circumstances so require, in***

order to protect public health.

Or. en

Amendment 169
Maria Gabriela Zoană

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

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 ***shall*** 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:

Or. ro

Amendment 170
Molly Scott Cato
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 – point 1

Text proposed by the Commission	*Amendment*
(1) the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion;	(1) the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion***, provided that the applicant demonstrates that such method does not entail emissions in the environment and has no harmful impacts on health and environment***;

Or. en

Amendment 171
Clara Eugenia Aguilera García, Paolo De Castro, Ricardo Serrão Santos

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

Text proposed by the Commission	*Amendment*
(1) the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion;	(1) the method***,*** and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion***, that must provide all the guarantees necessary to ensure respect for the environment and for public health***;

Or. es

Amendment 172
Annie Schreijer-Pierik

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

Justification

Even publication of the name of an undertaking in relation to the substance examined in a study may provide competitors with indications of an innovative product idea and thus give rise to a competitive disadvantage for the applicant.

Amendment 173

Jan Huitema, Fredrick Federley

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

Or. en

Amendment 174
Maria Lidia Senra Rodríguez

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 2 – point 4

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

Or. es

Amendment 175
Molly Scott Cato
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 – point 4

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

except when relevant to understanding the potential effects on health and environment.

Or. en

Amendment 176
Franc Bogovič

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 178/2002
Article 39 – paragraph 2 – point 4

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

Or. en

Justification

Properties belong to the know-how of an innovation and therefore need to be mentioned.

Amendment 177
Peter Jahr

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

Text proposed by the Commission	*Amendment*
3. The list of information referred to in paragraph 2 shall be without prejudice to any specific Union food law.	3. The list of information referred to in paragraph 2 shall be without prejudice to any specific Union food law. ***The Authority shall mark as confidential all features treated as confidential, e.g. quantitative composition.***

Or. de

Amendment 178
Molly Scott Cato
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) Where action is ***required*** to protect public health, animal health or the environment, the Authority may disclose the information referred to paragraphs 2 and 3; and,

Or. en

Amendment 179
Molly Scott Cato
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 b

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

Or. en

Amendment 180
Annie Schreijer-Pierik

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

Justification

Scientific data and studies and any other information in support of applications for authorisation should be publicly released only once the Authority publishes its scientific results. If that is done earlier, there is a risk that competitors may gain access to information about innovative product ideas or production processes. Moreover, there would otherwise be a real risk of undesirable political interference in the risk assessment process.

Amendment 181
Jan Huitema, Fredrick Federley

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

Text proposed by the Commission	*Amendment*
(c) inform the applicant in writing of its intention to disclose information and the reasons for it, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority it may state its views ***or*** withdraw its application within ***two*** weeks from the date on which it was notified of the Authority's position.	(c) inform the applicant in writing of its intention to disclose information and the reasons for it, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority it may ***(1)*** state its views***, (2)*** withdraw its application***, or (3) request a review*** within ***four*** weeks from the date on which it was notified of the Authority's position.

Or. en

Amendment 182
Anthea McIntyre, James Nicholson

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

Article 39 b – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) adopt a reasoned decision on the confidentiality request taking into account the observations of the applicant within ten weeks from the date of receipt of the confidentiality request with respect to applications for authorisation and without undue delay in the case of supplementary data and information and notify the applicant and inform the Commission and the Member States, as appropriate, of its decision; and,	(d) adopt a reasoned decision on the confidentiality request taking into account the observations of the applicant within 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; ***data contained in the application dossier shall not be disclosed before the decision on a first European Union authorisation or re-authorisation of a marketable product has been made;*** and,

Or. en

Amendment 183
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
(e) make public any ***additional*** data and information ***for which*** the confidentiality request ***has not been accepted as justified not earlier than two weeks after the notification of its decision to the applicant has taken place, pursuant to point (d)***.	(e) make public any ***non-confidential*** data and information ***concerning the application for authorisation only when a decision has been taken in accordance with this article on*** the confidentiality request ***and the Authority 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. nl

Justification

Scientific data and studies in support of applications for authorisation should be publicly released only once the Authority publishes its scientific results. If that is done earlier, there is a risk that competitors may gain access to information about innovative product ideas or production processes. Moreover, there would otherwise be a real danger of political interference in the risk assessment process. After its withdrawal, no information should be published.

Amendment 184
Peter Jahr

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

Text proposed by the Commission	*Amendment*
(e) make public any additional data and information for which the confidentiality request has not been accepted as justified not earlier than two weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).	(e) make public any additional data and information for which the confidentiality request has not been accepted as justified not earlier than two weeks ***and no later than four weeks*** after the notification of its decision to the applicant has taken place, pursuant to point (d)***, and after expiry of the period for appeal to the ECJ. If the applicant takes legal action, publication shall be suspended until the judgment enters into force. The definitive ruling shall be delivered by the ECJ***.

Or. de

Amendment 185
Maria Lidia Senra Rodríguez

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39 b – 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	(e) make public any additional data and information for which the confidentiality request has not been accepted as justified

not earlier than two weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).	***no*** earlier than two ***weeks and no later than four*** weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).

Or. es

Amendment 186
Jan Huitema, Fredrick Federley

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

Text proposed by the Commission	*Amendment*
(e) make public any additional data and information for which the confidentiality request has not been accepted as justified not earlier than ***two*** weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).	(e) make public any additional data and information for which the confidentiality request has not been accepted as justified not earlier than ***four*** weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).

Or. en

Amendment 187
Jan Huitema, Fredrick Federley

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

Text proposed by the Commission	*Amendment*
	(e a) The Authority shall not publish any information from the concerned application when the applicant has decided to withdraw it's application.

Or. en

Amendment 188
Annie Schreijer-Pierik

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

Justification

The wording would also give the European Parliament and the Member States access to this confidential information comprising business secrets. However, access to such information should be strictly reserved for the Authority carrying out the risk assessment.

Amendment 189
Franc Bogovič

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

Authority is not made public.	accepted by the Authority is not made public.

Or. en

Justification

Scientific data and studies and any other information supporting applications should be made public only once the Authority publishes its scientific results. Otherwise, there is a risk that competitors gain access to information about innovative product ideas or manufacturing processes. Moreover, there would otherwise be the danger of political interference in the risk assessment process.

Amendment 190
Annie Schreijer-Pierik

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 39 d – 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 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 ***it has published its scientific opinion***. 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. nl

Justification

Scientific data and studies and any other information in support of applications for authorisation should be publicly released only once the Authority publishes its scientific results. If that is done earlier, there is a risk that competitors may gain access to information about innovative product ideas or production processes. Moreover, there would otherwise be a real risk of undesirable political interference in the risk assessment process.

Amendment 191
Annie Schreijer-Pierik

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

Justification

Where an application is withdrawn before the EFSA publishes its opinion, there should no longer be any access to the information and studies. This would not serve a legitimate purpose and might damage competition in the future.

Amendment 192
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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

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

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

Or. en

Amendment 193
Marc Tarabella, Maria Noichl, Karine Gloanec Maurin

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

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

Or. en

Amendment 194
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available***, unless there is an overriding public interest***.	2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available.

Or. nl

Justification

Since the term 'overriding public interest' is not clearly defined, the clause concerned should be deleted.

Amendment 195
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals ***or in obtaining toxicological information*** shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available, unless there is an overriding public interest.	2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals 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.

Or. en

Amendment 196
Molly Scott Cato
on behalf of the Verts/ALE Group

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

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 197
Molly Scott Cato
on behalf of the Verts/ALE Group

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

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.***;***	***The Authority shall ensure wide access to the documents which it possesses.*** Where environmental information is concerned, ***Regulation (EC) 1049/2001 of the European Parliament and the Council[38a] and*** Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall apply.
_____	_____
	[38a] 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
[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).	[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 198
Maria Lidia Senra Rodríguez

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

Text proposed by the Commission	*Amendment*

(10a) the following new Article 57a is inserted:

Article 57b

Authorisations

The Commission shall not renew any authorisation, or grant any new authorisation, if there are scientific discrepancies, or without taking the precautionary principle into account.

Or. es

Amendment 199
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	1 a. In no case may the following information when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept confidential:
	- 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

Justification

This paragraph 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. Maintain existing detail as found in Dir 2001/18 Article 25(4).

Amendment 200
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, which shall apply mutatis mutandis, confidential treatment may be accepted with respect to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,	
(b) breeding patterns and strategies.;	

Or. en

Amendment 201
Maria Lidia Senra Rodríguez

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

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. es

Amendment 202
Maria Lidia Senra Rodríguez

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

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

Or. es

Amendment 203
Annie Schreijer-Pierik

Proposal for a regulation
Article 2 – paragraph 1 – point 4
Directive No 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. nl

Amendment 204
Maria Lidia Senra Rodríguez

Proposal for a regulation
Article 2 – paragraph 1 – point 4
Directive No 2001/18/EC

Article 28 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. It shall be forbidden to intentionally release genetically modified organisms into the environment in contravention of the precautionary principle, including where there is no scientific knowledge of the consequences for each different area (the environment, health, biodiversity, etc.).

Or. es

Amendment 205
Annie Schreijer-Pierik

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

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

Or. nl

Amendment 206
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Article 30

Text proposed by the Commission	*Amendment*
(10) Article 30 is replaced by the following:	(10) Article 30 is replaced by the following: ***Confidentiality*** ***1. In accordance with the conditions and the procedures laid down in Article 39 to 39f of Regulation (EC) No 178/2002 and this article,*** ***(a) the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,*** ***(b) the Authority shall assess the confidentiality request submitted by the applicant.*** ***2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision.*** ***3. 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.***

4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and Member States with all information in its possession.
5. The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.
6. The Commission, the Authority and the Member States shall 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.
7. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information as to the confidentiality of which the Commission and the applicant disagree.

Or. en

Amendment 207
Annie Schreijer-Pierik

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

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

Amendment 208
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(2) Article 18 is replaced by the following:	(2) Article 18 is replaced by the following: ***Article 18*** ***Transparency and confidentiality*** ***1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39 to39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.*** ***2. In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002 and this Article, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and, the Authority shall assess the confidentiality request submitted by the applicant.*** ***3. 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.
4. 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.
5. 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 209
Annie Schreijer-Pierik

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 opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.

Or. nl

Amendment 210
Molly Scott Cato
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 211
Michel Dantin

Proposal for a regulation
Article 4 a (new)
Directive No 2001/110/EC
Article 2 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*

Article 4a

Amendments to Council Directive 2001/110/EC relating to honey

Article 2 is amended as follows:

(a) in paragraph 4, point (a), the first subparagraph is replaced by the following:

'The country or countries of origin where the honey has been harvested shall be indicated on the label. The countries of origin shall be listed in descending order of the proportions, by percentage, used in the final product. The country or countries of origin listed must account for at least 75% of the blend of honeys.'

(b) in paragraph 4, point (a), the second subparagraph is replaced by the following:

'Furthermore, if the honey is a blend of honeys from more than one Member State or more than one third country, one of the following pieces of information may also appear on the label, as appropriate:

— "blend of EU honeys";

— "blend of non-EU honeys";

— "blend of EU and non-EU honeys".

Such information is supplementary to, and shall not replace, the country of origin information referred to in the first subparagraph.'

(d) the following paragraph 5 is added:

'Terms such as "contains honey" and "made with honey" may not be used in the designation of processed products, or in any graphic or non-graphic element, unless at least 20% of the (mono- and disaccharide) sugar content of the product in question originates from honey.'

Or. fr

Amendment 212

Norbert Erdős, Momchil Nekov, Mireille D'Ornano, Peter Jahr, Eric Andrieu, Vladimir Urutchev, Marijana Petir, Franc Bogovič, Othmar Karas

Proposal for a regulation
Article 4 a (new)
Directive No 2001/110/EC
Article 2 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
	Article 4 a
	Amendments to Directive (EC) No 2001/110 on honey
	Directive (EC) No 2001/110 is amended as follows:
	(1) Article 2 is amended as follows:
	(a) Article 2, paragraph (4) point a) is replaced by the following text:
	"The country or countries of origin where the honey has been harvested shall be indicated on the label by which country or countries the honey used in the final product come from, and that these shall be listed in the order which corresponds to the percentage proportions used in the final product additionally stating the percentage by country in a given product."
	(b) Article 2 is completed by the following paragraph (6):
	"The use of the word 'honey' or the terms 'containing honey' or 'made with honey' in the designation of processed food products, or in any graphic or non-graphic element indicating that the product contains honey may only be used if at least 50 % of the sugar- content of the product originates from honey."

Or. en

Amendment 213
Annie Schreijer-Pierik

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, in accordance with Articles 14 and 15***, at the same time as its scientific opinion is published***;

Or. nl

Amendment 214
Franc Bogovič

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. en

Justification

Scientific data and studies and any other information supporting applications should be made public only once the Authority publishes its scientific results. Otherwise, there is a risk that competitors gain access to information about innovative product ideas or manufacturing processes. Moreover, there would otherwise be the danger of political interference in the risk assessment process.

Amendment 215
Annie Schreijer-Pierik

Proposal for a regulation
Article 5 – paragraph 1 – point 2

Regulation (EC) No 2065/2003
Article 14 – paragaph 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 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.;

Or. nl

Amendment 216
Annie Schreijer-Pierik

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, in accordance with Articles 19 and 20***, at the same time as its scientific opinion is published***;

Or. nl

Amendment 217
Annie Schreijer-Pierik

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	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. ;	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. nl

Amendment 218
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:	***deleted***
(a) any information provided in detailed descriptions of starting substances and preparations used to manufacture the substance subject to the authorisation, the composition of preparations, materials or articles in which the applicant intends to use this substance, the manufacturing methods of these preparations, materials or articles, impurities, and migration testing results;	
(b) the trademark under which the substance, shall be marketed as well as the tradename of the preparations, material or articles in which it shall be used, where applicable; and,	

(c) any other information deemed confidential within the specific procedural rules referred to in Article 5(1)(n) of this Regulation..

Or. en

Amendment 219
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20 – paragraph 2 – point a

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 220
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation (EC) No 1935/2004
Article 20 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the trademark under which the substance, shall be marketed as well as the tradename of the preparations, material or articles in which it shall be used, where applicable; and,	***deleted***

Or. en

Amendment 221
Annie Schreijer-Pierik

Proposal for a regulation
Article 7 – paragraph 1 – point 2
Regulation (EC) No 1331/2008
Article 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 extension of period pursuant to Article 6(1) of this Regulation.;	***"***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 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 opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.;

Or. nl

Amendment 222
Anthea McIntyre, James Nicholson

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

Text proposed by the Commission	*Amendment*
1. In accordance with the conditions and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this article, the applicant may request certain information submitted under this Regulation to be kept confidential***,*** ***accompanied by*** verifiable justification.	1. In accordance with the conditions and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this article, the applicant may request certain information submitted under this Regulation to be kept confidential***. It shall provide*** verifiable justification ***to show that the disclosure of the information might undermine his commercial interests, or***

	the protection of privacy and the integrity of the individual.

Or. en

Amendment 223
Anthea McIntyre, James Nicholson

Proposal for a regulation
Article 8 – paragraph 1 – point 5
Regulation (EC) No 1107/2009
Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3), confidential treatment ***may be accepted with respect to the following*** information***, the disclosure of*** which ***may be deemed, upon verifiable justification, to significantly harm the interests concerned:***	2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3), ***the Authority shall not divulge to third parties confidential information that it receives for which*** confidential treatment ***has been requested and justified, except for*** information which ***must be made public if circumstances so require, in order to protect public health.***

Or. en

Amendment 224
Annie Schreijer-Pierik

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

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

Or. nl

Amendment 225
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
The Authority shall ensure public access to the application***, relevant supporting information and any supplementary information supplied by the applicant*** in accordance with Article ***23.;***	The Authority shall ensure ***that the*** public ***has*** access to the ***non-confidential data of the*** application ***in accordance with Article 23, as well as to the notification on safety issues*** in accordance with Article ***15, at the same time as the publication of its scientific opinion***.

Or. nl

Amendment 226
Annie Schreijer-Pierik

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, ***simultaneously with the publication of its opinion on the application,*** in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article.

Or. nl