

5.12.2018

A8-0417/132

Amendment 132

Renate Sommer

on behalf of the PPE Group

Report

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

A8-0417/2018

Proposal for a regulation

Recital 25

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

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

5.12.2018

A8-0417/133

Amendment 133

Renate Sommer

on behalf of the PPE Group

Report

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

A8-0417/2018

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32 b – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

5.12.2018

A8-0417/134

Amendment 134

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – point c

Text proposed by the Commission

Amendment

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

deleted

Or. en

Justification

The article needs to be structured better. The rapporteur distinguishes between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by the EFSA.

5.12.2018

A8-0417/135

Amendment 135

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) the information on which its scientific outputs, including scientific opinions are based, taking into account protection of confidential data and protection of personal data in accordance with Articles 39 to 39f;

deleted

Or. en

Justification

The article needs to be structured better. The rapporteur distinguishes between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by the EFSA.

5.12.2018

A8-0417/136

Amendment 136

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Proposal for a regulation

Article 1 – paragraph 1 – point 5 – point a

Regulation (EC) No 178/2002

Article 38 – paragraph 1 – point i

Text proposed by the Commission

Amendment

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

Or. en

Justification

The article needs to be structured better. The rapporteur distinguishes between (a) information to be published immediately and (b) information to be published only at the time of the adoption of the scientific opinion by the EFSA.

5.12.2018

A8-0417/137

Amendment 137

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

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, the Authority shall publish a draft scientific opinion.

At the same time, of the publication of the draft scientific opinion, the Authority shall make public the following information:

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

(b) the full application document taking into account protection of

AM\P8_AMA(2018)0417(132-140)_EN.docx

PE631.553v01-00

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 Articles 39 to 39f;

(d) information concerning the consultation sessions with applicants conducted by the Authority pursuant to Articles 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 is 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.

5.12.2018

A8-0417/138

Amendment 138

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) make public, without delay, the non-confidential version, as submitted by the applicant;

deleted

Or. en

Justification

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

5.12.2018

A8-0417/139

Amendment 139

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – point c

Text proposed by the Commission

Amendment

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

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

Or. en

Justification

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

5.12.2018

A8-0417/140

Amendment 140

Renate Sommer

on behalf of the PPE Group

Report

A8-0417/2018

Renate Sommer

Transparency and sustainability of the EU risk assessment in the food chain
(COM(2018)0179 – C8-0144/2018 – 2018/0088(COD))

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 39b – paragraph 1 – point e

Text proposed by the Commission

Amendment

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

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