Commission Implementing Regulation (EU) 2018/2018 of 18 December 2018 laying down specific rules concerning the procedure to be followed in order to carry out the risk assessment of high risk plants, plant products and other objects within the meaning of Article 42(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council

COMMISSION IMPLEMENTING REGULATION (EU) 2018/2018

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC[(1)], and in particular Article 42(6) thereof,

Whereas:

(1) Rules should be established to ensure that the risk assessment referred to in Article 42(4) of Regulation (EU) 2016/2031 is conducted within a reasonable period of time and on the basis of a timely processing of technical dossiers.

(2) In order for that risk assessment to be conducted, an application should be submitted to the Commission only by the National Plant Protection Organisation, within the meaning of the International Plant Protection Convention, of the third country. This is necessary to ensure that all the necessary elements for the assessment of the risk associated with plants, plant products or other objects to be introduced in the Union territory are certified by the responsible public authority of the third country. This would be necessary for the credibility and justification of the risk assessment as a basis of measures taken pursuant to Article 42(4) of Regulation (EU) 2016/2031. Those provisions should apply without prejudice to the right of the Commission to submit requests to the European Food Safety Authority (EFSA) to issue scientific opinions pursuant to Article 29 and provide scientific or technical assistance pursuant to Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[(2)].

(3) The technical dossier should contain data on the commodities to be introduced into the territory of the Union, as well as data on the identification of pests potentially associated with the commodity in the exporting country, data on national phytosanitary mitigation measures, inspections and treatments and processing of the commodity and contact details of the natural person responsible for liaising with the Commission and

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/2018. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

EFSA. Such data are essential in order to perform the commodity risk assessment and to identify the pest species for which phytosanitary mitigation measures may be required.

(4) In order to provide EFSA with all the necessary elements to conduct the risk assessment, the technical dossier should contain the information specified in the EFSA document entitled 'Information required for dossiers to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42 of Regulation (EU) 2016/2031[(3)]'.

(5) It is appropriate that, after acknowledging receipt of the technical dossier, the Commission examine whether it contains the required information and may ask, where necessary, for additional information or clarifications so that it is ensured that the application contains all the required and appropriate elements for the risk assessment.

(6) Rules should be established concerning the conduct of risk assessment by EFSA, its communication with the applicant and the publication of that assessment, in order to ensure a transparent, efficient and timely risk assessment process.

(7) In order to avoid that the disclosure of certain information harms the competitive position of certain third parties, the provisions concerning confidentiality of Regulation (EC) No 178/2002 should apply accordingly.

(8) For reasons of legal certainty, this Regulation should apply from the same date as Regulation (EU) 2016/2031.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down procedures for risk assessment foreseen under Article 42(4) of Regulation (EU) 2016/2031 with a view to ensuring that such assessment is conducted within a reasonable period of time and on the basis of a demand for import accompanied by a comprehensive technical dossier and subject to a defined procedure.

Article 2

Submission of technical dossiers

A technical dossier for carrying out the risk assessment referred to in Article 42(4) of Regulation (EU) 2016/2031 may only be submitted to the Commission by a National Plant Protection Organisation of a third country.

The technical dossier shall be accompanied by elements indicating that demand for import exists within the meaning of Article 42(5) of Regulation (EU) 2016/2031.

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Article 3

Content of the technical dossier

The technical dossier shall contain for each plant, plant product or other objects all of the following elements:

(a) information on the commodity, including treatments and processing of the commodity;

(b) information on the identification of pests potentially associated with the commodity in the exporting country;

(c) information on phytosanitary mitigation measures and inspections;

(d) the contact details of the National Plant Protection Organisation contact point of the third country responsible for liaising with the Commission and the European Food Safety Authority (EFSA).

The technical dossier shall also contain all the elements referred to in the EFSA document entitled 'Information required for dossiers to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42 of Regulation (EU) 2016/2031'.

The applicant may indicate the information, the disclosure of which might harm the competitive position of a certain third party and which should therefore be treated as confidential in accordance with Article 6 of this Regulation. Verifiable justification shall be given in such cases.

The dossier shall be submitted in one of the official languages of the Union.

Article 4

Reception and examination of the technical dossier by the Commission

The Commission shall acknowledge receipt of the technical dossier.

It shall examine whether the technical dossier contains the information described in points (a) to (d) of the first paragraph of Article 3, and may ask the applicant for additional information or clarifications, as required by the content and the subject of that technical dossier.

Where the Commission concludes that those requirements are fulfilled, it shall transmit the technical dossier to EFSA and inform Member States accordingly.

Article 5

Conduct and completion of the risk assessment

EFSA shall verify that the technical dossier complies with its document referred to in the second paragraph of Article 3, and may ask the applicant for additional information or clarifications, as required by the content and the subject of the technical dossier.

Following that verification, EFSA shall proceed with the risk assessment.