

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 5

Amendments to Regulation (EC) No 1935/2004

Regulation (EC) No 1935/2004 is amended as follows:

- (1) Article 9 is amended as follows:
 - (a) in paragraph 1, point (c) is replaced by the following:
 - (c) the Authority shall without delay:
 - (i) inform the Commission and the other Member States of the application and shall make the application and any supplementary information supplied by the applicant available to them; and
 - (ii) make public the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 19 and 20.;
 - (b) paragraph 2 is replaced by the following:
 2. The Authority shall publish detailed guidelines, following the agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.;
- (2) in Article 19, paragraph 1 is replaced by the following:
 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 Articles 38 to 39e of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*, and with Article 20 of this Regulation.;
- (3) Article 20 is replaced by the following:

Article 20

Confidentiality

- 1 In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and in this Article:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1381 of the European Parliament and of the Council, Article 5. (See end of Document for details)

- a the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification; and
- b the Authority shall assess the confidentiality request submitted by the applicant.

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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 any information provided in detailed descriptions of starting substances and mixtures used to manufacture the substance subject to the authorisation, the composition of mixtures, materials or articles in which the applicant intends to use that substance, the manufacturing methods of those mixtures, materials or articles, impurities, and migration testing results, except for information which is relevant to the assessment of safety;
- b the trademark under which the substance shall be marketed as well as the tradename of the mixtures, 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 point (n) of Article 5(1) of this Regulation.

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

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2019/1381 of the European Parliament and of the Council, Article 5.