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COMMISSION DELEGATED REGULATION (EU) 2026/1830

of 16 July 2026

supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council as regards the procedure to be followed to grant temporary derogations from the prohibition provided for in Article 40(1) and from the requirements referred to in Article 41(1) thereof

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 42a(3) thereof,

Whereas:

(1) Regulation (EU) 2016/2031, and in particular Article 40(1) thereof, sets out that the introduction of certain plants, plant products and other objects into the Union territory is prohibited. Furthermore, Article 41(2) of that Regulation provides for a list of plants, plant products and other objects, whose introduction into the Union territory is subject to special or equivalent requirements.

(2) Article 42a(1) of that Regulation provides for temporary derogations from the import prohibition provided for in Article 40(1) and from the special and equivalent requirements referred to in Article 41(2), where the conditions of Article 42a(2) have been fulfilled.

(3) Some cases referred to in Article 42a(2) require the submission of a request by a third country; it is therefore appropriate to establish a procedure to handle such requests.

(4) Such procedure should include rules concerning (i) the preparation, content and submission of the requests and dossiers by the third countries concerned; (ii) the actions to be taken following the reception of those requests and dossiers, including, where appropriate, the consultation of scientific bodies or the consideration of scientific opinions or studies; and (iii) the handling of the requests and dossiers concerning confidentiality and data protection.

(5) A request for such a temporary derogation should only be submitted by the National Plant Protection Organisation ('NPPO') of the third country concerned to the Commission, to ensure that all 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.

(6) For reasons of clarity, certain elements should be ensured during the preparation of the request, namely a specification of the detailed rules from which a temporary derogation is requested, a justification of the need for that derogation, and collection of the necessary information and data to support the content of the dossier. For the same reason, that request should contain a reference to whether the respective temporary derogation concerns Article 40(1) or Article 41(2) of Regulation (EU) 2016/2031 and be accompanied by the technical dossier and a brief summary of its content.

([1]) OJ L 317, 23.11.2016, p. 4, ELI: http://data.europa.eu/eli/reg/2016/2031/oj.

(7) The technical dossier accompanying that request should contain (i) information on the plant, plant product or other object concerned; (ii) information on the identification of all the pests potentially associated with the respective plant, plant product or other object in the third country concerned; (iii) data on phytosanitary mitigation measures and inspections carried out in the respective third country; (iv) contact details of the point of contact responsible for liaising with the Commission and the European Food Safety Authority ('the Authority'); and (v) the information, the disclosure of which might harm the competitive position of a certain third party and which should therefore be treated as confidential. Such data are essential to perform the assessment of the plant, plant product or other object concerned to identify the pest species for which phytosanitary mitigation measures may be required and ensure the confidential treatment of certain information.

(8) It is necessary to update the phytosanitary situation and any other relevant information, while ensuring that the administrative burden remains at the essential level. It is therefore appropriate that, for the purpose of carrying out the updated assessment to renew the derogation period, as referred to in Article 42a(6) of Regulation (EU) 2016/2031, the preparation and content of the request for derogation, and the content of the technical dossier, only concern the elements that have changed during that period or that were not covered by an earlier assessment.

(9) The Authority has already produced a 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' ([2]) for the commodity risk assessment of a plant considered as high-risk in the context of Article 42 of Regulation (EU) 2016/2031. Since the principles of the risk assessment applicable to a technical dossier of a high-risk plant are the same as those applicable for a technical dossier within the meaning of this Regulation, the same document should be used by third countries to submit the technical dossier to request a temporary derogation pursuant to Article 42a(1) of Regulation (EU) 2016/2031.

(10) In the case of a request for a temporary derogation from the Union's special and equivalent requirements, adopted pursuant to Article 41(2), for the import of a specific plant, plant product or other object concerned in relation to a specific pest or pests, the data on the identification of pests potentially associated with that plant, plant product or other object in the third country concerned should be submitted where the special import requirements apply for several quarantine pests but only one or certain of those quarantine pests are relevant for the third country concerned.

(11) It is appropriate that, after acknowledging receipt of the request and the technical dossier, the Commission carries out an administrative verification of the technical dossier by examining whether it contains the required information. The Commission should have the possibility to ask, where necessary, for additional information or clarifications, to ensure that the request contains all the required and appropriate elements for the risk assessment.

(12) The risk assessment should be carried out by the Authority according to its rules and procedures. Therefore, once the administrative verification has been completed, the Commission should request the third country concerned to submit the technical dossier through the designated electronic submission system, including the corresponding confidentiality requests. However, and in order to avoid unnecessary administrative burden, the risk assessment by the Authority should not be required in those cases where the Commission considers that an assessment is already available to allow for the adoption of the respective measure.

(13) Rules should be established concerning the conduct and completion of the risk assessment by the Authority, as well as its communication with the NPPO of the third country concerned, to ensure a transparent, efficient and timely risk assessment process.

([2]) European Food Safety Authority (EFSA), Dehnen-Schmutz K, Jaques Miret JA, Jeger M, Potting R, Corini A, Simone G, Kozelska S, Munoz Guajardo I, Stancanelli G and Gardi C, 2018. 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. *EFSA supporting publication* 2018:15(10):EN-1492, 22 pp., https://doi.org/10.2903/sp.efsa.2018.EN-1492.

(14) Rules should be established concerning the confidential treatment of certain pieces of information, in particular where that is requested by any person with a legitimate interest, in order to protect the interests of that person by the disclosure of that information. In order to cover the cases where confidential treatment would be necessary, those pieces of information should comprise the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety; commercial links between a producer or importer and the requesting person, where applicable; and commercial information revealing sourcing, market shares or business strategy of the requesting person,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the procedure to be followed in order to grant the following temporary derogations:

(a) temporary derogations from the prohibition provided for in Article 40(1) of Regulation (EU) 2016/2031;

(b) temporary derogations from the special and equivalent requirements referred to in Article 41(2) of that Regulation where the requirements for the third country concerned are not more stringent than those referred to in Article 41(2).

Article 2

Preparation and content of requests for derogation

1. The temporary derogations referred to in Article 1 may be adopted only if the National Plant Protection Organisation ('NPPO') of the third country concerned has submitted a request to the Commission.

2. The request shall:

(a) specify the detailed rules from which a temporary derogation is requested;

(b) justify the need for such derogation;

(c) be based on a collection of the necessary information and data to support the content of the dossier as provided for in Article 3(1);

(d) be accompanied by the relevant technical dossier, provided for in Article 3, and a brief summary of the content thereof.

Article 3

Content of technical dossiers

1. The technical dossier referred to in Article 2 shall contain, for each plant, plant product or other object, all of the following elements:

(a) information on the plant, plant product or other object concerned, including the characterisation of the product, a description of the production process, and the respective treatments and processing;

(b) information on the identification of all the pests potentially associated with the plant, plant product or other object concerned in the third country concerned;

(c) data on phytosanitary mitigation measures and inspections carried out in the respective third country;

(d) the contact details of the NPPO point of contact of the third country responsible for liaising with the Commission and the European Food Safety Authority ('the Authority');

(e) the information, the disclosure of which might harm the competitive position of a certain third party and which should therefore be treated as confidential, together with relevant verifiable justification.

2. The information and data referred to in points (a) to (d) of paragraph 1 shall be presented, provided and supported in accordance with the Authority's 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' or any of its updates.

3. Where requests concern temporary derogations from the special or equivalent requirements adopted pursuant to Article 41(2) of Regulation (EU) 2016/2031, the information referred to in point (b) of paragraph 1 of this Article and in the relevant section of the document referred to in paragraph 2 of this Article, shall only be submitted in the cases where:

(a) the special requirements are relevant for more than one species of Union quarantine pest, and only for those quarantine pests referred to in the relevant special requirements; or

(b) the special requirements concern a plant, plant product or other object for which more than one species of Union quarantine pest is relevant, and only for those relevant quarantine pests.

Article 4

Submission of requests and their accompanying technical dossiers

Any request for temporary derogations referred to in Article 1 and its accompanying technical dossier shall be submitted to the Commission by the NPPO of the third country concerned in one of the official languages of the Union.

Article 5

Preparation and content of requests, and content of dossiers, in the case of renewal of derogations

For the purpose of carrying out the updated assessment to renew the five-year period, as referred to in Article 42a(6) of Regulation (EU) 2016/2031, the preparation and content of the request for derogation, referred to in Article 2, and the content of the technical dossier, referred to in Article 3, shall only concern the elements set out in Articles 2(2) and 3(1) that have changed during that period or that were not covered by an earlier assessment.

Article 6

Reception and examination of requests and technical dossiers by the Commission

1. The Commission shall acknowledge receipt of the request, as referred to in Article 2(1) or Article 5 as applicable, and the respective technical dossier.

2. It shall examine whether the technical dossier contains the elements referred to in points (a) to (d) of Article 3(1), taking into account paragraph 3 of that Article, and may ask the NPPO of the third country concerned for additional information or clarifications considering the content of that technical dossier and the plant, plant product or other object concerned.

3. Where the Commission concludes that the technical dossier contains the elements referred to in points (a) to (d) of Article 3(1), or that the additional information or clarifications provided by the NPPO of the third country concerned are sufficient, it shall:

(a) request the NPPO concerned to submit the technical dossier through the electronic submission system established, or designated, by the Commission for that purpose;

(b) request the Authority to issue the respective opinion; and

(c) inform the Member States accordingly.

4. By way of derogation from paragraph 3(b), the Commission may decide not to request the Authority to issue an opinion, where it considers that an assessment is already available and sufficient concerning the request of the third country.

Article 7

Conduct and completion of the risk assessment by the Authority

1. The Authority shall check that the technical dossier, submitted pursuant to Article 2(1), or Article 5 as applicable, fulfils the requirements set out in the document referred to in Article 3(2) and may ask the NPPO of the third country concerned for additional information or clarifications, considering the content of the technical dossier and the plant, plant product or other object concerned.

2. Where the Authority concludes that the technical dossier fulfils the requirements set out in the document referred to in Article 3(2), or that the additional information or clarifications provided by the NPPO of the third country concerned are sufficient, it shall proceed with the risk assessment.

3. The Authority shall assess whether or not the plants, plant products or other objects concerned pose a risk that can be reduced to an acceptable level by applying the measures which are necessary to address the phytosanitary risk.

4. During the conduct of the risk assessment, the Authority may communicate directly with the NPPO of the third country concerned to request additional information or clarifications. The Authority shall inform the Commission of every communication with the NPPO of the third country concerned.

5. The Authority shall complete the risk assessment within a reasonable period of time and publish the risk assessment in its Journal.

Article 8

Commission act

Taking into account the risk assessment provided for in Article 7, the Commission shall, as appropriate, adopt an act granting the requested temporary derogation, or shall communicate to the NPPO of the third country concerned, its decision not to grant the requested derogation.

Article 9

Confidentiality

Any party participating in the procedure set out in this Regulation, shall not make public any confidential information. In assessing whether the information is confidential, account shall be taken of whether a person with a legitimate interest ('requesting person') requested confidential treatment of such information. That assessment shall take place without prejudice to the national rules on protection of confidential information.

The obligation not to make public confidential information shall concern the following pieces of information, where the disclosure of such information may potentially harm the competitive position or any other interest of the requesting person:

(a) the manufacturing or production process, including the method thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of phytosanitary risk;

(b) commercial links between a producer or importer and the requesting person, where applicable;

(c) commercial information revealing sourcing, market shares or business strategy of the requesting person.

Article 10

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 July 2026.

For the Commission
The President
Ursula VON DER LEYEN