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 7

Amendments to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended as follows:

(1) Article 7 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

> An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State (the "rapporteur Member State"), together with a summary and a complete dossier as provided for in Article 8(1) and (2) of this Regulation or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4 of this Regulation. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.;

(b) paragraph 3 is replaced by the following:

> 3. When submitting the application, the applicant may submit a request, pursuant to Article 63, to treat certain information, including certain parts of the dossier, as confidential and shall physically separate that information.
>
> Member States shall assess the confidentiality requests. After consultation with the Authority, the rapporteur Member States shall decide what information is to be treated as confidential, in accordance with Article 63.
>
> The Authority, following consultations with the Member States, shall lay down practical arrangements to ensure the consistency of those assessments.;

(2) Article 10 is replaced by the following:

Article 10

Public access to the dossiers

> The Authority shall without delay make the dossiers referred to in Article 8, including any supplementary information supplied by the applicant, available to the public, with the exception of any information to which the rapporteur Member State has granted confidential treatment pursuant to Article 63.;

(3) In Article 15, paragraph 1 is replaced by the following:

1. The application provided for in Article 14 of this Regulation shall be submitted by a producer of the active substance to a Member State, with a copy to the Commission, to the other Member States and to the Authority, no later than three years before the expiry of the approval. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.;

(4) Article 16 is replaced by the following:

Article 16

Public access to the information for renewal

The Authority shall assess, without delay, any confidentiality request and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which confidential treatment has been requested and granted by the Authority pursuant to Article 63.

The Authority, following consultations with the Member States, shall lay down practical arrangements to ensure the consistency of those assessments.;

(5) in Article 63, paragraphs 1, 2 and 3 are replaced by the following:

1. An applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification.

2 Confidential treatment may be granted only 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 information referred to in Article 39(2) of Regulation (EC) No 178/2002;
- b the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities;
- c results of production batches of the active substance including impurities; and
- d information on the complete composition of a plant protection product.

2a Where the Authority assesses confidentiality requests under this Regulation, the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and paragraph 2 of this Article shall apply.

2b Where Member States assess confidentiality requests under this Regulation, the following requirements and procedures apply:

- a confidentiality treatment may only be granted with respect to information listed in paragraph 2;
- b where the Member State has decided which information is to be treated as confidential, it shall inform the applicant of its decision;

c Member States, the Commission and the Authority shall take the necessary measures so that information for which confidential treatment has been granted is not made public;

d Article 39e of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*;

e notwithstanding paragraph 2 and points (c) and (d) of this paragraph:

(i) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Member State may disclose the information referred to in paragraph 2;

(ii) information which forms part of the conclusions of the scientific outputs delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment shall nevertheless be made public. In that case, Article 39c of Regulation (EC) No 178/2002 shall apply;

f if the applicant withdraws or has withdrawn an application, Member States, the Commission and the Authority shall respect the confidentiality as granted in accordance with this Article. Where the withdrawal of the application takes place before the Member State has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

3 This Article is without prejudice to Directive 2003/4/EC[(1)] and Regulations (EC) No 1049/2001[(2)] and (EC) No 1367/2006[(3)] of the European Parliament and of the Council..

(**1**) Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

(**2**) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

(**3**) Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).'.

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 7.