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## **Elements of a Draft Delegated Act**

### **Second meeting of the Expert Group on Plant Health (E00925) On a Delegated Act on Exceptions for Movement of Scientific Material**

**Centre de Conférence Albert Borschette CCAB  
26 March 2018, 09H00 - 13H00**

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#### **CHAPTER I SCOPE AND DEFINITIONS**

##### *Article 1*

##### **Scope**

This Regulation lays down the conditions for derogation from Articles 5(1), 32(1), 40(1), 41(1), 42(2), 49(1), 53(1) and 54(1) of the Regulation 2016/2031, under which specified pests and plants, plant products and other objects, as defined in Article 2, may be introduced into, or moved, held, multiplied, used or released 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 Commission concerning the introduction into, and movement within, or holding, multiplying, use or release 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 temporarily authorisation shall be granted by Member States 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, with the provisions laid down hereinafter.]

<p><i>Assistance of the experts: should the scope also cover official testing? This is not currently covered by Directive 2008/61</i></p>
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## *Article 2*

### **Definitions**

For the purpose 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 Article 40(2) and (3), Article 41(2) and (3), Article 42(2), Article 53(2) and (3), Article 54(2) and (3) and Article 49(1) of Regulation (EU) 2016/2031;
- (c) 'material' means any specified pests or plants, plant products or other objects;
- (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 related to official testing, scientific or educational purposes, trials, varietal selection or breeding, that involves the introduction into, the movement within, holding, multiplication, use or release in, the Union and protected zone thereof, of any material;
- (f) 'authorisation' means the authorisation referred to in Article 3 of the present Regulation.

## **CHAPTER II**

### **EXCHANGE OF INFORMATION BETWEEN MEMBER STATES AND THE COMMISSION**

## *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 of the pests, plants, plant products and other objects concerned
2. For the purpose of paragraph 1, Member States shall send, before 1 September each year, to the Commission and to the other Member States all of the following pieces of information:
  - (a) a list with quantities of material approved under this Decision, and introduced into or moved within the Union, during the preceding period of one year ending on 30 June;
  - (b) a report on any contamination by specified pests of such material, which has been confirmed under the quarantine measures carried out under Annex II during the same period;
  - (c) measures taken in case of non-compliance;
  - (c) the list of quarantine stations and confinement facilities used for the purpose of this Regulation.

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3. [The introduction into the Union of the material for the purposes of specified activities authorised pursuant to Article 5 shall be recorded in IMSOC as referred to in Article 131 of OCR]

***Comment from COM: DG SANTE will offer a briefing on the functioning of IMSOC.***

***-The Experts are invited also offer their views on whether internal movements of that material should be recorded in IMSOC.***

### CHAPTER III

## CONDITIONS, PROCEDURE AND GRANTING OF THE AUTHORISATION

### *Article 4*

#### **General conditions**

1. Prior to any specified activities on any material, an application shall be submitted to the competent authorities.
2. The authorisation shall be granted by Member States only where the following conditions are satisfied:
  - a) the application shall comply with the requirements under Annex I;
  - 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 the provisions of Articles 60 and 61 of the Regulation (EU) 2016/2031. The conditions of quarantine or confinement, and the quarantine stations and confinement facilities where the specified activities are to be undertaken have been proved to be sufficient to ensure a safe handling of the material, such that any risk of spread or accidental release of the specified pests is eliminated, and comply with the requirement provided in Article 61(1) and the rules adopted pursuant to Article 61(2) of Regulation (EU) 2016/2031.

### *Article 5*

#### **Authorisation**

Member States shall grant an authorisation for the performance of the specified activities, when it is assessed that the general conditions set out in Article 4, are satisfied.

Following that authorisation, Member States shall ensure that the material is held under quarantine or confinement conditions, as appropriate, during the said introduction or movement, and is moved directly and immediately to the site or sites specified in the application.

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## *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 concerned material.
2. In the case of material originating in the Union, the Letter of Authority shall conform to the format set out in Part A of Annex II and shall be officially endorsed by the Member State of origin for movement of the material under quarantine or confinement conditions, as appropriate.
3. In the case of material originating in third countries, the Letter of Authority shall conform to the format set out in Part B of Annex II and shall be officially endorsed by the Third Country of origin for movement of the material under quarantine or confinement conditions, as appropriate.
4. In the case of multiple introductions or moves, several times per year, of a specific type of material, under the same packaging conditions, from the same provider and to the same person responsible for the approved activities, and through the same entry point (if appropriate), one single Letter of Authority shall be issued by the competent authority at the moment of the first sending and covering all those introductions or moves.

The competent authority shall explicitly endorse in box 11 of the format of Part A or box 12 Part B of Annex II, that that endorsement covers multiple introductions into, or movements within, the Union of that material. That endorsement shall last from the date of issuance of the Letter of Authority up to the 31 December of the respective year of that issuance. It shall also provide for documentation ensuring the traceability of those introductions and movements.

#### **Assistance of the experts: :**

- *to confirm whether this Article 6 reflects their comments from the last meeting*
- *to offer their feedback on how to ensure traceability of multiple movements*

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## CHAPTER IV

### MONITORING OF COMPLIANCE AND ACTIONS TO BE TAKEN IN CASE OF NON-COMPLIANCE

#### *Article 8*

##### **General provisions concerning monitoring of compliance**

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

- a) the premises and activities are officially examined at appropriate times to ensure that the conditions referred to in Article 4 are complying with throughout the duration of the activities;
- b) any contamination of the material by specified pests, and any other pest considered a risk to the Union by the competent authority, and detected during the specified activities are notified immediately by the person responsible for the activities to the competent authority;
- c) any event resulting in the escape, or likelihood of escape, of pests referred to in point (b) 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.

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CHAPTER V  
FINAL PROVISIONS

*Article 10*

**Repeal of Directive 2008/61/EC**

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 [one year after the year of entry into force].

**Assistance of the experts:**

- *Should this Regulation apply at a date later than 14 December 2019?*
- *Is a transitional period needed?*

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

Done at Brussels,

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## ANNEX I

1. The application shall include, at least, the following elements:

- a) the name, 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 scientific name or the name of the material and any published references, including information on potential vectors, where relevant;
- c) the type of the material;
- d) the quantity of the material, justified according to the purpose of the specified activity concerned and to the capacity of the quarantine station or confinement facility;
- e) the place of origin of the material, including the name, address and phone number of the supplier and with appropriate documentary evidence in case the material is to be introduced from a third country;
- f) 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 trial or scientific purposes or work on varietal selections;
- g) the packaging conditions under which the organism will be imported;
- h) the point of entry into the Union for material to be introduced from a third country;
- i) the place of first storage;
- j) the name, the address and the description of the quarantine stations or confinement facilities containment;
- k) the final use of the material e.g.; destruction, collection, release;
- l) the method of destruction or treatment of material on completion of the specified activity where applicable.

2. Other information or clarification shall be provided, under request of the competent authority.

<p><i>Assistance of the experts:</i> <i>- Should there be other conditions, or should conditions be deleted?</i></p>
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ANNEX II

A. Model Letter of Authority for movement, within EU, of harmful organisms, plants, plant products and other objects for trial or scientific purposes and for work on varietal selections

1. Name, 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, 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 material, including scientific name of the harmful organism concerned.	- -
6. Quantity of material	-
7. Type of material	-
8. Packaging and import conditions**	- -
9. Additional information	This material is moved within the European Union territory under Act XX/XXX
10. Additional declaration if appropriate	-
11. Multiple sendings : [yes]/[no]*	If yes: Date of issuance : End date : 31 December/ .... *** Track number :
12. Endorsement by the responsible body of the Member state of origin of the 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:

\*strike out what does not apply.

\*\*postal/ delivery company/passenger ; road/train/flight/boat ; ambient temperature/controlled t° (which one).

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

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B. Model Letter of Authority for introduction into EU of harmful organisms, plants, plant products and other objects for trial or scientific purposes and for work on varietal selections.

1. Name, address and phone number of the [consignor]/[plant protection organisation]* of the Third Country state of origin	- -
2. Name of the responsible body of the Member state of issue	-
3. Name, 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 material, including scientific name of the harmful organism concerned.	- -
6. Quantity of material	-
7. Type of material	-
8. Packaging and import conditions**	- -
9. Point of entry	
10. Additional information	This material is moved within the European Union territory under the Act XX/XXX
11. Additional declaration if appropriate	-
12. Multiple sendings : [yes]/[no]*	If yes: Date of issuance : End date : 31 December/ .... *** Track number :
13. Endorsement by the responsible body of the Country of origin of the material.  Place of endorsement:  Date:  Name and signature of the authorised officer:	14. Stamp of the responsible official body issue  Place of issue:  Date:  Name and signature of the authorised officer:

\*strike out what does not apply.

\*\*postal/ delivery company/passenger ; road/train/flight/boat ; ambient temperature/controlled t° (which one).

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*Assistance of the experts:*

*- Should there be other information, including in the indexed texts (\*, \*\*, \*\*\*)?*

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