5.12.2018

**Amendment 141**  
**Renate Sommer**  
on behalf of the PPE Group

**Report**  
**Renate Sommer**  
Transparency and sustainability of the EU risk assessment in the food chain  

**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*  
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:

*Amendment*  
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.*
5.12.2018  A8-0417/142

**Amendment 142**

Renate Sommer  
on behalf of the PPE Group

**Report**  
Renate Sommer  
Transparency and sustainability of the EU risk assessment in the food chain  

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

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**Text proposed by the Commission**

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.

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**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 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
5.12.2018

Amendment 143
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

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

(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.

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.

Or. en

Justification

The passage should be deleted since the term ‘overriding public interest’ is not defined.
Amendment 144
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

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

Text proposed by the Commission

3. The list of information referred to in paragraph 2 shall be without prejudice to any specific Union food law.

Amendment

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 the presumption of confidentiality in that paragraph 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 145
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

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
5.12.2018

Amendment 146
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

Proposal for a regulation
Article 3 – paragraph 1 – point 9
Renate Sommer

Regulation (EC) No 1829/2003
Article 29 – paragraph 1

Text proposed by the Commission

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.

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, 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
5.12.2018

Amendment 147
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

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

Text proposed by the Commission

(c) ensure public access to the application and any information supplied by the applicant, in accordance with Article 18.;

Amendment

(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
5.12.2018

Amendment 148

Renate Sommer
on behalf of the PPE Group

Report

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

Proposal for a regulation

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

Text proposed by the Commission

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.

Amendment

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 149
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

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
(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.;

Amendment
(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
5.12.2018

Amendment 150
Renate Sommer
on behalf of the PPE Group

Report
Renate Sommer
Transparency and sustainability of the EU risk assessment in the food chain

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

Text proposed by the Commission

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.

Amendment

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