

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 (Codified version)

*Article 1*

1 Member States shall ensure that for any activity for trial or scientific purposes and for work on varietal selections, hereinafter referred to as ‘the activities’, which would involve the use of harmful organisms, plants, plant products and other objects pursuant to Article 3(8), 4(5), 5(5) or 13b(4) of Directive 2000/29/EC, hereinafter referred to as ‘the material’, an application shall be submitted to the responsible official bodies prior to the introduction into, or movement within, any Member State or relevant protected zones thereof, of any such material.

2 The application referred to in paragraph 1, shall specify at least the following:

- a the name and address of the person responsible for the activities;
- b the scientific name or names of the material, including the harmful organism concerned, where appropriate;
- c the type of material;
- d the quantity of material;
- e the place of origin of the material, with appropriate documentary evidence for material to be introduced from a third country;
- f the duration, nature and objectives of the activities envisaged, including, at least, a resumé of the work and a specification for trial or scientific purposes or work on varietal selections;
- g the address and description of the specific site or sites for quarantine containment and, where appropriate, for testing;
- h the place of first storage or of first planting, as appropriate, after the material has been officially released, where appropriate;
- i the proposed method of destruction or treatment of material on completion of the approved activities, where appropriate;
- j the proposed point of entry into the Community for material to be introduced from a third country.

*Article 2*

1 Member States, on receipt of the application referred to in Article 1, shall approve the activities concerned, if it is established that the general conditions laid down in Annex I are satisfied.

Member States shall withdraw the said approval at any time if it is established that the conditions laid down in Annex I cease to be met.

2 Following the approval of the activities referred to in paragraph 1, Member States shall approve the introduction into or movement within the Member State or relevant protected zones of the material referred to in the application, provided that such material is accompanied in all cases by a letter of authority for such introduction or movement of harmful organisms, plants, plant products and other objects for trial or scientific purposes and for work on varietal selections, hereinafter referred to as a ‘letter of authority’, conforming to the model set out in Annex II and issued by the responsible official body of the Member State in which the activities are to be undertaken, and

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- a in the case of material originating in the Community:
- (i) where the place of origin is in another Member State, the accompanying letter of authority shall be officially endorsed by the Member State of origin for movement of the material under quarantine containment conditions; and
  - (ii) for those plants, plant products and other objects listed in Annex V, Part A to Directive 2000/29/EC, the material shall also be accompanied by a plant passport issued in accordance with Article 10 of Directive 2000/29/EC, on the basis of the examination carried out pursuant to Article 6 of that Directive for compliance with the provisions laid down therein, other than those relating to any harmful organism in respect of which the activities have been approved under the first subparagraph of paragraph 1 of this Article. The plant passport shall contain the following statement: ‘This material is moved under Directive 2008/61/EC’.

In cases where the address of the specific site or sites for quarantine containment is located in another Member State, the Member State responsible for issuing the plant passport shall issue a plant passport only on the basis of information regarding the approval referred to in the first subparagraph of paragraph 1 of this Article received officially from the Member State responsible for the approval of the activities, and on the assurance that quarantine containment conditions shall be applied during movement of the material; and

- b in the case of material introduced from a third country:
- (i) Member States shall ensure that the letter of authority is issued on the basis of appropriate documentary evidence as regards the place of origin of the material; and
  - (ii) for plants, plant products and other objects listed in Annex V, Part B to Directive 2000/29/EC the material shall also be accompanied wherever possible by a phytosanitary certificate issued in the country of origin in accordance with Article 13(1) of Directive 2000/29/EC, on the basis of the examination carried out pursuant to Article 6 of that Directive for compliance with the provisions laid down therein, other than those relating to any harmful organism in respect of which the activities have been approved under the first subparagraph of paragraph 1 of this Article.

The certificate shall, under ‘Additional declaration’, contain the following indication: ‘This material is imported under Directive 2008/61/EC’. The relevant harmful organism or organisms shall also be specified, where appropriate.

In all cases Member States shall ensure that the material is held under quarantine containment conditions during the said introduction or movement, and is moved directly and immediately to the site or sites specified in the application.

- 3 The responsible official body shall monitor the approved activities and shall ensure that:
- a the quarantine containment conditions and other general conditions specified in accordance with Annex I are complied with throughout the duration of the activities, by examination of the premises and activities at appropriate times;
  - b the following procedures are applied according to the type of approved activities:

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- (i) for plants, plant products or other objects intended for release from quarantine:
  - the plants, plant products or other objects shall not be released without approval by the responsible official body, hereinafter referred to as ‘official release’. Prior to official release, the plants, plant products or other objects shall have been subject to quarantine measures, including testing, and must have been found free by such measures from any harmful organism, unless it is identified as one which is known to occur in the Community and is not listed in Directive 2000/29/EC,
  - the quarantine measures, including testing, shall be carried out by scientifically trained staff of that body or of any officially approved body, and shall be carried out in accordance with the provisions laid down in Annex III to this Directive for the plants, plant products and other objects specified,
  - any plants, plant products or other objects which have not been found free, by such measures, from harmful organisms as specified in the first indent, and any other plants, plant products or other objects with which they have been in contact or which may have become contaminated shall be destroyed or subjected to an appropriate treatment or quarantine measure aimed at eradicating the relevant harmful organisms; the provisions of (ii), second indent shall apply accordingly;
- (ii) for all other material (including harmful organisms), at the end of the duration of the approved activities, and for all material found to be contaminated during the activities:
  - the material (including the harmful organisms and any contaminated material) and any other plants, plant products or other objects with which it has been in contact or which may have become contaminated shall be destroyed, sterilised or otherwise treated in a manner to be specified by the responsible official body, and
  - the premises and facilities at which the activities in question have been undertaken shall be sterilised or otherwise cleaned, as necessary, in a manner to be specified by the responsible official body;
- c any contamination of the material by harmful organisms listed in Directive 2000/29/EC and any other harmful organism considered a risk to the Community by the responsible official body and detected during the activity shall be notified immediately to the responsible official body by the person responsible for the activities, along with notification of any event resulting in the escape of such organisms into the environment.

4 Member States shall ensure that for activities utilising plants, plant products and other objects listed in Annex III to Directive 2000/29/EC and not covered by Part A, Sections I, II and III of Annex III to this Directive, appropriate quarantine measures, including testing, shall be carried out. These quarantine measures shall be notified to the Commission and to the other Member States. The details of such quarantine measures shall be completed and inserted in Annex III to this Directive once the necessary technical information is available.

### *Article 3*

1 Before 1 September each year, Member States shall send to the Commission and to the other Member States a list, with quantities, of the introductions and movements of material

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approved under this Directive during the preceding period of one year ending on 30 June, and of any contamination by harmful organisms of such material, which has been confirmed under the quarantine measures, including testing, carried out under Annex III during the same period.

2 Member States shall cooperate administratively through the authorities established or designated pursuant to Article 1(4) of Directive 2000/29/EC, with regard to the provision of details of the quarantine containment conditions and measures imposed for activities approved under this Directive.

#### *Article 4*

Member States shall immediately communicate to the Commission all provisions of national law which they adopt in the field covered by this Directive. The Commission shall inform the other Member States thereof.

#### *Article 5*

Directive 95/44/EC, as amended by the Directive listed in Annex IV, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B.

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

#### *Article 6*

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

#### *Article 7*

This Directive is addressed to the Member States.

Done at Brussels, 17 June 2008.

*For the Commission*

*The President*

José Manuel BARROSO