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 8

Amendments to Regulation (EU) 2015/2283

Regulation (EU) 2015/2283 is amended as follows:

(1) Article 10 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States without delay. The Commission shall make a summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.;

(b) paragraph 3 is replaced by the following:

3. Where the Commission requests an opinion from the European Food Safety Authority (the "Authority"), the Authority shall make public the application in accordance with Article 23 and shall give its opinion as to whether the update is liable to have an effect on human health.;

(2) in Article 15, paragraph 2 is replaced by the following:

2. Within four months from the date on which a valid notification is forwarded by the Commission in accordance with paragraph 1 of this Article, a Member State or the Authority may submit to the Commission duly reasoned safety objections to the placing on the market within the Union of the traditional food concerned. Where the Authority submits duly reasoned safety objections, it shall make public, without delay, the notification, pursuant to Article 23, which shall apply *mutatis mutandis*.;

(3) Article 16 is amended as follows:

(a) in the first paragraph, the following sentence is added:

The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002.;

(b) in the second paragraph, the following sentence is added:

The Authority shall make public the application, relevant supporting information and any supplementary information supplied by the applicant in accordance with Article 23.;

(4) Article 23 is replaced by the following:

Article 23

Transparency and confidentiality

1 Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, 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 and with this Article.

2 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.

3 Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 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.

4 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 novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, 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, except for information which is relevant to the assessment of safety.

5 Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16 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 4 of this Article shall apply *mutatis mutandis*.

6 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 8.