

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 9

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

- (1) in Article 6, the following paragraph is inserted:
 - 2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist under Union law.;
- (2) in Article 13, the following paragraph is inserted:
 - 2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist under Union law.;
- (3) Article 25 is replaced by the following:

Article 25

Confidentiality

- 1 The notifier may submit a request to the competent authority to treat certain parts of the information submitted under this Directive as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.
- 2 The competent authority shall assess the confidentiality request submitted by the notifier.
- 3 Upon request of a notifier, the competent authority may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the notifier to potentially harm its interests to a significant degree:
 - a items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;
 - b DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and
 - c breeding patterns and strategies.
- 4 The competent authority shall, after consultation with the notifier, decide which information is to be treated as confidential and shall inform the notifier of its decision.
- 5 Member States, the Commission and the relevant Scientific Committee(s) shall take the necessary measures to ensure that confidential information notified or exchanged under this Directive is not made public.

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 9. (See end of Document for details)

6 The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.

7 Notwithstanding paragraphs 3, 5 and 6 of this Article:

- a where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the competent authority may disclose the information referred to in paragraph 3; and
- b information which forms part of the conclusions of the scientific outputs delivered by the relevant Scientific Committee(s) or the conclusions of the assessment reports 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.

8 In the event of a withdrawal of the notification by the notifier, Member States, the Commission and the relevant Scientific Committee(s) shall respect the confidentiality as granted by the competent authority in accordance with this Article. Where the withdrawal of the notification takes place before the competent authority has decided on the relevant confidentiality request, Member States, the Commission and the relevant Scientific Committee(s) shall not make public the information for which confidentiality has been requested.;

(4) in Article 28, the following paragraph is added:

4. Where the relevant Scientific Committee is consulted in accordance with paragraph 1 of this Article, it shall make public without delay the notification, relevant supporting information and any supplementary information supplied by the notifier, as well as its scientific opinions, with the exception of any information to which the competent authority has granted confidential treatment in accordance with Article 25..

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 9.