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 3

Amendments to Regulation (EC) No 1831/2003

Regulation (EC) No 1831/2003 is amended as follows:

(1) Article 7 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. An application for an authorisation as provided for in Article 4 of this Regulation shall be sent to the Commission, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*. The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority (hereinafter referred to as the "Authority").;

(b) in paragraph 2, point (c) is replaced by the following:

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

(2) Article 18 is replaced by the following:

Article 18

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 Articles 38 to 39e 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 39e of Regulation (EC) No 178/2002 and in this Article, the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification. The Authority shall assess the confidentiality request submitted by the applicant.

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 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) of, 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.

4 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 3.