COMMISSION DELEGATED REGULATION (EU) 2019/829

of 14 March 2019

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

for England, Wales and Scotland

Unofficial consolidated version. Amended by
M1 The Plant Health (Amendment etc.) (EU Exit) Regulations 2020, No. 1482
M2 The Pests of Plants (Authorisations) (Amendment) Regulations 2022, No. 1020
M3 The Plant Health and Phytosanitary Conditions (Oak Processionary Moth andPlant Pests) (Amendment) Regulations 2023, No 497

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/EC ([1]), 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, on the procedures and conditions for granting the respective authorisations, as well as on 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 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/EC ([2]).

(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 is carried out more frequently than the other specified activities. It would therefore be more efficient to allow a more flexible framework for official testing than for the other specified activities.

([1]) OJ L 317, 23.11.2016, p. 4.
([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 L 158, 18.6.2008, p. 41).

(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) This Regulation should apply without prejudice to any rules adopted pursuant to Article 48 of the Regulation (EU) 2017/625 of the European Parliament and of the Council ([3]) (Official Controls Regulation) with regard to goods exempted from official controls at border control posts.

(11) 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.

(12) 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 certain provisions 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, >**M1** Great Britain <, or >**M1** GB pest-free areas >therein, for official testing, scientific or educational purposes, trials, varietal selection or breeding. In particular, this Regulation sets out derogations from the following provisions of Regulation (EU) 2016/2031:

(a) Article 5(1), >**M1** ----- <;

(b) Article 30(1), >**M1** ----- <;

(c) Article 32(2), >**M1** ----- <;

(d) Article 40(1), >**M1** ----- <;

(e) Article 41(1), >**M1** ----- <;

(f) Article 42(2), >**M1** ----- <;

(g) Article 49(1), >**M1** ----- <;

(h) Article 53(1), >**M1** ----- <;

(i) Article 54(1), >**M1** ----- <.

([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).

In particular, this Regulation establishes:

(a) >**M1** ----- <

(b) the procedure and the conditions under which a temporary authorisation shall be granted by >**M1** competent authorities < for the performance of the specified activities;

(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) >**M1** GB quarantine pests <,

(ii) >**M1** provisional GB quarantine pests <,

(iii) >**M1** PFA quarantine pests < .

(b) 'plants, plant products or other objects' means the plants, plant products or other objects >**M1** that are subject to measures specified in regulations made under Article 30(A2) or 49(1), or are subject to Article 40(1), 41, 42(2), 53(1) or 54(1) <;

(c) 'specified material' means any specified pests, plants, plant products or other objects requiring an authorisation within the meaning of this Regulation;

(d) '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 >**M1** or the <, holding, multiplication or use in >**M1** Great Britain or any GB pest-free area <, of any specified material.

>**M1** Unless the context otherwise requires, any other words and expressions which are not defined in this Regulation and appear in Regulation (EU) 2016/2031 of the European Parliament and of the Council have the same meaning in this Regulation as they have in Regulation (EU) 2016/2031. <

▼M2

~~*Article 3*~~

~~**Exchange of information between Member States and the Commission**~~

deleted

<

Article 4

Application

Prior to any introduction into, and movement within, holding, multiplication, and use, in >**M1** Great Britain < 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 authority.

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 >**M1** Great Britain < 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 >**M1** competent authorities < 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 >**M1** will be < ensured that, following the completion of the specified activity concerned by that authorisation, the specified material has been destroyed and safely removed, stored under appropriate conditions for further use >**M1** or released and moved < in accordance with Article 64 of Regulation (EU) 2016/2031.

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 >**M1** -----<.

2. >**M1** ----- < The letter of authority shall conform to the format set out in >**M1** ----- < Annex II. >**M1** ----- <

3. >**M1** ----- <

4. >**M2** The letter of authority issued by the competent authority for a type of specified material covers all introductions into or movement within Great Britain of that material, subject to the following condition.

For movement within Great Britain, a copy of the letter of authority must be endorsed by the competent authority of the relevant territory of Great Britain from which the material is to be moved (where that authority is not the issuing authority).

The letter of authority is valid until the end of 31st December in the calendar year in which it is issued. <

Article 7

Special provisions for official testing

By way of derogation from Articles 4, 5 and 6, >**M1** the competent authority < shall grant an authorisation for the performance of official testing, carried out by the competent authority or by >**M1** the professional operator < under the official supervision of the competent authority, if all of the following conditions are fulfilled:

(a) the person responsible for the approved activities has notified official testing to the competent authority before it takes place;

(b) that notification contains the nature and objectives of that official 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 5;

(d) the official testing is carried out in such a way that there is no spread of specified pests during the handling and transport of the specified material prior, during, and after the official testing.

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 authorised under this Regulation, or by any other pests considered a risk to >**M1** Great Britain <, 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 authorised under this Regulation, or any other pests considered a risk to >**M1** Great Britain < 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.

>M1 ----- <

States. Done at Brussels, 14 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

1. The application referred to in Article 4 shall include, at least, the following elements, as applicable:

   (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, >**M2** ----- < 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 >**M2** and address (including country) >**M3** of the laboratory or institution from which the material originated <, with appropriate documentary evidence where < 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 additionally, a specification in case of trials, and scientific or educational works related to varietal selections;

   (f) the packaging conditions under which the specified material will be moved or imported;

   (g) the name, the address and the description of the quarantine station or confinement facility;

   (h) the final use of the specified material on completion of the specified activity e.g.; destruction, collection, storage >**M1** or release and movement to another quarantine station or confinement facility <;

   (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.

▼M2

SCHEDULE

Regulation 2

Model Letter of Authority for the introduction into, or movement within, Great Britain of pests, plants, plant products and other objects for scientific or educational purposes etc

1. Name and address of the place of origin of the specified material, including country	**Letter of Authority** for the introduction into, or movements within, England / Wales / Scotland of pests, plants, plant products and other objects for scientific or educational purposes, trials, varietal selection or breeding (issued under Articles 8 and 48(1) of Regulation (EU) 2016/2031 and Commission Delegated Regulation (EU 2019/829)
2. Name, address, email address and phone number of person responsible for the specified activities «OrgName» «ORGADDR1» «ORGADDR2» «ORGADDR3» «ORGADDR4» «ORGADDR5» «ORGPOSTCD»	3. Name of the responsible competent authority of issue (logo) delete other bodies as required. **Department for Environment, Food and Rural Affairs (Defra) / Welsh Government / Scottish Government**
4. Name and address of the Confinement facility/Quarantine station «Containment facilities - rooms specified» at the above address	5. Declared point of entry for material introduced from a third country Great Britain - «Point of entry»
6. Scientific name(s) when appropriate, or name of the specified material, including scientific name of the specified pest concerned and the country(s) of origin the material may be imported from: «Specified material covered by authorisation»	7. Quantity of specified material «Quantity covered by authorisation» If Annex 1 says N/A, please write As Required
8. Type of specified material Authorisation for the introduction into, movement within, and holding, multiplication and use of «specified material»	
9. Packaging and import / movement conditions	
10. Additional declaration **This specified material is introduced into / moved within Great Britain territory under Articles 8 and 48(1) of Regulation (EU) 2016/2031 and Delegated Regulation (EU) 2019/829** **and plant health authorisation no**********	
11. Date of issuance: Valid from «issue date» to 31 December of the same year. Reference number of the sending: Quantity per sending of the specified material:	12. Final Use (tick appropriate option or specify other): Destruction ☐ Collection ☐ Storage ☐ Other, specify..... ☐
13. For internal movement within GB only: endorsement by the competent authority of the relevant territory of GB from which material is moved: Place of endorsement: Date: ********** Signature of authorised officer: Name in BLOCK LETTERS NAME HERE	14. Stamp of the responsible competent authority of issue Place of issue: Date: xx/xx/xxx Signature of authorised officer: Name (BLOCK LETTERS) NAME HERE

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