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COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, authorising Member States to provide for temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections, or breeding

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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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 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/EC¹, and in particular Articles 8(5) and 48(5) thereof,

Whereas:

- (1) In accordance with Regulation (EU) 2016/2031, Member States may, on application, temporarily authorise the introduction into, the movement within, and the holding and multiplication in their territory of Union quarantine pests or pests subject to the measures adopted pursuant to Article 30(1) of that Regulation for official testing, scientific or educational purposes, trials, varietal selections, or breeding. Moreover, Member States may, on application, authorise temporarily the introduction into, and the movement within, their territory of plants, plant products and other objects used for official testing, scientific or educational purposes, trials, varietal selection or breeding.
- (2) It is necessary to supplement Regulation (EU) 2016/2031 by adopting rules on the exchange of information between Member States and the Commission concerning the introduction into, and movement within, the Union territory of the pests, plants, plant products and other objects concerned, the procedures and conditions for granting the respective authorisations, as well as the requirements for the monitoring of compliance and the actions to be taken in the event of non-compliance.
- (3) In order to ensure that the phytosanitary risk linked to the specified activities is eliminated or reduced to an acceptable level, the authorisation of the introduction into, and the movement within, the Union of any specified material should be subject to certain conditions ensuring the submission of a complete and appropriate application, the examination of the nature and objectives of the specified activities, the confirmation that the specified activities are performed in quarantine stations or confinement facilities and the destruction and safe removal of contaminated material.
- (4) In order to ensure monitoring and traceability of the specified material concerned, and to immediately address any associated phytosanitary risk, it is appropriate that, following the granting of that authorisation, the competent authority of the Member

¹ OJ L 317, 23.11.2016, p. 4.

State in which the approved specified activity is to be carried out should issue a letter of authority, which should always accompany the specified material concerned.

- (5) Since it has proven to be implemented in an effective and consistent manner, the format of the letter of authority should be similar to the format set out in Annex II to Commission Directive 2008/61/EC².
- (6) A single letter of authority should be used for the multiple introductions into, and movements within the Union of specified material subject to the specified activities, and in accordance with special conditions, so as to ensure a proportionate and effective framework for such introductions and movements.
- (7) Official testing presents a lower level of phytosanitary risk and is carried out more frequently than the other specified activities. It is therefore proportionate to allow less stringent conditions for official testing than for the other specified activities.
- (8) Rules should be established concerning the actions to be taken by the competent authorities, in the cases of non-compliance with the provisions of this Regulation, to ensure corrective actions as soon as possible. Those actions should include obligations for the person responsible for the specified activities.
- (9) For purposes of legal certainty and clarity Directive 2008/61/EC should be repealed.
- (10) In order to allow for the smooth termination of the activities authorised, it is appropriate to extend the validity of the approvals of those activities for a specified period of time.
- (11) For reasons of legal certainty, this Regulation should apply from the same date as Regulation (EU) 2016/2031,

HAS ADOPTED THIS REGULATION:

Article 1 *Scope*

This Regulation lays down the conditions for derogation from Articles 5(1), 30(1), 32(1), 40(1), 41(1), 42(2), 49(1), 53(1) and 54(1) of Regulation (EU) 2016/2031, under which specified pests and plants, plant products and other objects, as defined in Article 2 of this Regulation, may be introduced into, or moved, held, multiplied or used within, the Union, or protected zones therein, for official testing, scientific or educational purposes, trials, varietal selection or breeding.

In particular, this Regulation establishes:

- (a) the rules concerning the exchange of information between Member States and the Commission concerning the introduction into, and movement within, or holding, multiplying or use within the Union, or protected zones therein, of specified pests or plants, plant products and other objects;
- (b) the procedure and the conditions under which a temporary authorisation shall be granted by Member States for the performance of the specified activities;

² Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections (OJ L158, 18.6.2008, p. 41).

- (c) the rules concerning the monitoring of compliance, and the actions to be taken in case of non-compliance.

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'specified pests' means one of the following:
 - (i) Union quarantine pests, listed pursuant to Article 5 of Regulation (EU) 2016/2031,
 - (ii) pests subject to the measures adopted pursuant to Article 30(1) of that Regulation,
 - (iii) protected zone quarantine pests, listed pursuant to Article 32(3) of that Regulation.
- (b) 'plants, plant products or other objects' means the plants, plant products or other objects listed pursuant to Articles 40(2), 41(2), 42(2), 49(1), 53(2) and 54(2) of Regulation (EU) 2016/2031;
- (c) 'specified material' means any specified pests, plants, plant products or other objects requiring an authorisation within the meaning of this Regulation;
- (d) 'official testing' means testing carried out by competent authorities, or under the official supervision of the competent authorities;
- (e) 'specified activities' means any activity carried out by any person, including competent authorities, academic institutions, research institutions or professional operators, related to official testing, scientific or educational purposes, trials, varietal selection or breeding, that involves the introduction into, the movement within, holding, multiplication or use in the Union and protected zone thereof, of any specified material.

Article 3
Exchange of information between Member States and the Commission

1. Member States shall cooperate administratively with regard to the exchange of information between Member States and the Commission concerning the introduction into, movement within, and holding, multiplication and use in, the Union territory or protected zones thereof of any specified material.
2. For the purposes of paragraph 1, Member States shall send, before 31 March each year, to the Commission and to the other Member States all of the following information:
 - (a) a list with types and quantities of specified material authorized under this Regulation, and introduced into or moved within the Union, during the preceding calendar year;
 - (b) a report on the presence of the specified pests authorized under this Regulation, and, where applicable, on the infestation of the specified material by any other specified pests or any other pests considered as a risk to the Union by the competent authority, and detected during the specified activities. In the case where the specified material is a specified pest itself, the report shall concern,

where applicable, the presence of any other specified pests, or any other pests considered a risk to the Union by the competent authority, and detected during the specified activities;

- (c) measures taken in case of non-compliance;
 - (d) the list of quarantine stations and confinement facilities used for the purposes of this Regulation.
3. The introduction into the Union of the specified material for the purpose of specified activities authorised pursuant to Article 5 shall be recorded, together with the respective authorisation, in a computerised information management system for official controls (IMSOC) as referred to in Article 131 of Regulation (EU) 2017/625 of the European Parliament and of the Council³.

Article 4 Application

Prior to any introduction into, and movement within, holding, multiplication, and use, in the Union of the specified material, in accordance, as applicable, with Articles 8(1) and 48(1) of Regulation (EU) 2016/2031, an application shall be submitted to the competent authorities.

Its content shall comply with the requirements laid down in Annex I to this Regulation.

Article 5 Conditions to grant the authorisation

The authorisation of the introduction into, and movement within, holding, multiplication and use, in the Union of the specified material, in accordance, as applicable, with Articles 8(1) and 48(1) of Regulation (EU) 2016/2031 shall be granted by the Member States for a limited period of time and only where the following conditions are satisfied:

- (a) the application has been found to be in compliance with Article 4 of this Regulation;
- (b) the nature and objectives of the specified activities proposed in the application have been examined by the competent authority and found to comply with the definition of specified activities provided in Article 2 of this Regulation;
- (c) the specified activities have been confirmed to be performed in quarantine stations or confinement facilities indicated in the application and designated by the competent authority in compliance with Articles 60 and 61 of Regulation (EU) 2016/2031;
- (d) it has been ensured that, following the completion of the specified activity concerned by that authorisation, where the material is a specified pest or a plant, plant product or other object infested by a specified pest, it has been destroyed and safely removed, or stored under appropriate conditions for further use.

³ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

Article 6

Letter of authority following the authorisation

1. Following the granting of the authorisation referred to in Article 5, a letter of authority shall be issued by the competent authority of the Member State in which the approved specified activity is to be carried out. This letter of authority shall always accompany the specified material concerned.
2. In the case of specified material originating in the Union, the letter of authority shall conform to the format set out in Part A of Annex II. It shall be officially endorsed by the Member State of origin, for movement of the respective specified material under quarantine or confinement conditions.
3. In the case of specified material originating in third countries, the letter of authority shall conform to the format set out in Part B of Annex II. It shall be officially endorsed by the third country of origin, for introduction of the respective specified material under quarantine or confinement conditions.
4. In the case of multiple introductions into, or movements within, the Union, of a specific type of specified material, one single letter of authority may be issued by the competent authority at the moment of the first sending and covering all those introductions or movements, subject to all of the following conditions:
 - (a) the introductions or movements take place several times per year;
 - (b) the specified material is under the same packaging conditions;
 - (c) the specified material is from the same provider and to the same person responsible for the approved activities.

The competent authority shall explicitly indicate in box 10 of the format set out in Parts A and B of Annex II, that that endorsement covers multiple introductions into, or movements within, the Union of that specified material. That endorsement shall last from the date of issuance of the letter of authority up to the 31 December of the year of that issuance.

Article 7

Special provisions for official testing

By way of derogation from Articles 4, 5 and 6, Member States shall grant an authorisation for the performance of official testing, only if all of the following conditions are fulfilled:

- (a) the person responsible for the approved activities has notified that official testing to the competent authority;
- (b) that notification contains the nature and objectives of that testing;
- (c) the notification contains a confirmation that the official testing is performed in quarantine stations or confinement facilities as referred to in point (c) of Article 4(2).

Article 8

General provisions concerning monitoring of compliance

The competent authority shall monitor the specified activities to ensure that all of the following requirements are fulfilled:

- (a) any infestations of the specified material by any specified pests which are not authorized under this Regulation, or by any other pests considered a risk to the Union, and detected during the specified activities, are notified immediately by the

person responsible for the activities to the competent authority. Where the material is a specified pest itself, the monitoring shall concern its potential infestation by other specified pests not authorized under this Regulation, or any other pests considered a risk to the Union by the competent authority, and detected during the specified activities;

- (b) any event resulting in the escape, or likelihood of escape, of pests referred to in point (a) into the environment, is notified immediately to the competent authority by the person responsible for the activities.

Article 9

Actions to be taken in the event of non-compliance

1. The competent authority may require the person responsible for the activities to implement corrective actions to ensure compliance with the provisions set out in this Regulation, either immediately or within a specified period of time.
2. Where the competent authority concludes that the person responsible for the activities fails to comply with the provisions set out in this Regulation, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue. Those measures may include the revocation or the temporary suspension of the authorisation referred to in Article 5.
3. Where the competent authority has taken measures in accordance with paragraph 2, other than the revocation of the authorisation, and non-compliance with this Regulation continues, that authority shall without delay revoke that authorisation.

Article 10

Repeal of Directive 2008/61/EC and transitional period for its approved activities

Directive 2008/61/EC is repealed.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

The approvals of the activities granted pursuant to Article 2 of that Directive shall expire on 31 December 2020.

Article 11

Date of entry into force and date of application

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

It shall apply from 14 December 2019.

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER



Brussels, XXX
SANTE/10944/2018
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[...] (2018) XXX draft

ANNEXES 1 to 3

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, authorising Member States to provide for temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections, or breeding

ANNEX I

1. The application referred to in Article 4 shall include, at least, the following elements:
 - (a) the name, address, email address and phone number of the applicant, and of the person(s) responsible for the specified activity if different, including their scientific and technical qualifications for the purpose of the specified activities;
 - (b) the type of the specified material, the scientific name or the name of the specified material, and any published references where relevant, including information on potential vectors;
 - (c) the quantity of the specified material, justified according to the purpose of the specified activity concerned and to the capacity of the quarantine station or confinement facility;
 - (d) the place of origin of the specified material, including the name, address, email address and phone number of the supplier and with appropriate documentary evidence in case the specified material is to be introduced from a third country;
 - (e) the duration of the specified activity, as well as a summary of the nature and the objectives of the specified activity, and a specification in case of trials, and scientific or educational works for varietal selections;
 - (f) the packaging conditions under which the organism will be moved or imported;
 - (g) the name, the address and the description of the quarantine stations or confinement facilities containment;
 - (h) the final use of the specified material e.g.; destruction, collection, release;
 - (i) the method of destruction or treatment of the specified material on completion of the specified activity where applicable.
2. Other information or clarification shall be provided under request of the competent authority.

ANNEX II

- A. Model Letter of Authority for movement within the Union of pests, plants, plant products and other objects for scientific or educational purposes, trials, varietal selection or breeding, referred to in Article 6(2)

Title: Letter of Authority	Reference
1. Name, address email address and phone number of the [consignor]/[plant protection organisation]* of the Member State of origin	- -
2. Name of the responsible body of the Member State of issue	-
3. Name, address, email address and phone number of the person responsible for the specified activities	- -
4. Name and address of the [quarantine site]/[confinement facilities]*	- -
5. Scientific name when appropriate, or name of the specified material, including scientific name of the specified pest concerned.	- -
6. Quantity of specified material	-
7. Type of specified material	-
8. Packaging and movement conditions**	8.1. 8.2. 8.3.
9. Additional information	This specified material is moved within the Union territory under Regulation (EU) .../... [Office of Publication please Insert the reference of this Regulation]
10. Multiple sendings: [yes]/[no]*	If yes: Date of issuance: End date: 31 December/ *** Traceability number: Quantity of specified material:
11. End use	Destruction/storage/release*
12. Endorsement by the National Competent Authority of the Member State of origin of the specified material. Place of endorsement: Date: Name and signature of the authorised officer:	13. Stamp of the responsible official body issue Place of issue: Date: Name and signature of the authorised officer:
14. IMSOC reference	

* strike out what does not apply.

** 8.1. postal/ delivery company/passenger/other to precise; 8.2. road/train/flight/boat/other to precise; 8.3. ambient temperature/controlled t° (which one).

*** Obligatory the same year than the year of the issuance.

B. Model Letter of Authority for introduction into the Union of pests, plants, plant products and other objects for scientific or educational purposes, trials, varietal selection or breeding, referred to in Article 6(3)

Title : Letter of Authority	Reference
1. Name, address, email address and phone number of the [consignor]/[plant protection organisation]* of the third country of origin	- -
2. Name of the responsible body of the Member State of issue	-
3. Name, address, email address and phone number of the person responsible for the specified activities	- -
4. Name and address of the [quarantine site]/[confinement facilities]*	- -
5. Scientific name when appropriate, or name of the specified material, including scientific name of the specified pest concerned.	- -
6. Quantity of specified material	-
7. Type of specified material	-
8. Packaging and import conditions**	8.1. 8.2. 8.3.
9. Additional information	This specified material is imported within the Union territory under Regulation (EU) .../... [Office of Publication please Insert the reference of this Regulation]
10. Multiple sendings: [yes]/[no]*	If yes: Date of issuance: End date: 31 December/ *** Traceability number: Quantity of specified material:
11. End use	Destruction/collection or storage/release*
12. Endorsement by the National Plant Protection Organization (NPPO) of the third country of origin of the specified material. Place of endorsement: Date: Name and signature of the authorised officer:	13. Stamp of the responsible official body issue Place of issue: Date: Name and signature of the authorised officer:
14. IMSOC reference	

* strike out what does not apply.

** 8.1. postal/ delivery company/passenger/other to precise; 8.2. road/train/flight/boat/other to precise; 8.3. ambient temperature/controlled t° (which one).

*** Obligatory the same year than the year of the issuance.

ANNEX III

Correlation table

Directive 2008/61/EC	This Regulation
Article 1 (1)	Article 4
Article 1 (2)	Article 4, Annex I
Article 2 (1) first subparagraph	Article 5
Article 2 (1) second subparagraph	Article 9 (2)
Article 2 (2)	Article 6, Annex II
Article 2 (3)	Article 8
Article 2 (4)	—
Article 3	—
Article 4	—
Article 5	—
Article 6	Article 11
Article 7	—
Annex I, point 1	Article 5
Annex I, point 2	—
Annex II	Annex II
Annex III	—
Annex IV	—
Annex V	Annex III