

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance)

Article 6

Amendments to Regulation (EC) No 1331/2008

Regulation (EC) No 1331/2008 is amended as follows:

- (1) in Article 6, the following paragraph is added:
 5. The Authority shall make public the additional information supplied by the applicant in accordance with Articles 11 and 12.;
- (2) Article 11 is replaced by the following:

Article 11

Transparency

Where the Commission requests the opinion of the Authority in accordance with Article 3(2) of this Regulation, the Authority shall make public without delay the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002. The Authority shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.;

- (3) Article 12 is replaced by the following:

Article 12

Confidentiality

- 1 The applicant may submit a request to treat certain parts of the information submitted under this Regulation as 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 39e of Regulation (EC) No 178/2002.
- 3 In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:

- a where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety;
- b where applicable, detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety.

4 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, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 3 of this Article shall apply *mutatis mutandis*.

5 This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002..