European Parliament
2014-2019

Committee on the Environment, Public Health and Food Safety

2018/0088(COD)

21.9.2018

AMENDMENTS
297 - 539

Draft report
Renate Sommer
(PE623.765v02-00)

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_LegReport

Amendment 297
Fredrick Federley, Ulrike Müller, Jan Huitema

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 prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.	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 ***which are relevant for the risk assessment of the intended renewal***. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.

Or. en

Amendment 298
Martin Häusling

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	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.	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***, and such without prejudice to the Authority's own obligations under Article 33***. This provision does not apply to the submission of any supplementary information by the applicants during the risk assessment process.

Or. en

Justification

Public consultation should not be seen as the panacea for good quality and exhaustive risk assessment. Indeed public consultations generally touch a very narrow audience. This responsibility lies with the EFSA. The rigorous identification of relevant scientific data should be done by the Authority itself, as laid down in Article 33. Public consultation should not exempt EFSA from this obligation.

Amendment 299
Fredrick Federley, Ulrike Müller, Jan Huitema

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 ***that have been carried out in accordance with international guidelines and Good Laboratory Practices (GLP)*** 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. en

Amendment 300
Anja Hazekamp

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***, within four 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. en

Justification

Sufficient time should be given to all stakeholders and the public to submit other relevant available data.

Amendment 301
Martin Häusling

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 controls, including audits, ***on a regular basis*** 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 ***also include checks if the raw data complies with the outcome of safety studies. These controls shall be unannounced and*** organised in cooperation with the competent authorities of the Member States.

Or. en

Amendment 302
Michel Dantin, Angélique Delahaye

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 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 303
Anja Hazekamp

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 controls, including audits, to ***ensure*** that testing facilities ***in the Union 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 ***concerned countries***

Or. en

Justification

In order to ensure the quality and a level playing field, these controls and audits should be inside and outside the EU, such as with other agri-food chain products and installations.

Amendment 304
Karin Kadenbach

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

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

Or. en

Amendment 305
Anja Hazekamp

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, 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 power of initiative for the commissioning of verification studies, shall also be given to the citizens under the same conditions as the European Citizen's Initiative. Once the conditions***

are fulfilled and verified, the Commission shall consult with the initiators and the Authority, about the specifications of the studies and the process of the commissioning will start immediately. The studies many have a wider scope than the evidence subject to verification or the demand of the Citizens' verification initiative, but the scope shall correspond at least to the request(s) and shall have the approval of the initiators. For this purpose the Commission shall create the platform and the mechanism that allow the public to submit their request for commissioning of verification studies;

Or. en

Justification

This way the public participation would be enhanced and it would be given to the citizens the right to indicate to the decision-makers where their concerns are focused and to have the public money spend serving public requests.

Amendment 306
Michel Dantin, Angélique Delahaye

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 and the Member States***, 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."
Where it considers necessary, the Authority may also order verification studies after consulting its Management Board. A quadripartite selection panel comprising the Commission, the Member States, the EFSA and the European Parliament shall be set up. Its mission shall be to identify and prioritise requests for verification studies.

Or. fr

Justification

The amendment proposes that verification studies be carried out in as wide and open a supervisory context as possible encompassing not only the Commission but also Parliament, the Member States and the EFSA. These studies are launched at the behest of a multipartite selection committee. Finally, the funding thereof is already provided for under the additional EFSA allocation proposed by Commission.

Amendment 307
Martin Häusling

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 ***and without prejudice to the application of the precautionary principle in presence of scientific uncertainty***, the Commission***, the Member States or the European Parliament may***, in exceptional circumstances, request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Verification studies shall be funded via the contributions of applicants to a common fund. The Commission shall adopt a delegated act in accordance with Article 57a to determine the modalities of this fund.

Or. en

Justification

The reference to the precautionary principle (PP) is important in order to make sure that the verification studies are not conducted instead of applying the PP, i.e. they should not be commissioned to keep a product on the market if gaps have been identified. Public money shall not be used in order to safety test products of companies.

Amendment 308
Guillaume Balas

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 and Member States,*** in exceptional circumstances, ***can*** 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. ***When deemed necessary and after consulting its Board members, the Authority may also request verification studies.***

Or. en

Amendment 309
Pavel Poc, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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 ***and without prejudice to the application of the precautionary principle in presence of scientific uncertainty***, the Commission***, the Member States or the European 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.

Or. en

Justification

EFSA can only assess regulated products on the basis of the authorisation dossiers submitted by applicants. It cannot commission additional studies to verify the safety of a given substance or product. The verification studies foreseen in the Commission proposal could therefore be a positive element in case of a scientific uncertainty if they are not used instead of the precautionary principle.

Amendment 310
Annie Schreijer-Pierik

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, in exceptional circumstances ***and after careful consultation***, 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. nl

Amendment 311
Fredrick Federley, Ulrike Müller, 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***, in exceptional circumstances, ***when there are data gaps or scientific uncertainty,*** 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 312
Piernicola Pedicini, Eleonora Evi

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, in exceptional circumstances, may commission ***independent*** 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 313
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	(4a) The following Article 32ea is inserted:
	"Safety Mandatory Tests
	Safety testing of chemicals shall be paid for by the applicant of a substance and shall be managed by EFSA in cooperation with independent laboratories. EFSA shall define the set of mandatory laboratory tests based on legal requirements and additional concerns for hazards observed in scientific literature and put forward in public consultation."

Or. en

Amendment 314
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(4b) The following Article 32ea is inserted:
	"Safety testing
	Safety testing of products falling within EFSA's remit shall be based on a set of mandatory tests defined by the Authority. Any studies based on so-called good laboratory practice need to be complemented and verified by other, independent research."

Or. en

Amendment 315
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 4 a (new)
Regulation (EC) No 178/2002
Article 33 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(4a) In Article 33(1), the following point is inserted:
	(da) combinatorial and accumulated effects.

Or. en

Amendment 316
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 4 a (new)
Regulation (EC) No 178/2002
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*
	(4a) In Article 33, paragraph 2 is replaced by the following:
	"For the purposes of paragraph 1, the Authority shall work in close cooperation with all independent organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies."

Or. en

Justification

new word: "independent "It is not desirable that EFSA relies on non-independent organisations for its data collection activities.

Amendment 317
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 4 b (new)
Regulation (EC) No 178/2002
Article 36 – paragraph 1

Text proposed by the Commission	*Amendment*
	(4b) In Article 36, paragraph 1 is replaced by the following:
	"1. The Authority shall promote the European networking of independent organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information,

the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission."

Or. en

Justification

add "independent "It is not desirable that EFSA coordinate a network where non-independent organisations could be affiliated.

Amendment 318
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 4 c (new)
Regulation (EC) No 178/2002
Article 36 – paragraph 2

Text proposed by the Commission	*Amendment*
	(4c) In Article 36, paragraph 2 is replaced by the following:
	"2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent independent organisations and public research institutes designated in the Member States by the Commission which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific studies, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support."

Or. en

Justification

insert: independent; public research institutes; "in the MS" by the "Commission"; "scientific studies "It is desirable that EFSA has a list of public research institutes with which it may collaborate for the realisation on scientific studies, if necessary. The Commission should draw that list, rather than the Member States.

Amendment 319
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 4 d (new)
Regulation (EC) No 178/2002
Article 36 – paragraph 3

Text proposed by the Commission	*Amendment*
	(4d) In Article 36, paragraph 3 is replaced by following:
	"3. The Commission shall, after consulting the Authority, adopt delegated acts in accordance with Article 57a in order to supplement this Regulation by laying down rules establishing the criteria for inclusion of a public research institute on the list of competent independent organisations, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.
	3a. The Commission shall, after consulting the Authority, by means of implementing acts lay down implementing rules for the application of paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with Article 58(2)."

Or. en

Justification

new: a public research before institute; independent. It is desirable that EFSA has a network of public research institutes with which it may collaborate for the realisation on scientific studies, if necessary.

Amendment 320
Guillaume Balas

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

Text proposed by the Commission	*Amendment*
The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:	The Authority shall carry out its activities with a high level of transparency ***and proactively publish the information in its possession, in line with the Aarhus Convention and Regulation 1367/2006, in particular Article 4***. It shall in particular make public without delay:

Or. en

Amendment 321
Martin Häusling

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

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

Or. en

Amendment 322
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:	The Authority shall carry out its activities with a high level of transparency ***in line with the Aarhus Convention and without prejudice to Regulations (EC) No 1049/2001 and (EC) No 1367/2006 and Directive 2003/4/EC***. It shall in particular make public without delay:

Or. en

Justification

The new proposal should enhance transparency, therefore it should not limit the rights deriving from existing EU legislation and International Conventions.

Amendment 323
Pavel Poc, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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

Text proposed by the Commission	*Amendment*
The Authority shall ***carry out its activities with a*** high level of transparency. It shall in particular make public without delay:	The Authority shall ***actively disseminate the information it possesses to ensure*** high level of transparency ***in line with the Aarhus Convention and Regulation (EC) No 1367/2006***. It shall in particular make public without delay:

Or. en

Amendment 324
Martin Häusling

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

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

Or. en

Justification

There is no reason for exempting the Managing Board and the Advisory Committee from the transparency requirements on their agendas and minutes.

Amendment 325
Anja Hazekamp

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

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

Or. en

Amendment 326
Guillaume Balas

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

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

Or. en

Amendment 327
Karin Kadenbach

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

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

Or. en

Amendment 328
Karin Kadenbach

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	(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.	scientific output, including a scientific opinion, taking into account ***the overriding public interest in disclosure and the*** protection of confidential information and protection of personal data in accordance with Articles 39 to 39f.

Or. en

Amendment 329
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
(c) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, ***taking into account protection of confidential information and protection of personal data*** in accordance with ***Articles 39 to 39f.***	(c) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, in accordance with ***Regulations (EC) No 1049/2001 and (EC) No 1367/2006.***

Or. en

Amendment 330
Piernicola Pedicini, Eleonora Evi

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

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

Or. en

Justification

Scientific opinions are produced by scientific panels and scientific committee, but there are others scientific outputs produced by EFSA staff.

Amendment 331
Karin Kadenbach

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

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

Or. en

Amendment 332
Renate Sommer

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

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

Text proposed by the Commission	*Amendment*
	(ha) information on the name of the applicant and the title of the application;

Or. en

Amendment 333
Lukas Mandl

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.	(i) ***the general*** advice provided by the Authority to potential applicants at pre-submission phase pursuant to Article 32a and 32c.

Or. de

Justification

In order to support the competitiveness and capacity for innovation of SMEs, it is essential for them to receive advice before they lodge an application. The crucial source of costs is often the studies required for the authorisation process. The advice should therefore also cover these aspects in order to avoid unnecessary or misdirected studies.

Amendment 334
Renate Sommer

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

Text proposed by the Commission	*Amendment*
Those items referred to in the first	Those items referred to in the first

subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to ***download, print and*** search through in an electronic format.***"***,	subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible ***subject to clear undertakings recorded electronically by those accessing it and subject to measures and penalties which are effective, proportionate and dissuasive against any non-permitted use, such as commercial***. The relevant items shall be available to search through in an electronic format. ***The dedicated section of the Authority`s website will include all necessary measures to protect against the use by those accessing it of items referred to in points (c), (d) and (i) of the first subparagraph***, ***for commercial purposes. These measures will focus on the commercial use of documents (their submission) and use of the information contained therein (without being submitted as such). Such protective measures will be designed to protect effectively against commercial use both within the Union and in third-countries.***

Or. en

Justification

The Commission proposal is not sufficiently robust it its protection against commercial use of disclosed information. It is possible to improve transparency and sustainability of the EU risk assessment process without facilitating misuse by commercial parties of information for their own commercial ends. Such unfair competition would be inconsistent with recent EU policy to create "A renewed EU Industrial Policy Strategy", COM(2017) 479 final .

Amendment 335
Fredrick Federley, Ulrike Müller, Jan Huitema

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

Text proposed by the Commission	*Amendment*
Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.",	Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print ***watermarked for tractability*** and search through in an electronic format. ***The dedicated section of the Authority's website will include necessary measures to protect against non-permitted use, such as for commercial purposes. Measures and penalties which are effective and proportionate should be introduced in cases of non-permitted use of documents. Protective measures will be designed to protect effectively against commercial use both within in the Union and in third-countries.***"

Or. en

Justification

The disclosure of information should ensure easy access to information whilst ensuring that the data provider is protected against non-permitted use of this data by competitors. Sanctions for misuse should also be enforceable.

Amendment 336
Martin Häusling

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

Text proposed by the Commission	*Amendment*
Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly	Those items referred to in the first subparagraph shall be made public ***in a structured way*** on a dedicated section of the Authority's website. That section shall

available ***and*** easily accessible. The relevant items shall be available to download, print and search through in an electronic format.”,	be publicly available**,** easily accessible**,** ***and regularly updated***. The relevant items shall be available to download, print and search through in an electronic format**,** ***which is “machine-readable***.”

Or. en

Amendment 337
Pavel Poc, Nicola Caputo, Jytte Guteland, Daciana Octavia Sârbu, Karin Kadenbach

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

Text proposed by the Commission	*Amendment*
Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority’s website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.	Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority’s website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic ***and as appropriate machine-readable*** format.

Or. en

Amendment 338
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
The disclosure of the information mentioned in paragraph (1)(c) to the public shall ***be without prejudice***:	The disclosure of the information mentioned in paragraph (1)(c) to the public shall ***take into account the Union’s interest to promote access to environmental information in accordance***

with Regulation (EC) No 1367/2002 on the application of the provisions of the Aarhus Convention, in particular when information relates to emissions in the environment.

Or. en

Amendment 339
Fredrick Federley, Ulrike Müller, Jan Huitema

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

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

Or. en

Justification

For readability: (c) authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests, (d) the information on which its scientific outputs, including scientific opinions are based, (i) advice provided by the Authority to potential applicants at pre-submission phase pursuant to Article 32a and 32c.

Amendment 340
Renate Sommer

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

Text proposed by the Commission	*Amendment*
The disclosure of the information mentioned in paragraph (1)(c) to the public	The disclosure of the information mentioned in paragraph (1)(c)***, (d) and (i)***

shall be without prejudice:	to the public shall be without prejudice:

Or. en

Amendment 341
Lukas Mandl

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

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

Or. de

Amendment 342
Martin Häusling

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

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

Or. en

Justification

There is no reason to put the whole disclosure requirements with reservation as regards intellectual property rights (IPR). Moreover, there is no need to refer to IPR at this point: 'Hard IPRs', such as patents, copyrights or trademarks will already be protected under Article 38.1a (b). 'Soft IPRs' (trade secrets) will be covered by Article 39(2).

Amendment 343
Guillaume Balas

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

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

Or. en

Amendment 344
Piernicola Pedicini, Eleonora Evi

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

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

Or. en

Justification

Article 39(2) is meant to be an exhaustive list of information which may be claimed confidential because commercially sensitive. Thus, leaving Article 38(1a)a in the text may lead to misinterpretation.

Amendment 345
Anja Hazekamp

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

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

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

Or. en

Amendment 346
Lukas Mandl

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

Text proposed by the Commission	*Amendment*
(a) to any intellectual property right which may exist ***over*** documents or their content; and,	(a) to any intellectual property right***, and the protection of business secrets as referred to in Directive (EU) 2016/943,*** which may exist ***in relation to*** documents or their content; and,

Or. de

Justification

Business secrets as referred to in Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure must not be allowed to enter the public domain. The intellectual property of SMEs, in particular, is often inadequately protected. Business secrets as referred to in Directive (EU) 2016/943 should therefore be protected as fully as possible, both in connection with the publication of studies and in the provision of advice.

Amendment 347
Anja Hazekamp

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

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

Or. en

Amendment 348
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point b
Regulation (EC) No 178/2002
Article 38 – paragraph 1 a – subparagraph 1 – 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 ***giving the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant*** ('data exclusivity rules').

Or. en

Amendment 349
Renate Sommer

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

Text proposed by the Commission	*Amendment*
The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the	The disclosure to the public of the information mentioned in paragraph (1)(c)***, (d) and (i)*** shall not be considered as an explicit or implicit permission or license

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.	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. ***Member States shall put in place all necessary measures to address 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, such as commercial use.***

Or. en

Justification

See above.

Amendment 350
Fredrick Federley, Ulrike Müller, Jan Huitema

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

Text proposed by the Commission	*Amendment*
The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third parties shall not engage the responsibility of the European Union.	The disclosure to the public of the information mentioned in paragraph (1)(c)***, (d) and (i)*** 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. ***Member States shall put in place necessary measures and penalties to address non-permitted use by those accessing the dedicated section of the Authority's website. These measures and penalties shall be effective and proportionate.***

Or. en

Justification

For readability: (c) authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests, (d) the information on which its scientific outputs, including scientific opinions are based, (i) advice provided by the Authority to potential applicants at pre-submission phase pursuant to Article 32a and 32c.

Amendment 351
Martin Häusling

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

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

Or. en

Justification

It must be possible for independent scientists to use relevant data or reproduce relevant studies. To be 100% safe, it could be discussed (EMA example) to apply a watermark to the published information to emphasise the prohibition of its use for commercial purposes.

Amendment 352
Renate Sommer

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

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

Text proposed by the Commission	*Amendment*
	1b. By [30 months after the entry into force] Member States shall submit to the Commission a report, on the basis of experience gained with the application of this Regulation, on any breach of measures and penalties and their effectiveness.
	On this basis, by [6 months later] the Commission shall submit to the European Parliament and the Council a report on the extent to which this Regulation requires amending.

Or. en

Justification

Feedback should be provided on the effectiveness of measures and penalties within a relatively short period so that any necessary amendments to the system of disclosure and confidential business information ("CBI") protection can be amended as appropriate.

Amendment 353
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(ca) The following paragraph is added:
	"3a. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information justification and to Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006."

Or. en

Amendment 354
Renate Sommer

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

Text proposed by the Commission	*Amendment*
	(5a) The following Article 38a is inserted:
	"Article 38a
	Following the EFSA guidelines on consultations that aim at increasing the transparency of the risk assessment the authority follows a three-step-procedure. First it publishes a draft scientific opinion.
	At the same time of the publication of the draft scientific opinion the Authority makes public the following information:
	(a) scientific date, studies and other information supporting applications for authorization 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 full application document taking into account protection of confidential information and protection of personal data in accordance with Articles 39 to 39f.
	(c) 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 Article 39 to 39f.

(d) information concerning the consultation sessions with applicants conducted by the Authority pursuant to Article 32a and 32c prior to their applications.

After the publication of its draft opinion the Authority shall, within six weeks, consult stakeholders and the public regarding the studies supporting applications for authorisation in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application for authorisation. The results of the consultation including comments provided by stakeholders shall be made public in a technical report that will be attached to the final scientific opinion of the Authority. In its final scientific opinion the authority shall indicate how the comments made by stakeholders were addressed."

Or. en

Justification

The author introduces a three-step-approach in order to improve transparency of the risk assessment procedure based on the guidelines on EFSA Consultations that the authority already uses for substances that are not subject to an official application procedure (e.g. aspartame, BPA, caffeine). Using this method provides a good balance between the need to protect commercial interests of applicants and the need to increase transparency, visibility and openness of the scientific risk assessment towards stakeholders.

Amendment 355
Guillaume Balas

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

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

Or. en

Amendment 356
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 38, the Authority shall not make public information for which confidential treatment has been requested under the conditions laid down in this Article.	1. By way of derogation from Article 38 ***and without prejudice to Regulation (EC) No 1049/2001***, the Authority shall not make public information for which confidential treatment has been requested under the conditions laid down in this Article.

Or. en

Amendment 357
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 38, the Authority shall not make public information for which confidential treatment has been ***requested*** under the conditions laid down in this Article.	1. By way of derogation from Article 38, the Authority shall not make public information for which confidential treatment has been ***granted*** under the conditions laid down in this Article.

Or. en

Amendment 358
Guillaume Balas

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

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

Or. en

Amendment 359
Martin Häusling

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

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

Or. en

Amendment 360
Pavel Poc, Jytte Guteland, Nicola Caputo, Martin Häusling, Daciana Octavia Sârbu, Karin Kadenbach

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

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

Or. en

Amendment 361
Renate Sommer

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

Text proposed by the Commission	*Amendment*
2. The Authority ***may only*** accept to provide confidential treatment in relation to the following information, the disclosure of which ***may be*** deemed***, upon verifiable justification,*** to significantly harm the interests concerned:	2. The Authority ***shall*** accept to provide confidential treatment in relation to the following information, the disclosure of which ***is*** deemed to significantly harm the interests concerned ***unless this is proven not to be the case***:

Or. en

Justification

The Commission proposal reverses the burden proof for certain key pieces of information

which have long been acknowledged to constitute confidential business information ("CBI"), in EU sectoral legislation falling within Union food law. It does so without providing an explanation of this significant change. This unjustified reversal should be corrected.

Amendment 362
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
2. The Authority may only accept to provide confidential treatment in relation to the following information, the disclosure of which ***may be deemed***, upon verifiable justification, ***to*** significantly harm the interests concerned:	2. The Authority may only accept to provide confidential treatment in relation to the following information, the disclosure of which ***it concludes***, upon verifiable justification, ***would*** significantly harm the interests concerned:

Or. en

Amendment 363
Anja Hazekamp

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

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

Or. en

Amendment 364
Guillaume Balas

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 with verifiable justification that such method does not entail information about emissions in the environment and about impacts on health and environment***;

Or. en

Amendment 365
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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 366
Martin Häusling

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***, except when relevant to understanding the potential effects on health and the environment***;

Or. en

Amendment 367
Anja Hazekamp

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;

Or. en

Amendment 368
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
(2) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;	***deleted***

Or. en

Amendment 369
Anja Hazekamp

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,	***deleted***

Or. en

Amendment 370
Renate Sommer

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 ***and trade secrets*** of the applicant ***in the meaning of Article 2 (1) of Directive (EU)***

2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

Or. en

Justification

Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure applies to trade secrets and should be fully applied in the context of the decision for keeping certain information eligible for confidential treatment.

Amendment 371
Guillaume Balas

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

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

Or. en

Amendment 372
Anja Hazekamp

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	***deleted***

subject matter of the request for a scientific output, including a scientific opinion.

Or. en

Amendment 373
Martin Häusling

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 the environment***.

Or. en

Amendment 374
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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 the environment***.

Or. en

Amendment 375
Martin Häusling

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. These derogations shall be construed restrictively.

Or. en

Amendment 376
Renate Sommer

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 not preclude a request for confidentiality being submitted for other information which does not benefit from presumption of confidentiality in paragraph 2 of this Article and*** shall be without prejudice to any specific Union food law.

Or. en

Justification

The Commission proposal reduces the information for which confidential treatment may be requested to an exhaustive list of information. The effect is that it no longer allows decisions on disclosure taken by EFSA to consider the individual circumstances of each case. This contrasts sharply with Regulation (EC) 1049/2001 regarding public access to European Parliament, Council and Commission documents - which also applies to documents held by EFSA.

Amendment 377
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
4. ***Notwithstanding paragraphs 2 and 3,*** the following information ***shall nevertheless be made public***:	4. ***The Authority shall not provide confidential treatment to*** the following information:

Or. en

Amendment 378
Guillaume Balas

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 ***there is an overriding*** public ***interest in disclosure***,

Or. en

Amendment 379
Karin Kadenbach

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) ***Information relating to human*** health, animal health or the environment, ***including*** emergency situations, ***or***

Or. en

Amendment 380
Anja Hazekamp

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) ***Information that may be deemed*** essential to protect public health, ***animal*** health or the environment, such as in emergency situations

Or. en

Amendment 381
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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	(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***,	information referred to paragraphs 2 and 3; ***or***,

Or. en

Amendment 382
Piernicola Pedicini, Eleonora Evi

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 ***timely*** action is essential to protect public health, animal health or the environment, the Authority ***shall*** disclose the information referred to paragraphs 2 and 3; and,

Or. en

Amendment 383
Anja Hazekamp

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 essential to protect public health, animal health or the environment, ***including*** in emergency situations, the Authority ***will*** disclose ***any*** information ***necessary***;

Or. en

Amendment 384
Martin Häusling

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

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

Or. en

Justification

It is not acceptable that information relevant for health or environmental protection is only disclosed when an actual danger has already appeared. The current rules in both the GMO ("If circumstances so require in order to protect human health, animal health or the environment") and in the Pesticides Regulation ("Where there is an overriding public interest in disclosure") go much further than restricting the safeguard to emergency situations only. The new proposal would thus lead to a decreased level of transparency, which is not acceptable.

Amendment 385
Anja Hazekamp

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 foreseeable ***(human and animal)*** health effects ***and/ or environmental impacts.***

Or. en

Amendment 386
Guillaume Balas

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 foreseeable effects ***on human health, biodiversity or the environment***.

Or. en

Amendment 387
Martin Häusling

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 foreseeable ***human*** health***, animal health, or environmental*** effects.

Or. en

Justification

The legislation covered by this proposal does not relate to human health only, but also to legislation in the fields of pesticides, GMOs or animal health.

Amendment 388
Karin Kadenbach

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

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

Or. en

Amendment 389
Piernicola Pedicini, Eleonora Evi

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

Text proposed by the Commission	*Amendment*
	(ba) any information for which there is an overriding public interest in disclosure as per Article 4(2) of Regulation 1049/2001 and Article 6 of Regulation 1367/2006, in particular where the information relates to emissions into the environment.

Or. en

Amendment 390
Martin Häusling

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

Regulation (EC) No 178/2002
Article 39 – paragraph 4 – point b a (new)

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

Or. en

Justification

This provision is, already today, included in the pesticides Regulation, and should not be abolished.

Amendment 391
Anja Hazekamp

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

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

Or. en

Amendment 392
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	(ba) information relating to potential emissions in the environment.

Or. en

Amendment 393
Martin Häusling

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

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

Or. en

Amendment 394
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
1. When submitting an application for an authorisation, supporting scientific data and other supplementary information in accordance with Union food law, the applicant may request certain parts of the information submitted to be kept confidential in accordance with paragraphs 2 and 3 of Article 39. This request shall be accompanied by verifiable justification demonstrating how making public the information concerned significantly harms the interests concerned in accordance with paragraphs 2 and 3 of Article 39.	***deleted***

Or. en

Amendment 395
Renate Sommer

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

Text proposed by the Commission	*Amendment*
1. When submitting an application for an authorisation, supporting scientific data and other supplementary information in accordance with Union food law, the applicant may request certain parts of the information submitted to be kept confidential in accordance with paragraphs 2 and 3 of Article 39. ***This*** request shall be accompanied by verifiable ***justification*** demonstrating how making public the information concerned ***significantly harms*** the interests concerned ***in accordance with paragraphs 2 and 3 of Article 39***.	1. When submitting an application for an authorisation, supporting scientific data and other supplementary information in accordance with Union food law, the applicant may request certain parts of the information submitted to be kept confidential in accordance with paragraphs 2 and 3 of Article 39. ***A*** request ***pursuant to paragraph 3 of Article 39*** shall be accompanied by ***a reasoned statement, with appropriate*** verifiable ***evidence,*** demonstrating how making public the information concerned ***might undermine*** the interests concerned.

Or. en

Amendment 396
Martin Häusling

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

Text proposed by the Commission	*Amendment*
2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall be without the information the applicant ***deems*** confidential in accordance with paragraphs 2 and 3 of Article 39. The	2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall be without the information the applicant ***requests*** confidential ***treatment for*** in accordance with paragraphs 2 and 3

confidential version shall contain all information submitted, including information the applicant ***deems*** confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the ***grounds*** on the basis of which confidentiality is requested for the different pieces of information.

of Article 39***. This information shall be garbled by black bars***. The confidential version shall contain all information submitted, including information the applicant ***considers*** confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the ***verifiable justifications*** on the basis of which confidentiality is requested for ***each of*** the different pieces of information.

Or. en

Justification

It is important to state how the information the applicant considers to be confidential must be treated. Using black bars is an easy and acknowledged way and permits to assess at least the amount of information which is to be kept confidential.

Amendment 397
Guillaume Balas

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

Text proposed by the Commission

2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall ***be without*** the information the applicant ***deems*** confidential in accordance with paragraphs 2 and 3 of Article 39. The confidential version shall contain all information submitted, including information the applicant ***deems*** confidential. Information requested to be treated as confidential in the confidential

Amendment

2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall ***redact with back bars*** the information the applicant ***requests the*** confidential ***treatment of,*** in accordance with paragraphs 2 and 3 of Article 39. The confidential version shall contain all information submitted, including information the applicant ***considers*** confidential. Information requested to be

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

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

Or. en

Amendment 398
Anja Hazekamp

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

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

Or. en

Justification

In order to have a continuity and understanding of the rest of the text, only the confidential

parts shall be hidden.

Amendment 399
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	2a. The Authority shall keep a record of requests for confidentiality received, and annually publish statistics about the amounts and categories of information for which confidentiality has been requested. It shall specify amounts and categories of information for which confidentiality request have been granted as well as for which it has been rejected, including the grounds on the basis of which confidentiality has been granted or rejected.

Or. en

Amendment 400
Fredrick Federley, Ulrike Müller, Jan Huitema

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	(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***

from the date on which it was notified of the Authority's position.	***review to the EFSA Board of Appeal*** within ***four*** weeks from the date on which it was notified of the Authority's position. ***The applicant may provide written notice to the Authority that he wishes to request a re-examination of the opinion to the EFSA Board of Appeal. In that case the applicant shall forward to the Authority the detailed grounds for the request within 60 days after receipt of the opinion. Within 60 days after receipt of the grounds for the request, the EFSA Board of Appeal shall re-examine its opinion.***

Or. en

Justification

Both EMA and EFSA has a Board of Appeal of some sort. This is to provide the applicant the possibility for a re-examination of the opinion. The Commission should, by means of a delegated act, set up this same possibility in EFSA.

Amendment 401
Renate Sommer

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) ***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 draft scientific opinion in line with Article 38. 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. en

Justification

Scientific data and studies and any other information supporting applications should be made public only once the Authority publishes its draft scientific opinion in accordance with Article 38. Otherwise, there is a risk that competitors gain access to information about innovative product ideas or manufacturing processes. Moreover, there would be the danger of political interference in the risk assessment process. If a company withdraws its application there is no need to publish all the information.

Amendment 402
Christofer Fjellner

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 ***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. en

Amendment 403
Guillaume Balas

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).

Or. en

Amendment 404
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 405
Anja Hazekamp

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*
	(ea) In case the Authority considers that the applicant misuses of the confidentiality claims, a proportionate, effective and dissuasive fine maybe charged for the additional administrative burden creating by respective application.

Or. en

Amendment 406
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice of the European Union, under the conditions laid down in Articles 263 and 278 of the Treaty respectively.	***deleted***

Or. en

Amendment 407
Fredrick Federley, Ulrike Müller, Jan Huitema

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

Text proposed by the Commission	*Amendment*
Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice of the European Union***,*** under the conditions laid down in	Decisions taken by the Authority pursuant to this Article may be subject to an action before the ***Authority Board of Appeal, which will be established by means of***

Articles 263 ***and 278*** of the Treaty ***respectively***.	***delegated acts. Those delegated acts shall be adopted in accordance with Article 57a of this Regulation. A submission of an appeal pursuant to this paragraph shall have suspensive effect. The applicant may provide written notice to the Authority that he wishes to request a re-examination of the opinion to the EFSA Board of Appeal. In that case the applicant shall forward to the Authority the detailed grounds for the request within 60 days after receipt of the opinion. Within 60 days after receipt of the grounds for the request, the EFSA Board of Appeal shall re-examine its opinion. In case of a contesting decision taken by the EFSA Board of appeal, a case may be brought before the*** Court of Justice of the European Union under the conditions laid down in Articles 263 of the Treaty.

Or. en

Justification

Both EMA and EFSA has a Board of Appeal of some sort. This is to provide the applicant the possibility for a re-examination of the opinion. The Commission should, by means of a delegated act, set up this same possibility in EFSA. This will render the system more efficient than waiting for a decision by the CoJ.

Amendment 408
Martin Häusling

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

Text proposed by the Commission	*Amendment*
Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice of the European Union, under the conditions laid down in Articles 263 and 278 of the Treaty respectively.	Decisions taken by the Authority pursuant to this Article may be subject to an action ***of any natural or legal person*** before the Court of Justice of the European Union, under the conditions laid down in Articles 263 and 278 of the Treaty respectively.

Or. en

Justification

Any decisions might be appealed before the ECJ, both by companies, as well as by any natural person with regard to EFSA's decision on confidentiality requests.

Amendment 409
Guillaume Balas

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

Text proposed by the Commission	*Amendment*
Decisions taken by the Authority ***pursuant to this Article may be subject to an action before the Court of Justice of the European Union, under the conditions laid down in Articles 263 and 278 of the Treaty respectively***.	The Authority ***may charge a fine for the unnecessary burden created by abusive confidentiality claims from the applicant. The fine should be effective, proportionate and dissuasive***.

Or. en

Amendment 410
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential ***may*** nevertheless be made public in accordance with paragraph 4(b) of Article 39. Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply mutatis	Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential ***shall*** nevertheless be made public in accordance with paragraph 4(b) ***and (c)*** of Article 39. Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply

mutandis.	mutatis mutandis.

Or. en

Amendment 411
Fredrick Federley, Ulrike Müller, Jan Huitema

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 has become definitive***, except for when access to information is requested in accordance with directive 2003/4/EC or national law on access to documents***. 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***, except for when access to information is requested in accordance with directive 2003/4/EC or national law on access to documents***.

Or. en

Justification

Clarification needs to be made regarding when EFSA:s obligation to confidentiality decision applies, notably only when the authorities proactively publish information. When access to information is requested, an individual assessment must be made, even if the institution previously have decided on confidentiality.

Amendment 412
Anja Hazekamp

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 has become definitive***, unless it concerns information that may be deemed essential to protect public health, animal health or it is clear that such information relates to emissions in the environment***. 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. en

Amendment 413
Renate Sommer

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	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.	confidentiality request has been taken by the Authority and ***its draft scientific opinion has been published in line with Article 38***. 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. en

Amendment 414
Fredrick Federley, Ulrike Müller, Jan Huitema

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. The Authority shall not ***publish any*** information***, confidential or non-confidential, should an applicant decide to withdraw its application***.

Or. en

Amendment 415
Anja Hazekamp

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 ***and observers*** in meetings of the Scientific Committee and the Scientific Panels***,*** their Working Groups ***and any other ad hoc Group meeting on the subject.***

Or. en

Amendment 416
Guillaume Balas

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 417
Martin Häusling

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

Justification

Including persons involved in obtaining toxicological information would enlarge the exemption enormously. In particular, it must be clear that the name of authors of the toxicological studies can never be kept confidential. There is no reason to include them; on the contrary, in order to foster excellent research it is necessary to identify authors of studies.

Amendment 418
Renate Sommer

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

Text proposed by the Commission	*Amendment*
	2a. The standard data formats and data packages shall only apply to data generated after adoption of the implementing acts in accordance with paragraph 2(b) of this Article.

Or. en

Amendment 419
Anja Hazekamp

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

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

[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

Justification

Adding the phrase might be interpreted as the rest of the Regulation 1367/2006 shall not apply. This would be contrary to the spirit of the proposal, of that Regulation, of our International Obligation and of the Courts rulings on access to documents, such as C-280/11, Council v. Access Info Europa.par.30)

Amendment 420
Anja Hazekamp

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) Article 41 ***is amended as follows:***
	1. The Authority shall ensure wide access to the documents which it possesses, in accordance with Regulations (EC) No 1049/2001 and No 1367/2006 of the European Parliament and of the Council.
	2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1***, in accordance with the general principles and conditions governing the right of access to the Community institutions' documents.***
	3. The proactive disclosure mechanisms set out in Articles 38 and 39 are without prejudice to the rights to access conferred on the public by Regulations (EC) 1049/2001 and No 1367/2006 of the European Parliament and of the Council.

Or. en

Amendment 421
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(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:
Where environmental information is concerned, Articles 6 and Article 7 of	***"The Authority shall ensure wide access upon request to the documents which it***

Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall ***also*** apply.***;***	***possesses. Regulation 1049/2001 of the European Parliament and the Council and 1367/2006*** of the European Parliament and of the Council shall apply.***”***
[39] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).	[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 422
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
Where environmental information is concerned, Articles 6 and Article 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall also apply.;	***deleted***
[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 423
Guillaume Balas

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

Text proposed by the Commission	*Amendment*
Where environmental information is concerned, Articles 6 and Article 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall also apply.***;***	***For the purpose of ensuring an efficient access to documents that it possesses, the Authority shall answer requests to access information.*** 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. ***Upon request, information found confidential under the proactive disclosure procedures set out in Article 38 and 39 shall be disclosed , if the conditions for disclosure are met under Regulation (EC) No 1367/2006 and Regulation 1949/2001.***
[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 424
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
Where environmental information is concerned, ***Articles 6 and Article 7 of*** Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall also apply.;	Where environmental information is concerned, Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall also apply. ***Articles 38 to 39d of this Regulation shall apply without prejudice to the application of Regulation 1049/2001 and Regulation 1367/2006.***;
[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 425
Fredrick Federley, Ulrike Müller, Jan Huitema

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

Text proposed by the Commission	*Amendment*
Where environmental information is concerned, Articles 6 and Article 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall also apply.;	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]***, as well as the provisions of the Arhus convention,*** shall also apply.;
[39] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation	[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).	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 426
Martin Häusling

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 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) at an early stage of the risk management process, the draft risk management measures under consideration;
	(b) the agendas and the detailed minutes of meetings of the Member States working groups in which the risk management measures are discussed; and
	(c) the agendas and detailed summary reports of the meetings of the regulatory committees where the risk management measures are discussed and put to a vote, including the results of votes in the committees in which regulatory proposals are adopted, and an explanation of the votes by individual Member States.

2. The 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 public health, animal health and the environment, on the society and on food manufacturers as indicated by the impact assessment, and

(d) the results of the public consultation pursuant to Article 9.';

Or. en

Justification

Based on amendment 48 by the Rapporteur.

Amendment 427
Piernicola Pedicini, Eleonora Evi

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 Commission shall carry out its activities with a high level of transparency. It shall in particular make public without delay which other factors legitimate to the matter under consideration according to Article 6(3) of Regulation (EC) No 178/2002 were taken

into account in analysing the opinion of the Authority and its application of the precautionary principle according to Article 7(1) of Regulation (EC) No 178/2002.

2. The Member States shall carry out their activities with a high level of transparency. They shall in particular make public without delay:

(a) agendas and minutes of the meetings of the Council working groups in which the risk management measures are discussed;

(b) agendas and minutes of the meetings of the Standing Committees, included but not limited to the Appeal Committee, as well as the votes for each Member state.

Those items referred to in the first and second subparagraph shall be made public on a dedicated section of the Commission's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.

Or. en

Justification

Risk managers should be accountable for their decisions.

Amendment 428
Pilar Ayuso

Proposal for a regulation
Article 1 – paragraph 1 – point 9 a (new)
Regulation (EC) No 178/2002
Article 50 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Article 50 is amended as follows:

Paragraph 1a is inserted:

Article 50

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network.

1a. The Commission shall, by delegated act, amend Regulation 16/2011 to develop a harmonised food alert network management system between the Commission and the Member States

Or. es

Justification

Regulation (EC) No 178/2002 (Articles 50 to 54), establishes the RASFF, together with its basic provisions, scope and operation. Weaknesses were subsequently identified, requiring rectification through the adoption of Regulation (EU) No 16/2011 which did not include harmonised procedures to be followed by all MS or the necessary enhancement of the Commission's powers for dealing with alerts. A joint, compulsory and enhanced procedure for managing food alerts is necessary.

Amendment 429
Martin Häusling

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 178/2002
Article 57 a – paragraph 2

Text proposed by the Commission	*Amendment*
2. The powers to adopt delegated acts referred to in Article 8(c) shall be conferred upon the Commission for ***an indeterminate*** period of ***time*** from [date of entry into force of this Regulation].	2. The powers to adopt delegated acts referred to in Article 8(c) ***and 32c*** shall be conferred upon the Commission for ***a*** period of ***five years*** from [date of entry into force of this Regulation].

Or. en

Amendment 430
Martin Häusling

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

Or. en

Justification

Based on amendment 49 by the Rapporteur.

Amendment 431
Michel Dantin, Angélique Delahaye

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

Text proposed by the Commission	*Amendment*
2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall assess the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.	2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall assess the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. That evaluation shall address the possible need to modify the mandate of the Authority***, especially when it comes to coordinating and dovetailing the Agency's activities more closely with those of the competent bodies in the Member States and other Union agencies*** and the financial implications of any such modification.

Or. fr

Amendment 432
Pavel Poc, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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 location. 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. en

Amendment 433
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall ***assess*** the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.	2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall ***commission an independent external evaluation of*** the Authority's ***achievements and*** performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines ***and the Management Board's work programme***. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.

Or. en

Justification

The current Reg. foresees and independent external evaluation. This provision should remain in order to strengthen transparency and accountability of the process.

Amendment 434
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu, Karin Kadenbach

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. en

Amendment 435
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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. en

Justification

This paragraph would give undue power to the Commission.

Amendment 436
Anja Hazekamp

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**.**	3. Where the ***Management Board*** considers that the continuation of the Authority is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose ***to the Commission to initiate the legislative process so*** that the relevant provisions of this Regulation be amended accordingly or repealed

Or. en

Amendment 437
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
4. The ***Commission*** shall report to the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public**.**	4. The ***external evaluator*** shall report to ***the Commission,*** the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public

Or. en

Amendment 438
Martin Häusling

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

Text proposed by the Commission	*Amendment*
4. The ***Commission*** shall ***report to*** the European Parliament, ***the Council and the***	4. The ***evaluations and recommendations referred to in***

Management Board on the evaluation findings. The findings of the evaluation shall be made public.

paragraphs 1 and 2 shall ***be forwarded to the Council and*** the European Parliament, ***and*** be made public.

Or. en

Amendment 439
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(2a) In Article 24, the following paragraph is inserted:
	"3a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, including Article 25 below, and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation 1367/2006."

Or. en

Amendment 440
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(3) Article 25 is replaced by the following:	(3) Article 25 is replaced by the following:
"Article 25	"Article 25

Confidentiality	Confidentiality
1. In accordance with the conditions and the procedures laid down in Article 39 to 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*, and this article,	1. In accordance with the conditions and the procedures laid down in Article 39 to 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*, and this article,
(a) the notifier/applicant may request certain information submitted under this Directive to be kept confidential, accompanied by verifiable justification; and,	(a) the notifier/applicant may request certain information submitted under this Directive to be kept confidential, accompanied by verifiable justification; and,
(b) the competent authority shall assess the confidentiality request submitted by the notifier/applicant.	(b) the competent authority shall assess the confidentiality request submitted by the notifier/applicant.
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***:	2. ***In no case may the following information when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept*** confidential:
(a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,	***– general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;***
(b) breeding patterns and strategies.";	***– methods and plans for monitoring of the GMO or GMOs and for emergency response;***
	– environmental risk assessment."

Or. en

Justification

Paragraph 2 simply reinstates the current wording of Directive 2001/18/EC. If the aim of the proposal is to strengthen transparency, then, instead of enlarging the list of information which can be kept confidential, the current provisions relating to information that can never be kept confidential must be kept.

Amendment 441
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
(a) the notifier/applicant may request certain information submitted under this Directive to be kept confidential, accompanied by verifiable justification; and,	(a) the notifier/applicant may request certain information***, the disclosure of which could harm his/her competitive position and*** submitted under this Directive to be kept confidential, accompanied by verifiable justification; and,

Or. en

Amendment 442
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	(ba) 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

Amendment 443
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, which shall apply mutatis mutandis, confidential treatment may be accepted with respect to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the 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 444
Guillaume Balas

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

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

interests concerned:

(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 445
Anja Hazekamp

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

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

Justification

Dir. 2001/18 had foreseen that some data, should not be deemed confidential. Not including that same list, not only does it put in doubt the pursuit of high level of transparency, but will also create legal uncertainty and administrative burden to both applicants and the EC.

Amendment 446
Anja Hazekamp

Proposal for a regulation
Article 2 – paragraph 1 – point 3
Directive 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. en

Amendment 447
Anja Hazekamp

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. en

Amendment 448
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	The provisions on active dissemination

	laid down in Article 24 and 25 of this Directive, and Article 38 and 39 of Regulation 178/2002, are without prejudice to the right of access to documents upon request set in Regulation 1049/2001 and 1367/2006.

Or. en

Amendment 449
Renate Sommer

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 ***draft*** 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. en

Amendment 450
Anja Hazekamp

Proposal for a regulation
Article 3 – paragraph 1 – point 1 – point b
Regulation (EC) No 1829/2003
Article 5 – paragraph 3 – point e

Text proposed by the Commission	*Amendment*
(l) an identification of the parts of the	(l) an identification of the parts of the

application and any other supplementary information that the applicant requests to be kept confidential, accompanied by verifiable justification, pursuant to Articles 30 of this Regulation and Article 39 of Regulation (EC) No 178/2002; ***;***	application and any other supplementary information that the applicant requests to be kept confidential, accompanied by verifiable justification ***on how the disclosure of those would have his/hers competitive advantage***, pursuant to Articles 30 of this Regulation and Article 39 of Regulation (EC) No 178/2002;

Or. en

Amendment 451
Renate Sommer

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 its scientific opinions and opinions from the competent authorities referred to in Article 4 of Directive 2001/18/EC, ***at the same time as its draft 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. en

Amendment 452
Martin Häusling

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, ***monitoring reports*** 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.

Or. en

Justification

This provision is taken from the current Regulation 1829/2003, Article 29.

Amendment 453
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(9a) In Article 29, the following paragraph 1a is inserted:
	"1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, including Article 30 below, and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation 1367/2006."

Or. en

Amendment 454
Martin Häusling

Proposal for a regulation
Article 3 – paragraph 1 – point 10
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:
"Article 30	"Article 30
Confidentiality	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,	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,	(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.	(b) the Authority shall assess the confidentiality request submitted by the applicant.
2. ***In addition to Article 39(2) and pursuant to Article 39(3) of Regulation (EC) No 178/2002, the Authority may also accept to provide*** confidential ***treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned***:	2. ***Information relating to the following shall not be considered*** confidential:
(a) ***DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,***	(a) ***name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;***
(b) ***breeding patterns and strategies.***	(b) ***general description of the GMO and the name and address of the authorisation-holder;***
	(ba) physico-chemical and biological

	characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);
	(bb) 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;
	(bc) 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;
	(bd) 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);
	(bf) information on waste treatment and emergency response.
3. 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.”	3. 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.”

Or. en

Justification

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

Amendment 455
Anja Hazekamp

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

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

Or. en

Amendment 456
Guillaume Balas

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

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

Amendment 457
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
2. ***In addition to Article 39(2) and pursuant to Article 39(3) of Regulation (EC) No 178/2002, the Authority may also accept to provide confidential treatment*** to the following information***, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:***	2. ***Information relating*** to the following ***shall not be considered confidential:***
(a) ***DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,***	(a) ***name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;***
(b) ***breeding patterns and strategies.***	(b) ***general description of the GMO and the name and address of the authorisation-holder;***
	(c) physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and15(1);
	(d) effects of the GMO, food or feed referred to in Articles 3(1) and15(1) on human and animal health and on the environment;
	(e) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;
	(f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles

3(1) and 15(1); (g) information ***on waste treatment and emergency response.***

Or. en

Justification

The current list provides for certainty, predictability and transparency both for assessors and applicants. It should be expanded instead of being deleted

Amendment 458
Anja Hazekamp

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

Amendment 459
Anja Hazekamp

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

Amendment 460
Anja Hazekamp

Proposal for a regulation
Article 3 – paragraph 1 – point 10
Regulation (EC) 1829/2003
Article 30 – paragraph 2 – point b

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

Or. en

Amendment 461
Anja Hazekamp

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

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

Or. en

Amendment 462
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

Proposal for a regulation
Article 3 – paragraph 1 – point 10
Regulation (EC) No 1829/2003
Article 30 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The provisions on active dissemination laid down in Article 29 and 30 of this Directive, and Article 38 and 39

of Regulation 178/2002, are without prejudice to the right of access to documents upon request set in Regulation 1049/2001 and 1367/2006.

Or. en

Amendment 463
Renate Sommer

Proposal for a regulation
Article 4 – paragraph 1 – point 1 – point b
Regulation (EC) 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 the Authority publishes its draft scientific opinion,*** in accordance with Article 18.;

Or. en

Amendment 464
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(1a) In Article 17, the following paragraph is inserted:
	"2a. The obligation to proactively disseminate information set out in this Article and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation

1367/2006.”

Or. en

Amendment 465
Martin Häusling

Proposal for a regulation
Article 4 – paragraph 1 – point 2
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	“Article 18
Transparency and confidentiality	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 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, 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.
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.	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. ***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***	3. ***The following information shall not be considered*** confidential:

which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

(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.".***

(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;***

(ba) the conclusions of the study results on effects of the feed additive on human and animal health and on the environment;

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

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

3a. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council when handling applications for access to documents held by the Authority.

3b. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of

Regulation (EC) No 1049/2001."

Or. en

Justification

Paragraph 3 simply reinstates the current wording of Regulation 1831/2003 . If the aim of the proposal is to strengthen transparency, then, instead of enlarging the list of information which can be kept confidential, the current provisions relating to information that can never be kept confidential must be kept. Likewise, paragraphs 4 and 5 simply keep the current text of Regulation 1831/2003.

Amendment 466
Renate Sommer

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 ***draft*** 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. en

Amendment 467
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
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.	2. In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) ***No178/2002*** and this Article, the applicant may request certain information ***which might significantly harm his competitive position*** submitted under this Regulation ***to be*** kept confidential, accompanied by verifiable justification; and, the Authority shall assess the confidentiality request submitted by the applicant.

Or. en

Justification

In the current Reg. it is clearly named that there must exist verifiable reasons which might harm significantly. In order to allow for legal certainty and predictability to the evaluators and the applicant, the current language should remain

Amendment 468
Guillaume Balas

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 469
Anja Hazekamp

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 470
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
3. ***In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide*** confidential treatment to the following information, ***the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned***:	3. Confidential treatment ***may not be accepted with respect*** to the following information, ***in light of their relevance for the protection of public and animal health***:

Or. en

Amendment 471
Anja Hazekamp

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EC) 1831/2003
Article 18 – paragraph 3 – point b

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

Or. en

Amendment 472
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	3a. The provisions on active dissemination laid down in this Article, and in Articles 38 and 39 of Regulation (EC) No 178/2002, are without prejudice to the right of access to documents upon request set in Regulation 1049/2001.

Or. en

Amendment 473
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	3a. Notwithstanding paragraph 2, 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.

3b. Notwithstanding paragraph 2, the Authority shall, on request, supply the Commission and Member States with all information in its possession, including any identified as confidential pursuant to that paragraph.

3c. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council [1a] when handling applications for access to documents held by the Authority.

3d. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraphs 2 and 3 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.

3e. If an applicant withdraws or has withdrawn an application, the Member States, the Commission and the Authority shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Commission and the applicant disagree as to its confidentiality.

[1a] 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 (OJ L 145, 31.5.2001, p. 43).

Or. en

Justification

In order to maintain at least the same level of transparency and legal objectivity and predictability, the list of non-confidential information should continue to exist and well as the rest of the information on access to document, unless it is covered on the final text of Reg. 178/2002 as it will be amended.

Amendment 474
Renate Sommer

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 draft scientific opinion***, in accordance with Articles 14 and 15.;

Or. en

Amendment 475
Anja Hazekamp

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, ***the principles of Regulation 1049/2001***.

Or. en

Justification

Regulation 1049/2001 provided the legal base for access to documents. The current Regulation 2065/2003 on art. 7 (2) clearly reconfirms it and if we wish to keep the same of access and transparency, this provision should remain.

Amendment 476
Renate Sommer

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 ***draft*** scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002.

Or. en

Amendment 477
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(2a) In Article 14, the following paragraph is inserted:
	"1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article and Articles 38

and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001 and Regulation 1367/2006."

Or. en

Amendment 478
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
(3) Article 15 is replaced by the following:	***deleted***
'Article 15	
Confidentiality	
In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002,	
(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. '	

Or. en

Justification

The current list of items is a more transparent, objective and predictable way on assessing the confidentiality claims. It should not be replaced.

Amendment 479
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(3) Article 15 is replaced by the following:	(3) Article 15 is replaced by the following:
"Article 15	"Article 15
Confidentiality	Confidentiality
In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002,	***1.*** In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002,
(a) the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,	(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.".	(b) the Authority shall assess the confidentiality request submitted by the applicant.
	1a. Without prejudice to Article 39(3) of Regulation (EC) No 178/2002, information relating to the following shall not be considered confidential:
	(a) the name and address of the applicant and the name of the product;
	(b) in the case of an opinion in favour of authorising the evaluated product, the particulars mentioned in Article 6(2);
	(c) information of direct relevance to the assessment of the safety of the product;
	(d) the analytical method referred to in point 4 of Annex II."

Or. en

Justification

Paragraph 2 simply reinstates the current wording of Regulation 2065/2003. If the aim of the proposal is to strengthen transparency, then, instead of enlarging the list of information which can be kept confidential, the current provisions relating to information that can never be kept confidential must be kept.

Amendment 480
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	1a. The provisions on active dissemination laid down in Articles 14 and 15 of this Regulation, and Articles 38 and 39 of Regulation (EC) No 178/2002, are without prejudice to the right of access to documents upon request set in Regulation (EC) No 1049/2001.

Or. en

Amendment 481
Renate Sommer

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 it publishes its draft scientific opinion,*** in accordance with Articles 19 and 20.

Or. en

Amendment 482
Renate Sommer

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 ***draft*** 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.

Or. en

Amendment 483
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(2a) In Article 19, the following paragraph is inserted:
	"(2a) The obligation to proactively disseminate information set out in paragraph 1 of this Article, including Article 20 below, and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulation 1049/2001

and Regulation 1367/2006."

Or. en

Amendment 484
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(3) Article 20 is replaced by the following:	(3) Article 20 is replaced by the following:
"Article 20	"Article 20
Confidentiality	Confidentiality
1. In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002 and this article:	1. In accordance with the conditions and the procedures laid down in Articles 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,	(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.	(b) the Authority shall assess the confidentiality request submitted by the applicant.
2. ***In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide*** confidential ***treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned***:	2. ***Information relating to the following shall not be considered*** confidential:
(a) ***any information provided in detailed descriptions of starting substances and preparations used to manufacture the substance subject to the authorisation, the composition of***	(a) ***the name and address of the applicant and the chemical name of the substance;***

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,***	(b) ***information of direct relevance to the assessment of the safety of the substance;***
(c) ***any other information deemed confidential within the specific procedural rules referred to in Article 5(1)(n) of this Regulation.".***	(c) ***the analytical method or methods."***

Or. en

Amendment 485
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	2a. The provisions on active dissemination laid down in Articles 19 and 20 of this Regulation, and Articles 38 and 39 of Regulation (EC) No 178/2002, are without prejudice to the right of access to documents upon request set in Regulation (EC) No 1049/2001.

Or. en

Amendment 486
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	(ba) the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.

Or. en

Amendment 487
Anja Hazekamp

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 488
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
2. ***In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide*** confidential treatment to the following information, ***the disclosure of which*** may be deemed***, upon verifiable justification, to significantly harm the interests concerned***:	2. Confidential treatment ***may not be accepted with respect*** to the following information, ***when it*** may be deemed ***to relate to emissions in the environment or may be deemed relevant to protect public health and/or animal health***:

Or. en

Amendment 489
Guillaume Balas

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation 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	***deleted***

which the applicant intends to use this substance, the manufacturing methods of these preparations, materials or articles, impurities, and migration testing results;

Or. en

Amendment 490
Piernicola Pedicini, Eleonora Evi

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***;	(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;

Or. en

Justification

The issue of migration is a healthcare matter. There is no reason why it should be confidential.

Amendment 491
Guillaume Balas

Proposal for a regulation
Article 6 – paragraph 1 – point 3
Regulation 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 492
Piernicola Pedicini, Eleonora Evi

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

Justification

There is no reason why there should be these additions to the list of confidential requirements already provided under Reg 178/2002.

Amendment 493
Piernicola Pedicini, Eleonora Evi

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

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

Or. en

Justification

There is no reason why there should be these additions to the list of confidential requirements already provided under Regulation 178/2002.

Amendment 494
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	2a. Information relating to the following shall not be considered confidential:
	(a) the name and address of the applicant and the chemical name of the substance;
	(b) information of direct relevance to the assessment of the safety of the substance;
	(c) the analytical method or methods.

Or. en

Justification

This reconfirm the existing legal framework. With the current proposal the analytical methods could be considered confidential. This would be detrimental for food safety reasons. As identified in the EPRS Implementation Assessment 5/2016 and expressed in the EP Resolution on the implementation of the FCM Regulation (2015/2259) INI, it is very difficult to identify

and control the nanomaterials used and their organoleptic properties. Less information would lead to even higher risk.

Amendment 495
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	2b. 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.

Or. en

Justification

Currently par.5 of the Regulation.

Amendment 496
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(2) Article 11 is replaced by the following:	(2) Article 11 is replaced by the following:
"Where the Commission requests its opinion in accordance with Article 3(2) of this Regulation, the Authority shall make public the application for authorisation,	***"1.*** 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.”;	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. ***1a. The obligation to proactively disseminate information set out in paragraph 1 of this Article, in Article 12 of this Regulation and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulations (EC) No 1049/2001 and (EC) No 1367/2006.”***

Or. en

Amendment 497
Anja Hazekamp

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

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.	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.

Or. en

Justification

Art. 3(2) allows the EC to update the lists of additives, enzymes and flavourings without asking the EFSA, if it deems that the updates are not liable to have an effect on human health. The condition that the Authority shall make public only where the EC, requests its opinion, will create less transparency, more pressure from industry, higher risk for human health and lesser democratisation of the process and it is contrary to the spirit of the transparency and the existing art 11.

Amendment 498
Renate Sommer

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

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 it publishes its draft*** 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.;

Or. en

Amendment 499
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
(3) Article 12 is replaced by the following:	***deleted***
'Article 12	
Confidentiality	
1. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.	
2. Where an opinion by the Authority is required in accordance with Article 3(2) of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39f of Regulation (EC) No 178/2002.	
3. Where an opinion by the Authority is not required in accordance with Article 3(2) of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39 to 39f of Regulation (EC) No 178/2002 shall apply mutatis mutandis.; '	

Or. en

Justification

The current art.12 provides more transparency and predictability and allow (par.5 the waiving of the confidentiality 'if circumstances so require in order to protect human health, animal health or the environment'. It has of no use amending a regulation for reaching lower levels of transparency, risk for public health and criticism from the citizens.

Amendment 500
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(3) Article 12 is replaced by the following:	(3) Article 12 is replaced by the following:
“Article 12	“Article 12
Confidentiality	Confidentiality
1. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.	1. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.
2. Where an opinion by the Authority is required in accordance with Article 3(2) of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39f of Regulation (EC) No 178/2002.	2. Where an opinion by the Authority is required in accordance with Article 3(2) of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39f of Regulation (EC) No 178/2002.
3. Where an opinion by the Authority is not required in accordance with Article 3(2) of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39 to 39f of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.”;	3. Where an opinion by the Authority is not required in accordance with Article 3(2) of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39 to 39f of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.
	3a. Information relating to the following shall not, in any circumstances, be regarded as confidential:
	(a) the name and address of the applicant;
	(b) the name and a clear description of the substance;
	(c) the justification for the use of the substance in or on specific foodstuffs or food categories;
	(d) information that is relevant to the assessment of the safety of the substance;
	(e) where applicable, the analysis method(s).
	3b. The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, take the necessary measures to

ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment."

Or. en

Justification

Paragraph 4 and 5 simply reinstate the current wording of Directive 2001/18/EC. If the aim of the proposal is to strengthen transparency, then, instead of enlarging the list of information which can be kept confidential, the current provisions relating to information that can never be kept confidential must be kept.

Amendment 501
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	3a. The provisions on active dissemination laid down in Articles 11 and 12 of this Regulation, and Articles 38 and 39 of Regulation (EC) No 178/2002, are without prejudice to the right of access to documents upon request set in Regulation (EC) No 1049/2001.

Or. en

Amendment 502
Anja Hazekamp

Proposal for a regulation
Article 8 – paragraph 1 – point 1 – point b
Regulation (EC) No 1107/2009
Article 7 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.	When submitting the application, the applicant may pursuant to Article 63 request ***for*** certain information, including certain parts of the dossier ***that may significantly harm its commercial interests***, to be kept confidential and shall physically separate that information.

Or. en

Amendment 503
Anja Hazekamp

Proposal for a regulation
Article 8 – paragraph 1 – point 1 – point b
Regulation (EC) No 1107/2009
Article 7 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
Member States shall assess the confidentiality requests. Upon a request for access to information and after consultation ***with*** the Authority***,*** the rapporteur Member States ***shall decide*** what information is to be kept confidential, in accordance with Article 63.;	***The Authority*** shall assess the confidentiality requests. Upon a request for access to information and after consultation ***between*** the Authority ***and*** the rapporteur Member States ***it will be decided*** what information is to be kept confidential, in accordance with Article 63.;

Or. en

Justification

EFSA is the most appropriate player to identify which scientific parts could be commercially interesting and which not. This way, the assessment is more scientific-based and provides for equal treatment, as the assessment will be done for all application by EFSA based on the same criteria and not according to the Rapporteur MS

Amendment 504
Anja Hazekamp

Proposal for a regulation
Article 8 – paragraph 1 – point 2
Regulation (EC) No 1107/2009
Article 10

Text proposed by the Commission	*Amendment*
The Authority shall without delay make the dossiers referred to in Article 8 of this Regulation including any supplementary information supplied by the applicant, available to the public, excluding any information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation.***;**	The Authority shall without delay make the dossiers referred to in Article 8 of this Regulation including any supplementary information supplied by the applicant, available to the public, excluding any information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation.***, unless there is an overriding public interest in its disclosure.***

Or. en

Justification

The proposal 178/2002 as it stands, does not foresee the derogation for overriding public interest, as it is the case for the current art. 10 of Reg. 1107/2009. Therefore, it is necessary to re-insert it in order at least to maintain the current lever of public access;

Amendment 505
Martin Häusling

Proposal for a regulation
Article 8 – paragraph 1 – point 4
Regulation (EC) No 1107/2009
Article 16

Text proposed by the Commission	*Amendment*
The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant,	The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant,

except for information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation.;	except for information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation***, unless there is an overriding public interest in its disclosure***.

Or. en

Justification

This provision is taken from the current Regulation 1107/2009, Article 16. There is no reason why the new rules should waive it.

Amendment 506
Anja Hazekamp

Proposal for a regulation
Article 8 – paragraph 1 – point 4
Regulation (EC) No 1107/2009
Article 16

Text proposed by the Commission	*Amendment*
The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation.;	The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply mutatis mutandis and pursuant to Article 63 of this Regulation. ***unless there is an overriding public interest in its disclosure***.

Or. en

Justification

For the moment, the EC proposal does not foresee the derogation based on overriding public interest, as the current Regulation foresees. Unless this derogation is inserting in the new articles of Regulation (EC) No 178/2002, then without this insertions, we head towards less transparent and accessibility from public even in cases of risk to health as foreseen in art. 4 (2) of 1049/2001 on public access to documents.

Amendment 507
Martin Häusling

Proposal for a regulation
Article 8 – paragraph 1 – point 4 a (new)
Regulation (EC) No 1107/2009
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
	(4a) In Article 23, the last sentence of paragraph 1 is replaced by the following:
	"For the purpose of this Regulation, an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as an approved basic substance."

Or. en

Justification

add: and "approved" This is an amendment of clarification, as many doubts remain on which substances may be considered as basic substances.

Amendment 508
Anja Hazekamp

Proposal for a regulation
Article 8 – paragraph 1 – point 5 – introductory part

Text proposed by the Commission	*Amendment*
(5) in Article 63, paragraphs 1 ***and 2*** are replaced by the following:	(5) in Article 63, paragraphs 1***, 2 and 3*** are replaced by the following:

Or. en

Amendment 509
Anja Hazekamp

Proposal for a regulation
Article 8 – paragraph 1 – point 5 – introductory part

Text proposed by the Commission	*Amendment*
(5) in Article 63, ***paragraphs 1 and 2 are*** replaced by the following:	(5) in Article 63, ***paragraph 1 is*** replaced by the following:

Or. en

Amendment 510
Fredrick Federley, Ulrike Müller, Jan Huitema

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, accompanied by verifiable justification. ***The justification shall include verifiable evidence 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

Justification

This is a clarification, this is provided for in Article 63 of Regulation 1107/2009.

Amendment 511
Guillaume Balas

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, ***except for information that is considered toxicologically, ecotoxicologically or environmentally relevant,*** the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by ***adequate and*** verifiable justification.

Or. en

Amendment 512
Anja Hazekamp

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 ***if the*** accompanied verifiable justification ***proves that the disclosure of those might undermine commercial interests, the protection of privacy and the integrity of the individual***.

Or. en

Justification

Insertion to bring in line with the correct status

Amendment 513
Anja Hazekamp

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:	***deleted***
(a) the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for these impurities;	
(b) results of production batches of the active substance including impurities; and,	
(c) information on the complete composition of a plant protection product.;	

Or. en

Amendment 514
Martin Häusling

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:	***deleted***
(a) the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for these impurities;	
(b) results of production batches of the active substance including impurities; and,	
(c) information on the complete composition of a plant protection product.;	

Or. en

Justification

As the aim of the proposal is to increase transparency, the addition of further information that may be kept confidential is not useful.

Amendment 515
Fredrick Federley, Ulrike Müller, Jan Huitema

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

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 provide*** confidential treatment ***in relation*** to the following information, ***if*** the disclosure of which ***is*** deemed to significantly harm the interests concerned ***until proven otherwise***:

Or. en

Amendment 516
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
(a) the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for these impurities;	***deleted***

Or. en

Amendment 517
Anja Hazekamp

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

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

Or. en

Amendment 518
Guillaume Balas

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

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

Or. en

Amendment 519
Piernicola Pedicini, Eleonora Evi

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

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

Or. en

Amendment 520
Anja Hazekamp

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

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

Or. en

Amendment 521
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	(5a) in Article 63, paragraph 3 is replaced by the following:
	"3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and 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 522
Martin Häusling

Proposal for a regulation
Article 8 – paragraph 1 – point 5 a (new)

Regulation (EC) No 1107/2009
Article 63 – paragraph 3

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

Or. en

Amendment 523
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	(5a) in Article 63, the following paragraph is added after paragraph 3:
	"3a. The provisions on active dissemination laid down in Article 63 of this Regulation, and Article 38 and 39 of Regulation 178/2002, are without prejudice to the right of access to documents upon request set in Regulations (EC) No 1049/2001 and (EC) No 1367/2006."

Or. en

Amendment 524
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States without delay;	1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States ***and the summary of the application publicly available*** without delay;

Or. en

Justification

In order to ensure, at least, equal level of transparency, the amended Regulation should include access of the summary to the public, as it is currently foreseen in art.10 (1).

Amendment 525
Renate Sommer

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	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 ***at the same time as it publishes its draft*** opinion ***in response to the question***

health;	whether the update is liable to have an effect on human health;

Or. en

Amendment 526
Anja Hazekamp

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. ***For every update,*** the Commission ***shall request*** from, the European Food Safety Authority ('the Authority') ***to*** give its opinion as to whether the update is liable to have an effect on human health. ***The Authority shall ensure public access to the application and its opinion in accordance with Article 23.***

Or. en

Justification

In order to ensure food safety, EFSA should always ask for any update on novel foods. In order to enhance transparency and trust in the process, it is imperative to give public access to as many information as possible, as long as they are not covered by justified confidentiality restrictions;

Amendment 527
Renate Sommer

Proposal for a regulation
Article 9 – paragraph 1 – point 2
Regulation (EC) No 2015/2283
Article 15 – paragraph 1 – last sentence

Text proposed by the Commission	*Amendment*
The Authority shall ensure public access to	The Authority shall ensure public access to

the notification pursuant to Article 23.	the notification pursuant to Article 23 ***when it publishes its technical report***.

Or. en

Amendment 528
Renate Sommer

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 public access to ***the non-confidential elements of*** the application, relevant supporting information and any supplementary information supplied by the applicant ***as well as to the notification concerning safety concerns at the same time as it publishes its draft scientific opinion and*** in accordance with Article 23.

Or. en

Amendment 529
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(4) Article 23 is replaced by the following:	(4) Article 23 is replaced by the following:
“Article 23	“Article 23
Transparency and confidentiality	Transparency and confidentiality
1. Where the Commission ***requests*** its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority	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.

2. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.

3. Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.

4. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16, the Commission shall assess the confidentiality request submitted by the applicant. Article 39 and 39a of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.".

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.

2. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.

3. Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.

4. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16, the Commission shall assess the confidentiality request submitted by the applicant. Article 39 and 39a of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.

4a. Confidentiality shall not apply to the following information:

(a) the name and address of the applicant;

(b) the name and description of the novel food;

(c) the proposed conditions of use of the novel food;

(d) a summary of the studies submitted by the applicant;

(e) the results of the studies carried out to demonstrate the safety of the food;

(f) where appropriate, the analysis method(s);

(g) any prohibition or restriction imposed in respect of the food by a third country."

Or. en

Amendment 530
Anja Hazekamp

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. 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.

Or. en

Amendment 531
Renate Sommer

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	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, ***at the same time*** as its ***draft*** scientific ***opinion***, in accordance with Article 38,

39f and Article 40 of Regulation (EC) No 178/2002 and with this Article.	Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article.

Or. en

Amendment 532
Anja Hazekamp

Proposal for a regulation
Article 9 – paragraph 1 – point 4
Regulation (EC) No 2015/2283
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation,*** the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.	3. The Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.

Or. en

Amendment 533
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
4. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16, the Commission shall assess the confidentiality request submitted by the applicant. Article 39 and 39a of Regulation (EC) No 178/2002 shall apply mutatis mutandis.	***deleted***

Or. en

Amendment 534
Pavel Poc, Jytte Guteland, Nicola Caputo, Daciana Octavia Sârbu

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

Text proposed by the Commission	*Amendment*
	4a. The provisions on active dissemination laid down in Article 23 of this Regulation, and Articles 38 and 39 of Regulation 178/2002, are without prejudice to the right of access to documents upon request set in Regulation (EC) No 1049/2001.

Or. en

Amendment 535
Anja Hazekamp

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

Text proposed by the Commission	*Amendment*
	4a. Confidentiality shall not apply to the following information:
	(a) the name and address of the applicant;
	(b) the name and description of the novel food;
	(c) the proposed conditions of use of the novel food;
	(d) a summary of the studies submitted by the applicant;
	(e) the results of the studies carried out to demonstrate the safety of the food;

(f) where appropriate, the analysis method(s);

(g) any prohibition or restriction imposed in respect of the food by a third country.

The Commission, the Member States and the Authority shall take necessary measures to ensure appropriate confidentiality of the information as referred to in paragraph 4, and received by them under this Regulation, except for information which is required to be made public in order to protect human health.

Or. en

Justification

Necessary insertion (identical to the current status) in order to avoid a backlash in transparency, accessibility and predictability.

Amendment 536
Renate Sommer

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

Text proposed by the Commission	*Amendment*
	4a. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 4 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

Or. en

Justification

Regulation (EU) 2283/2015 foresaw in Article 23 (8) that the Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6. This is

required because of the specificities of Novel Foos that can cover aspects that are new and not known today. This provision must remain.

Amendment 537
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	(4a) In Article 25, the following paragraph is inserted:
	"1a. The obligation to proactively disseminate information set out in this Regulation and Articles 38 and 39 of Regulation 178/2002, is without prejudice to the right of any natural or legal person to access document upon request as set by Regulations (EC) No 1049/2001 and (EC) No 1367/2006."

Or. en

Amendment 538
Michel Dantin

Proposal for a regulation
Article 9 a (new)
Directive 2001/110/EC
Article 2

Text proposed by the Commission	*Amendment*
	Article 9a
	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. At least 75% of blended honeys must come from the indicated country or countries of origin'.

(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 is added:

« 5a. '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 539
Marijana Petir, Norbert Erdős, Franc Bogovič

Proposal for a regulation
Article 9a (new)
Directive 2001/110/EC
Article 2

Text proposed by the Commission	*Amendment*
	Article 9a
	Amendments to Directive 2001/110/EC on

honey

Directive 2001/110/EC is amended as follows:

Article 2 is amended as follows:

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

"(a) 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) the following point is added:

"5a. 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