European Parliament
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Committee on the Environment, Public Health and Food Safety

2018/0088(COD)

10.7.2018

***I
DRAFT REPORT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Renate Sommer

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2018)0179),

– having regard to Article 294(2) and Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0144/2018),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Agriculture and Rural Development, the Committee on Fisheries and the Committee on Legal Affairs (A8-0000/2018),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

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***. In this connection,*** the respective roles of risk assessors and managers ***should be taken into account and their mutual independence guaranteed***.

Or. de

Amendment 2

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. de

Justification

Adaptation of the recital to take account of the Commission proposals concerning the Management Board under Article 25(1a)c.

Amendment 3

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) The Fitness Check of the General Food Law identified certain shortcomings in the long-term capability of the Authority to maintain its high-level expertise. ***In particular***, there has been a decrease in the number of candidates applying to be members of the Scientific Panels. The system has thus to be strengthened ***and Member States should take a more active role*** to ensure that a sufficient pool of experts is available to meet the needs of the Union risk assessment system in terms of high level of scientific expertise, independence and multidisciplinary expertise.	(13) The Fitness Check of the General Food Law identified certain shortcomings in the long-term capability of the Authority to maintain its high-level expertise. ***Moreover***, there has been a decrease in the number of candidates applying to be members of the Scientific Panels. ***Six Member States provide two thirds of the experts on the scientific panels. As the United Kingdom currently provides approximately 20% of the national experts, the problem will be further exacerbated with the withdrawal of the United Kingdome from the EU.*** The system has thus to be strengthened 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. de

Justification

Explanation of the causes of the Authority's human resources problems.

Amendment 4

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels ***by the Member States, their selection by the Executive Director of the Authority*** and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and	(14) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel.

independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to defend EFSA's interests and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures should also be put in place to ensure that scientific experts have the means to act independently.	It is also essential to this end that the Executive Director whose function is to defend EFSA's interests and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures should also be put in place to ensure that scientific experts have the means to act independently.

Or. de

Amendment 5

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) A comparison of EU agencies shows that the Authority needs up to 55 months for an authorisation procedure or five times as long as the European Medicines Agency (EMA). This discourages firms from investing in innovative products and reduces EU competitiveness in the long run. In addition, long authorisation procedures weaken confidence in the Authority. It is therefore urgently advisable to ensure the efficiency of the risk assessment by means of better human and financial resources.

Or. de

Amendment 6

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Provisions exist on the 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.***	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. de

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 7

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	(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***.	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. de

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 8

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Studies, including tests, submitted by business operators in support of applications for authorisations under Union sectoral food law usually comply with internationally recognised principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, issues of compliance with the applicable standards may arise in some cases and this is why national systems are in place to verify such compliance. It is appropriate to provide an ***additional level of guarantees to reassure the general public on the quality of studies and to lay down an*** enhanced auditing system whereby ***Member State controls on the implementation of those principles by*** the laboratories carrying out such studies and tests would be verified by the Commission.	(21) Studies, including tests, submitted ***pursuant to Directive 2004/10/EC*** by business operators in support of applications for authorisations under Union sectoral food law usually comply with internationally recognised principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, issues of compliance with the applicable standards may arise in some cases and this is why national systems are in place to verify such compliance. It is appropriate to provide an enhanced auditing system whereby the laboratories carrying out such studies and tests would be verified by ***the Food and Veterinary Office (FVO) of*** the Commission.

Or. de

Justification

Directive 2004/10/EC harmonises the laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. The Food and Veterinary Office based in Ireland works to assure effective control systems and to evaluate compliance with EU standards within the EU, and in third countries in relation to their exports to the EU. The FVO should in the future also carry out audits of laboratories in third countries, if they are entrusted with studies in relation to an application to EFSA.

Amendment 9

Proposal for a regulation
Recital 22

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

Or. de

Justification

The risk assessment process and the risk management process should be clearly separated. It must be left to the discretion of the Authority to decide whether additional verification studies

are necessary, e.g. because there are conflicting study results. Otherwise, there is a risk that verification studies will be commissioned as a result of political pressure.

Amendment 10

Proposal for a regulation
Recital 25

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

Or. de

Justification

Publishing the information when the Authority's scientific opinion is published meets the need both for public access and for the protection of investment and intellectual property.

Amendment 11

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	(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.	account the objectives of Regulation (EC) No 178/2002***, the principle of proportionality and the TRIPS Agreement***.

Or. de

Justification

Additional provision in line with the protection of intellectual property referred to in Recital 25. The TRIPS Agreement is an international agreement on trade-related aspects of intellectual property rights.

Amendment 12

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) Accordingly and with respect to the procedures governing requests for authorisation procedures provided in Union food law, experience gained so far has shown that certain information items are generally considered sensitive and should remain confidential across the different sectoral authorisation procedures. It is appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of information items whose disclosure may be considered to significantly harm the commercial interests concerned and should not therefore be disclosed to the public, ("general horizontal list of confidential items"). Only in very limited and exceptional circumstances ***relating to foreseeable health effects and*** urgent ***needs*** to protect human health, animal health or the environment, such information should be disclosed.	(28) Accordingly and with respect to the procedures governing requests for authorisation procedures provided in Union food law, experience gained so far has shown that certain information items are generally considered sensitive and should remain confidential across the different sectoral authorisation procedures. It is appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of information items whose disclosure may be considered to significantly harm the commercial interests concerned and should not therefore be disclosed to the public, ("general horizontal list of confidential items"). Only in 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.

Or. de

Justification

Doppelung

Amendment 13

Proposal for a regulation
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39a) Since the amendments contained in this proposal serve to transfer far-reaching competencies for risk assessment and confidentiality checks to the Authority, a significant increase in the budget for the Authority pursuant to Annex 3 of the Commission's proposal is necessary. The financing proposal is compatible with the current multiannual financial framework but may entail the use of special instruments as defined in Council Regulation (EU, Euratom) No 1311/2013. Should discussions between the Parliament and the Member States on the EU budget not leave sufficient room for the necessary budgetary resources, then the Commission would have to propose an alternative financing proposal under a delegated act.

Or. de

Justification

Given the impact of Brexit on the EU budget, the outcome of the negotiations on the multiannual financial framework is still completely uncertain. Should the Council of Ministers and the European Parliament not be able to agree on an appropriate budget for the EFSA, we would be saddling the Authority with a mandate that it could simply not carry out with the existing financial and human resources. The negotiations on the Commission proposal should also cover an alternative to take account of this eventuality.

Amendment 14

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

Regulation (EC) No 178/2002
Article 8a – point f a (new)

Text proposed by the Commission	*Amendment*
	fa) inform consumers about risk prevention strategies;

Or. de

Justification

Risk prevention strategies, such as information on the proper washing and cooking of meat and poultry products, are an important element of risk communication.

Amendment 15

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

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

Or. de

Justification

The Commission could, for example, react to misleading reports in the media through a dedicated website to debunk false information.

Amendment 16

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

Text proposed by the Commission	*Amendment*
	Article 8d
	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. de

Justification

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

Amendment 17

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	c) ***five*** members with the right to vote representing civil society and food chain interests namely, one from consumers organisations, one from environmental non-governmental organisations, one from farmers organisations and one from ***the agrochemical*** industry ***and one from the food industry***. Those members shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the

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.	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

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 completely different. The Management Board should therefore comprise two representatives of industry.

Amendment 18

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

Text proposed by the Commission	*Amendment*
(5) The members of the Scientific Committee who are not members of Scientific Panels ***and the additional members referred to in paragraph 5b*** shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a five year term of office, which may be renewable, following publication in the Official Journal of the European Union, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.",	(5) The members of the Scientific Committee who are not members of Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a five year term of office, which may be renewable, following publication in the Official Journal of the European Union, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.",

Or. de

Amendment 19

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

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

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

Or. de

Amendment 20

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

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

Or. de

Justification

There is a need to prevent the independence of the Authority from being compromised by

political interference and greater involvement of Member States. It is therefore appropriate to ensure that the Authority, in parallel with the nomination of scientific experts by the Member States, can draw up its own list of experts and select them from it. Moreover, Member States should not be obliged to nominate experts.

Amendment 21

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

Text proposed by the Commission	*Amendment*
	ba) In addition to the experts possibly nominated by the Member States, the Authority shall publish a call for expressions of interest in the Official Journal of the European, in relevant leading scientific publications and on the Authority's website.

Or. de

Amendment 22

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

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

for appointment.

Or. de

Amendment 23

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

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

Amendment 24

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

Text proposed by the Commission	*Amendment*
	(5fa) The Authority shall offer members of Panels comprehensive training on the

risk assessment process.

Or. de

Justification

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

Amendment 25

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

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

Or. de

Justification

Harmonisation with the structure and wording of the EMA consultation process.

Amendment 26

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

Regulation (EC) No 178/2002
Article 32b – paragraph 1

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

Or. de

Justification

Laboratories located in third countries outside the EU must also be covered.

Amendment 27

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

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

Or. de

Amendment 28

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

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

Or. de

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 29

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

Text proposed by the Commission	*Amendment*
	(4a) This Article shall not be applicable to studies commissioned before [date of entry into force of this Regulation].

Or. de

Justification

The obligation to publish studies shall not have retroactive effect.

Amendment 30

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

Regulation (EC) No 178/2002
Article 32b – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) The Commission shall establish, as part of a delegated act, penalties for breaches of the notification obligation.

Or. de

Justification

The imposition of sanctions cannot be left to the Authority.

Amendment 31

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

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

Or. de

Justification

The consultation period must be clearly defined in order to provide a clear structure for the overall duration of the authorisation process.

Amendment 32

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

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

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 33

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

Text proposed by the Commission	*Amendment*
Without prejudice to the obligation of applicants for authorisations under food law to demonstrate the safety of a subject matter submitted to a system of authorisation, the ***Commission***, in ***exceptional circumstances, may request the Authority to*** commission scientific studies with the objective of verifying	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***, in ***the event of conflicting scientific findings,*** commission scientific studies with the objective of verifying evidence used in its

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

Or. de

Justification

The risk assessment process and the risk management process should be clearly separated. It must be left to the discretion of the Authority to decide whether additional verification studies are necessary, e.g. because there are conflicting study results. Otherwise, there is a risk that verification studies will be commissioned as a result of political pressure. The wording 'exceptional circumstances' leaves too much room for manoeuvre.

Amendment 34

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

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

Or. de

Justification

The article needs to be structured better. The rapporteur distinguishes 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 the EFSA.

Amendment 35

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. de

Justification

The article needs to be structured better. The rapporteur distinguishes 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 the EFSA.

Amendment 36

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. de

Justification

The article needs to be structured better. The rapporteur distinguishes 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 the EFSA.

Amendment 37

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

Text proposed by the Commission	*Amendment*
	aa) The following paragraph 1 -a shall be added:
	(1 -a) At the time of publication of its scientific opinion, the Authority shall also make the following public:
	a) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States 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 applicants conducted by the Authority pursuant to Article 32a and 32c prior to their applications.

Or. de

Justification

Eine bessere Strukturierung des Artikels ist notwendig. Die Berichterstatterin nimmt eine Einteilung vor in a) Informationen, die unmittelbar veröffentlicht werden sollen und b) Informationen, die erst zum Zeitpunkt der Annahme der wissenschaftlichen Stellungnahme der EFSA veröffentlicht werden sollen. Wissenschaftliche Daten und Studien sowie sonstige

Informationen zur Stützung von Zulassungsanträgen sollten erst dann veröffentlicht werden, wenn die Behörde ihre wissenschaftlichen Ergebnisse veröffentlicht. Ansonsten besteht die Gefahr, dass Wettbewerber Zugang zu Informationen über innovative Produktideen oder Herstellungsprozesse erhalten. Außerdem besteht ansonsten die Gefahr der politischen Einflussnahme auf den Prozess der Risikobewertung.

Amendment 38

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

Text proposed by the Commission	*Amendment*
(3) commercial information revealing sourcing, market shares or business strategy of the applicant; and,	(3) commercial information revealing sourcing, market shares***, innovative product ideas*** or business strategy of the applicant; and,

Or. de

Justification

The mere publication of the name of an undertaking in relation to the substance of a study may give competitors an indication as to innovative product ideas.

Amendment 39

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

Text proposed by the Commission	*Amendment*
	(2a) The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules pursuant to paragraphs 1 to 4.

Or. de

Justification

The current definition of the four criteria for the positive list is too loose. The EFSA should

therefore lay down detailed rules.

Amendment 40

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

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

Or. de

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 products or manufacturing processes. Moreover, there would otherwise be the danger of political interference in the risk assessment process.

Amendment 41

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

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

Or. de

Justification

Applicants must be able to make legally certain whether the planned publication of the data may compromise commercially sensitive secrets. In particular, SMEs that do not have their own legal department require more time to do so.

Amendment 42

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

Text proposed by the Commission	*Amendment*
e) ***make public any additional*** data and information ***for which*** the ***confidentiality request has not*** been ***accepted as justified not earlier than two weeks after*** the ***notification of*** its ***decision to the*** applicant ***has taken place,*** pursuant to ***point*** (***d***).	e) ***publish non-confidential*** data and information ***relating to*** the ***application only once a final decision has*** been ***taken in respect of the confidentiality request pursuant to this Article and*** the ***Authority 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. de

Justification

Wissenschaftliche Daten und Studien sowie sonstige Informationen zur Stützung von Zulassungsanträgen sollten erst dann veröffentlicht werden, wenn die Behörde ihre wissenschaftlichen Ergebnisse veröffentlicht. Ansonsten besteht die Gefahr, dass Wettbewerber Zugang zu Informationen über innovative Produktideen oder Herstellungsprozesse erhalten. Außerdem besteht ansonsten die Gefahr der politischen Einflussnahme auf den Prozess der Risikobewertung. Zieht ein Hersteller seinen Antrag zurück, gibt es keine Notwendigkeit die Veröffentlichung der Information zu betreiben.

Amendment 43

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

Regulation (EC) No 178/2002
Article 39d – paragraph 1

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

Or. de

Justification

The wording would also give the European Parliament and the Member States access to confidential information. Access to such information should be reserved for the Authority carrying out the risk assessment.

Amendment 44

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

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

Or. de

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 45

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

Text proposed by the Commission	*Amendment*
(3) If an applicant in the context of an authorisation procedure withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39to 39f. The application shall be considered withdrawn as of the moment the written request is received by the competent body that had received the original application. Where the withdrawal of the application takes place before the Authority has decided on the relevant confidentiality request, the Authority, the Commission and the Member States shall not make public ***the*** information ***for which confidentiality has been requested***.	(3) If an applicant in the context of an authorisation procedure withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39to 39f. The application shall be considered withdrawn as of the moment the written request is received by the competent body that had received the original application. Where the withdrawal of the application takes place before the Authority has decided on the relevant confidentiality request, the Authority, the Commission and the Member States shall not make public ***any*** information ***relating to the planned application***.

Or. de

Justification

Where an application is withdrawn before the EFSA publishes its opinion, there should be no access to the information and studies.

Amendment 46

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

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

Or. de

Justification

The passage should be deleted since the term 'overriding public interest' is not defined.

Amendment 47

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

Text proposed by the Commission	*Amendment*
(1) For the purposes of Article 38(1)(c) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats and software packages shall be adopted to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union food law. These draft standard data formats and software packages shall not be based on proprietary standards and shall ensure interoperability with existing data submission approaches	(1) For the purposes of Article 38(1)(c) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats and software packages shall be adopted to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union food law ***and feasibility for small and medium-sized enterprises***. These draft standard data formats and software packages shall not be based on proprietary standards and shall ensure interoperability with existing data

to the extent possible.	submission approaches to the extent possible.

Or. de

Justification

SMEs have limited technical possibilities. It should nonetheless also be possible for them to use the standard data formats without knowledge or possession of the latest software programmes.

Amendment 48

Proposal for a regulation
Article 1 – paragraph 1 – point 9 a (new)
Regulation (EC) No 178/2002
Article 55 a (new)

Text proposed by the Commission	*Amendment*
	(9a) the following Article 55a is inserted after Article 55:
	'Article 55a
	Transparency of risk management
	(1) The European Commission and the Member States shall carry out their risk management activities in the context of food law with a high level of transparency. They shall in particular make public without delay:
	a) the agendas and the minutes of meetings of the Member States working group in which the risk management measures are discussed; and
	b) the agendas and proceedings of meetings and regulatory proposals put forward for adoption, including the results of votes in the committees in which regulatory proposals are adopted, in particular of the Committee referred to under Article 58 of the Regulation.
	(2) The European Commission shall attach to each regulatory proposal an explanatory statement comprising:

a) the reasons for and objectives of the measure,

b) the justification of the measure taking into consideration both need and proportionality,

c) the impact of the measure on society and on food manufacturers as indicated by the impact assessment, and

d) the results of the public consultation pursuant to Article 9 of this Regulation';

Or. de

Justification

The requirement for more stringent transparency rules should also apply in the area of risk management. To this end, the Commission and the Member States should be required to publish, in particular, the minutes of the working group meetings and the results of the voting in the standing committees. Only if the whole risk analysis process is subject to the same principles of transparency, will it be possible to restore citizens' confidence in food safety.

Amendment 49

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

Text proposed by the Commission	*Amendment*
(2) Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall ***assess the Authority's*** performance in relation to ***its*** objectives, ***mandate***, tasks, procedures and ***location, in accordance with Commission guidelines***. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.	(2) Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the ***Authority jointly with the*** Commission shall ***commission an independent evaluation of their*** performance in relation to ***their*** objectives, ***mandates***, tasks, procedures and ***locations***. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification. ***The evaluation shall take into account the views of the stakeholders, at both Community and national level.***

Or. de

Justification

The evaluation of the Authority should continue to be performed by independent experts.

Amendment 50

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

Text proposed by the Commission	*Amendment*
	(2a) The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority.

Or. de

Justification

In order to preserve the independence of the Authority, any proposals for possible adjustments should be formulated by the EFSA.

Amendment 51

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

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

Or. de

Justification

This paragraph would give the Commission the possibility of independently withdrawing the Authority's mandate. Such a far-reaching decision should, however, be reserved for the European legislator.

Amendment 52

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

Text proposed by the Commission	*Amendment*
(4) Where the relevant Scientific Committee is consulted under paragraph 1, it shall make public the notification/application, relevant supporting information and any supplementary information supplied by the notifier/applicant, ***as well*** as its scientific opinions, in accordance with Article 38 and Articles 39 to 39f of Regulation (EC) No 178/2002, which shall apply mutatis mutandis, and Article 25 of this Directive.	(4) Where the relevant Scientific Committee is consulted under paragraph 1, it shall make public the notification/application, relevant supporting information and any supplementary information supplied by the notifier/applicant, ***at the same time*** as its scientific 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.

Or. de

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 53

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 ***and the*** 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. de

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 54

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, ***at the same time as to its scientific opinion,*** in accordance with Article 18”;

Or. de

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 55

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

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

Or. de

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 56

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	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.	accordance with Articles 14 and 15.

Or. de

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 57

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

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

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 58

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

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

Or. de

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 59

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

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

Or. de

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 60

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, ***when it publishes*** its scientific ***opinion***, in accordance with Article 38, Articles 39to 39f and Article 40 of Regulation (EC) No 178/2002. It shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.

Or. de

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 61

Proposal for a regulation
Article 9 – paragraph 1 – point 1 – point b
Regulation (EU) 2015/2283
Article 10 – paragraph 3

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

Or. de

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 62

Proposal for a regulation
Article 9 – paragraph 1 – point 3 – point b
Regulation (EU) 2015/2283
Article 16 – paragraph 2

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

Or. de

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 63

Proposal for a regulation
Article 9 – paragraph 1 – point 4
Regulation (EU) 2015/2283
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
(1) Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article.	(1) Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article***, when it publishes its opinion concerning the application***.

Or. de

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.

EXPLANATORY STATEMENT

1. Background

Following a number of serious food scandals, Regulation (EC) No 178/2002 established the independent European Food Safety Authority with responsibility for scientific risk assessment. Risk management is a matter for the Institutions of the Union, notably the Commission. Today, food safety in the Union is considered the best in the world. Through a Fitness Check, the Commission established that the Regulation met the objectives of ensuring a high level of food safety and harmonisation of the internal market.

Widespread scepticism with regard to GMOs and the associated herbicide glyphosate resulted in a public controversy regarding herbicides and pesticides in general, which gave rise to a citizens' initiative. In view of the success of this citizens' initiative, the Commission concluded that there was a need to improve public confidence in risk assessment and pledged to put forward a corresponding legislative proposal.

2. Commission proposal

In April 2018, the Commission submitted to Parliament and the Council a proposal for a recast of Regulation (EC) No 178/2002 comprising the following key points:

- a tightening of the rules on transparency of the EFSA;
- stricter rules to guarantee reliability, objectivity and independence of studies used by the EFSA in its risk assessment;
- improvement of the functioning and governance of the EFSA;
- greater involvement of the Member States;
- making the EFSA more attractive to scientific experts;
- a comprehensive and effective risk communication strategy, involving the Commission, Member States and the EFSA.

In the interests of coherence, eight legal acts relating to the sector are to be harmonised as regards transparency and confidentiality.

3. Rapporteur's comments

In principle, your rapporteur welcomes the Commission's proposal for a regulation. The EFSA publishes a lot of information but it has to date not been legally obliged to do so. As result, the only way the public can gain access to information from the applications and studies submitted is by asserting the rights conferred under Regulation EC No 1049/2001 on public access to documents. A comparison with other EU agencies and the debate on the authorisation procedures for plant protection products show that the EFSA transparency rules are in need of revision. In addition, the EFSA is finding it increasingly difficult to find experts for the scientific panels.

The proposed amendments, however, are more likely to create new problems than solve existing ones. Moreover, the timing of the publication, the significant shortening of the consultation period and the absence of an impact assessment run counter to the Commission's better law-making principles.

Your rapporteur is particularly critical of the following:

Lack of an impact assessment

Whereas the REFIT of the basic Regulation referred to the general principles of food law as well as to the rapid alert system and crisis management, the Commission is now proposing amendments to articles which were not covered by REFIT. The proposed transparency rules could seriously damage the innovative strength and competitiveness of the European food industry. It would have been appropriate to consider different options with regard to the time of publication of sensitive data from applications. It is equally hard to understand why the Commission chose not to carry out an impact assessment. Similarly, no impact assessments were carried out for the eight sectoral legislative acts.

The Commission provides for a significant increase (+80 %) in the EFSA's budget. Should the European legislator, however, not be able to come to an agreement as regards the budget, then the Authority would not be able to fulfil its mandate in accordance with the revised regulation. An impact assessment with different funding models would also have been necessary in this connection.

Timing of the Commission proposal

The Commission essentially justified its proposal with the need to respond to the Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides'. In March 2018, the European Parliament set up a special committee (PEST) to look into the authorisation procedure and propose possible courses of action. The Commission ignored this process of democratic opinion forming and pre-empted its outcome.

By cutting the consultation period from the usual twelve weeks to eight, the Commission left the stakeholders scant time for consultation. Moreover, it was also only possible to react to general questions but not to the specific plans of the Commission. The publication of the Commission proposal shortly after the completion of the public consultation suggests that the draft regulation had already been finalised and that it was a consultation in name only.

Owing to time constraints in view of the 2019 European elections, there is hardly any possibility for the European Parliament to exercise due diligence and to obtain external expertise. Your rapporteur hopes that this was not the intention.

Rules on transparency

Unlike with the ECHA and EMA, which publish information and underlying studies in relation to applications simultaneously with their scientific opinions, the Commission proposes that in the authorisation procedures under food law such information be published already at the time of the submission of applications. This could, however, have far-reaching consequences for the competitiveness and innovative capacity of applicants. Competitors

from third countries could tap into product ideas and realise them already whilst the European authorisation process is still on-going, particularly since innovations in the food sector cannot, as a rule, be protected by patents. The Commission proposal therefore puts important jobs in jeopardy. Moreover, the new rules could lead companies to transfer their research and development activities to third countries. In addition, such early publication might potentially expose the EFSA to public pressure.

As it is, in controversial cases, the EFSA already grants interested parties the opportunity to comment on the studies commissioned as part of a consultation following the publication of its draft scientific opinion. In the case of aspartame, for example, this consultation led to the EFSA reviewing its opinion.

Appointment of members of scientific panels

The involvement of the Member States in the appointment of members of scientific panels through the obligation to nominate numerous experts could result in political interference with the EFSA. Moreover, it is questionable whether all disciplines would be appropriately covered if each Member State issued its own call for expressions of interest. A constant exchange of information between Member States on the state of play in their search for experts would result in a further significant increase in the additional administrative burden, which is already enormous. It would therefore be appropriate to allow Member States to nominate experts but not to oblige them to do so. Ultimately, EFSA should draw up the lists of experts from as many Member States as possible and make the appointments on the basis of such lists.

4. Rapporteur's amendments

Your rapporteur proposes to bring the EFSA rules on transparency into line with those of other agencies so that non-confidential information from applications, studies and consultation sessions are only made accessible when the EFSA publishes its scientific opinion and not at the time of the submission of the application. This is the only way to eliminate the theft of ideas. Information should only be published if an application is maintained.

The requirement for stringent transparency should also apply in the areas of risk management and risk communication. The Commission and Member States should be required to publish minutes of working group meetings and voting results in standing committees.

The audit obligation should also extend to laboratories in third countries commissioned by European companies to carry out studies. This should fall under the responsibility of the Commission's Food and Veterinary Office (FVO).

Your rapporteur welcomes the involvement of stakeholder representatives in the EFSA Management Board, as is the case with the ECHA and EMA. However, in view of the broad range of products covered by Regulation 178/2002, your rapporteur considers it necessary to include not one but two representatives of industry (GMOs/plant protection products as well as foodstuffs/additives). This is also envisaged for non-governmental organisations (environment and consumer protection).

5. Conclusions

Regulation (EC) No 178/2002 on general food law is a success story. With it, the EU created

the world's highest food safety standards for its internal market. The Fitness Check of the basic Regulation confirmed this.

The structure and transparency of EFSA should be brought into line with those of other EU agencies. The Commission's proposals, however, go well beyond the ECHA and EMA rules. This is just as hard to understand as the fact that the Commission intends to envelop the whole of the food sector with new rules liable to threaten the very survival of undertakings simply because of the public discourse on the authorisation procedure for a plant protection product and it intends to do so without the due impact assessment.

The Commission proposal also lacks precision. Many details are to be determined later in the Authority's internal rules, making the evaluation of the proposals difficult. This is equally true for risk communication, which constitutes an important element if the EU is to restore public confidence in food safety.