

Draft paper on plant health

Plant health is a key factor for sustainable and competitive agriculture, horticulture and forestry. Healthy seeds and propagating material are required for profitable crops and for ensuring jobs, plant innovation and food security. In the case of trees and shrubs, protecting plant health is essential for the preservation of the Union's forests, landscape and public and private green.

Pests from other continents are especially dangerous. European plants and trees usually lack adequate genetic resistance against foreign pests, which moreover often do not have natural enemies here. When introduced into Europe, foreign pests cause severe economic damage. They may jump to previously unaffected host species, spread fast across countries, and cause lasting yield reduction and permanently increased costs for production and control. The often severe economic losses undermine the profitability and competitiveness of agriculture and forestry. The establishment of new pests may elicit trade bans from third countries, damaging EU exports. Not all pests can be controlled with pesticides and, where available, pesticide use may be undesirable.

Regulatory framework

The current EU regulatory framework for plant health aims to protect European agriculture and forestry by preventing the entry and spread of non-native pests. The main tool hereby is Council Directive 2000/29/EC¹, which also reflects international trade agreements in this area. The EU plant health regime is unique in that it is an open regime: movements of plants and plant products into and within the Union are allowed on condition that specific restrictions and requirements are respected (e.g. provenance from a pest free area or appropriate treatment). The high volumes of imports from other continents nevertheless imply a high probability of future outbreaks of foreign pests.

The regime is indispensable for protecting the health, economy and competitiveness of the EU plant production sector as well as for maintaining the Union's open trade policy. However, the existing regulatory framework is being criticised for being unable to stop the increased influx of dangerous new pests caused by globalisation of trade. Moreover climate change enables those pests to survive in Europe, while they could not in the past, and renders crops and ecosystems more vulnerable to new pests. Major outbreaks in the past decade of dangerous import-related pests affecting forestry have raised societal and political awareness of the costs and impacts of inadequate protection.

Problem analysis

An evaluation of the regime (2010)² has shown that the basic legislation has to be amended in order to be able to fully address these increased risks. The main problems identified relate to insufficient focus on prevention in relation to increased imports of high-risk commodities, the need for prioritising pests at EU level across

¹ OJ L 169, 10.7.2000, p. 1.

² http://ec.europa.eu/food/plant/plant_health_biosafety/rules/index_en.htm

all 27 Member States, the need for better instruments for controlling the presence and natural spread of pests in case they eventually reach the Union territory, a need for modernising and upgrading the instruments concerning intra-EU movements (plant passports and protected zones), and a need to foresee additional resources.

A need for "greening" of the regime has furthermore emerged and objectives relating to the natural environment have gained importance. This requires changes to the intervention logic, also in terms of financing, of the regime, which is moving from a private good regime for agriculture to a mixed public/private good regime for agriculture, forestry, natural environment and landscape.

The science base of the regime (research, laboratories) needs to be reinforced. There has been a steady erosion of the classical plant pathology and pest taxonomy in universities, endangering the support from science to assess risks from new pests and to adequately diagnose those pests in the laboratory. A State of Emergency declaration has been issued in this respect by the European and Mediterranean Plant Protection Organisation.

Finally, a new balance needs to be struck as concerns costs and responsibility sharing (partnership development) and there is a need to increase effectiveness and reduce unnecessary costs and administrative burden. A need for modernisation of the regime furthermore exists in terms of incentives for compliance.

Objective of the proposal

The present revision aims to overcome these flaws and to put in place a robust, transparent and sustainable regulatory framework that is 'fit for purpose'. The proposed Regulation replaces and repeals Directive 2000/29/EC.

Relationship to other proposals in the package

The proposal is part of a package of reviews relating to the health of plants, quality of plant reproductive material, health of animals, official controls concerning plants, animals, food and feed, and Union expenditures for those policies.

The proposal reinforces the synergies with the plant reproductive material regime, while removing avoidable duplications and unnecessary burden from those duplications. This is achieved by repositioning the pests that are currently regulated under the so-called marketing Directives for seed and plant propagating material under the proposed plant health Regulation. That repositioning will introduce flexibility to change the status of widespread quarantine pests into quality pests, as requested by operators and Member States, so as to use the resources available to the plant health quarantine authorities for true Union priorities. In the meanwhile, the proposal ensures that the existing practical arrangements in the Member States concerning the certification of plant reproductive material for quality pests can remain. Altogether, the rearrangements between the EU plant health regime and plant reproductive material regime should reinforce the coherence between those two regimes (through shared use of certification schemes, labels and registers) and thus in reduced burden for operators. The proposed new arrangements will, however, require enhanced coordination between the competent authorities in the Member States for plant health and plant reproductive material.

The proposal does not contain provisions concerning official controls by the competent authorities of compliance by operators with the Union plant health legislation, as are currently present in Directive 2000/29/EC. Those controls are now being positioned exclusively in the proposal for a Regulation on Official Controls (replacing Regulation (EC) 882/2004³). This will also allow improved coherence with the new Customs Code and allow simplified procedures at import.

The proposal does not contain provisions on expenditures eligible for a financial contribution from the Union, as exist in Directive 2000/29/EC. The provisions concerned, drafted in accordance with the preferred option of the impact assessment, are included in the accompanying legal proposal for a Regulation on Union expenditures for food and feed, animal health and welfare, plant health and plant reproductive material.

The proposal will be complementary to the proposal concerning Invasive Alien Species foreseen for 2012 under the EU Biodiversity Strategy in the Commission Work Programme⁴.

Chapter I: Subject matter, scope and definitions

The territorial scope of the regime does not include any overseas departments of Member States, as those departments belong to other biogeographic regions of the world, where exactly those pests occur against which the European territories of the Member States require protection. The territorial scope of the regime does include part of the Macaronesian archipelago (the island of Madeira and the Azores), which forms a biogeographic area overlapping with the Mediterranean region, in particular the Iberian peninsula, in terms of natural vegetation. It is therefore appropriate to include that archipelago in the scope of the regime. Annex I lists the territories of the Member States that are covered by the Treaty on the Functioning of European Union but, for the purpose of this Regulation, are considered as third countries.

Invasive plants other than parasitic plants (physically feeding on host plants) are excluded from the scope, in line with the outcome of the impact assessment.

Definitions are provided as necessary.

Chapter II: Quarantine pests

In Directive 2000/29/EC, pests are listed in specific Annexes. The proposal, instead, sets out the conceptual nature of quarantine pests and subsequently lists them in implementing acts, either as Union quarantine pests or Protected Zone quarantine pests. Union quarantine pests require eradication measures in the entire Union territory, while for Protected Zone quarantine pests that is only the case within specified protected zones where certain pests are absent, while they are known to occur in other parts of the Union territory. The proposal empowers the Commission to list certain quarantine pests as priority pests for the Union, up to a maximum of 10% of the listed Union quarantine pests. Those pests will be subject to an enhanced level of obligations concerning preparedness and eradication, supplemented by

³ OJ L 191, 28.5.2004, p. 1.

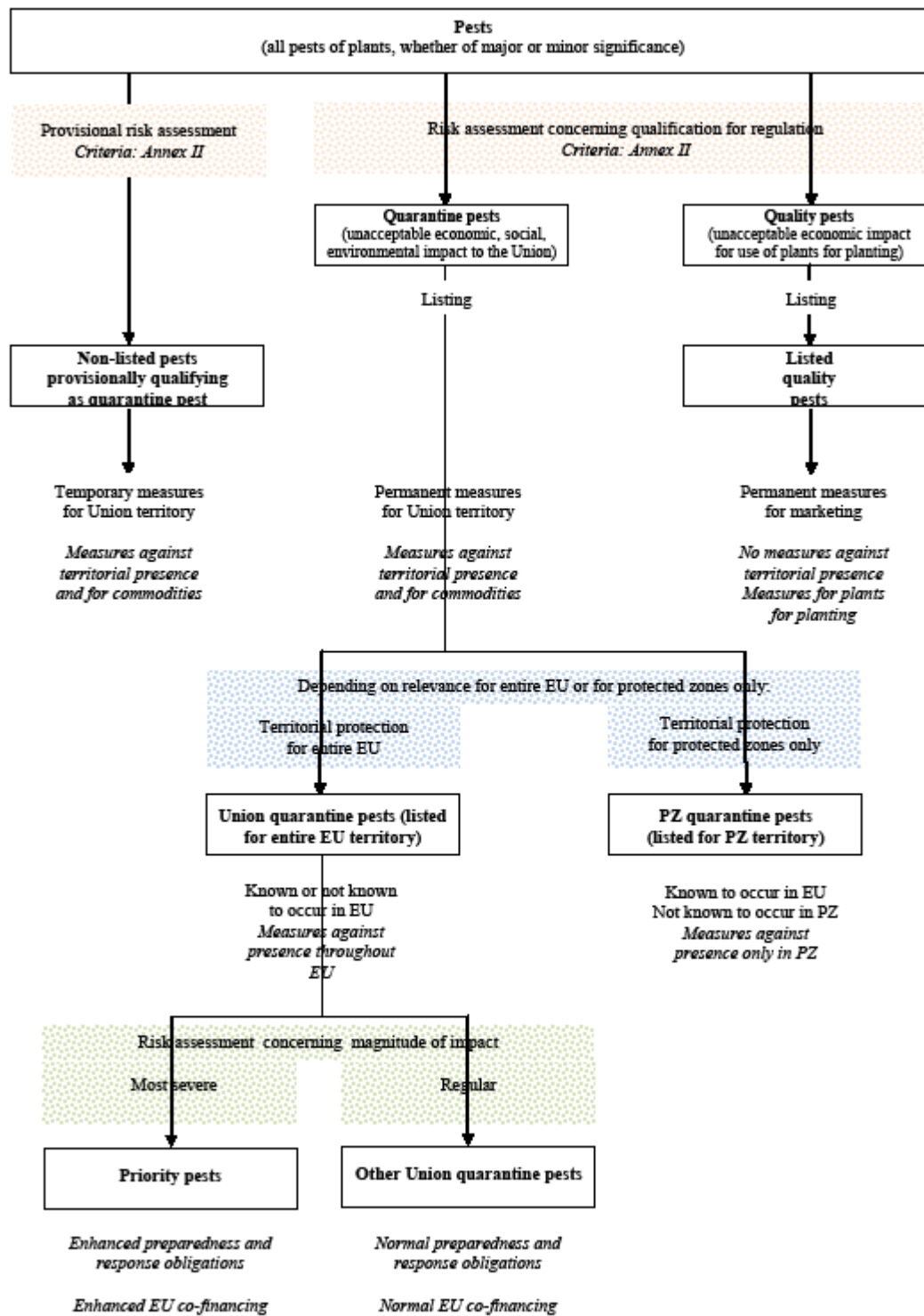
⁴ http://ec.europa.eu/atwork/programmes/docs/cwp2012_annex_en.pdf

enhanced financial support from the Union for the required actions. Criteria to decide whether a harmful pest qualifies as a quarantine pest, Union or Protected Zone quarantine pest, or priority pest are provided in Annex II of the Regulation. A transfer is foreseen of the pests currently listed in Annexes I and II of Directive 2000/29/EC to the appropriate lists of the future implementing acts. No distinction will be made any longer between pests currently listed in Annex I and Annex II of Directive 2000/29/EC.

This chapter furthermore sets out detailed rules on notification of the presence of quarantine pests, measures to be taken for the eradication of those pests including the restriction of areas subject to eradication measures, surveys to be carried out for the presence of harmful pests and the establishment of contingency plans and eradication programmes concerning outbreaks of priority pests.

The provisions in this chapter empower the Commission to adopt implementing acts on permanent measures to manage quarantine pests that have become established in the Union territory. Those acts can also be adopted on a temporary basis for non-listed quarantine pests requiring emergency measures, if necessary using the urgency procedure established under the Lisbon Treaty. The tools developed in this chapter exist today under Directive 2000/29/EC, however the proposal develops those tools explicitly. A provision is included allowing Member States to take stricter measures against harmful pests than foreseen in the Union legislation, on condition that those measures do not restrict in any way the free movement of plants, plant products and other regulated objects on the internal market.

The chapter also covers the provisions concerning protected zones, which maintain the existing system, however explicitly reinforced to ensure that protected zones are technically justified and that any outbreaks of the Protected Zone quarantine pests concerned are properly and timely eradicated. If not, the protected zone will be revoked. With these changes, the Union's protected zone system aligns with the pest-free area system under the International Plant Protection Convention (IPPC), as requested by the regime's stakeholders and by third countries.



Schematic representation of the various types of pests in the proposal, the decision process for their qualification and the measures required against them.

Chapter III: Quality pests

Harmful pests that affect the intended use of plants for planting, but do not require eradication, are regulated today under the marketing Directives for seed and plant propagating material and, partly, in Annex II to Directive 2000/29/EC. The proposal lists them all as quality pests. It sets out the conceptual nature of quality pests and subsequently lists them through implementing acts. Criteria to decide whether a pest qualifies as a quality pest are provided in Annex II. Quality pests will not be regulated under the proposal for Plant Reproductive Material.

Chapter IV: Measures concerning plants, plant products and other objects

Directive 2000/29/EC has Annexes listing prohibitions for certain plants, plants products and other objects (Annex III), and specific requirements for the introduction into and movement within the Union (Annex IV). The proposal empowers the Commission to adopt such lists through implementing acts. The provisions in Chapter IV furthermore concern rules for recognition of measures of third countries as equivalent to the Union measures, and derogations to the prohibitions. The respective rules concerning the movement of plants, plant products and other objects into and within protected zones are also addressed.

New to the Union plant health regime is an Article empowering the Commission to adopt implementing acts to address emerging risks from certain plants, plant products and other objects from certain third countries which require precautionary measures. Listed plant materials will require intensified inspection and testing, or subjection to a quarantine period, or will be subject to a temporary prohibition of introduction into the Union. Those measures shall apply for two years, prolongable once. During that time, a full risk assessment shall be developed, followed by a decision to regulate the material concerned on a permanent basis, or to drop the temporary measures.

New is also an article setting out the basic rules for quarantine stations, when the use of those stations is required by the Regulation or by secondary acts under the Regulation.

The introduction into the Union of regulated plants by passengers in their luggage will no longer be exempted from the respective requirements and prohibitions. This is necessary because plants in passenger luggage have been found an increasing risk for the plant health status of the Union and jeopardise the success of the regime.

New is finally an Article requiring that exports of plants, plant products and other objects to third countries shall take place either in accordance to the Union rules, or, if the third country's rules so allow or the third country explicitly so agrees through bilateral agreements or otherwise, in accordance to the requirements of that third country.

Chapter V: Registration of operators and traceability

The proposal requires the relevant operators to be registered, in a register which will also contain the operators required to be registered under the plant reproductive material Regulation. This should reduce burden for operators. Registered operators

shall fulfil certain requirements for the traceability of the plant material under their control.

Chapter VI: Certification of plants, plant products and other objects

Directive 2000/29/EC has an Annex (V) listing requirements concerning certification of plants, plant products and other objects introduced into or moved within the Union. The proposal empowers the Commission to adopt such lists through delegated acts. The respective rules concerning the certification of plants, plant products and other objects introduced into and moved within protected zones are also addressed.

The proposal foresees that all plants for planting, other than certain seeds, shall require a phytosanitary certificate for introduction into the Union and a plant passport for movement within the Union. Plant passports shall be required for all movements between operators, but not for sales to final non-professional users. The plant passport will be simplified and harmonised. Instead of a lot number, the plant passport may use a chip, barcode or hologram linking to the internal traceability systems of operators.

Examinations on plants, plant products and other objects requiring a plant passport may require the use of certification schemes with regard to certain quarantine pests and/or quality pests, where examinations in the field during the growing season are indispensable. This possibility could be created thanks to the inclusion of quality pests in the plant health Regulation. Where certification schemes are required under the plant health Regulation, it is provided that those certification schemes shall coincide with those created under the plant reproductive material Regulation. This should preclude that double schemes are set up, which would result in double costs for operators.

Plant passports shall be issued by registered operators that are authorised so by the competent authorities, or, on their request, by the competent authorities. Where plant material requires a plant passport under the plant health Regulation and a certification label under the plant reproductive material Regulation, the plant passport and the certification label shall be combined in a single document. This should preclude double costs for operators, where the issuance is done by the competent authorities.

Rules are foreseen concerning the authorisation and supervision of operators issuing plant passports and for the examination of the plant material concerned, in order to ensure that that material complies with all provisions of the Regulation.

Rules are also foreseen concerning the authorisation and supervision of wood packaging material producers who apply a certain mark to that material, following its treatment according to the International Standard for Phytosanitary Measures No. 15 on Regulation of wood packaging material in international trade.

For export purposes, the proposal foresees the introduction of a pre-export certificate, for cases where plant material is exported from a Member State which is not the Member State of origin. The pre-export certificate will replace the currently used informal guidance document agreed by the Member States.

Chapter VII: Measures supporting the implementation of this Regulation

The proposal foresees the establishment of a team of phytosanitary experts to provide assistance to the competent authorities in the implementation of this Regulation. It also foresees the establishment of an application system for notification and reporting.

Chapter VIII: Final provisions

The proposal foresees that the Commission will be assisted by a new Standing Committee, which will include the existing Committees dealing with the food chain, animal and plant health and plant reproductive material (instead of the existing Standing Committee on Plant Health).

The proposal repeals six so-called Control Directives concerning the management of certain quarantine pests (potato wart fungus, potato cyst nematodes, potato brown rot, potato ring rot, carnation leaf rollers and San José scale) that are known to be present in the Union. Acts of such nature will in future be adopted as secondary acts under the proposed Regulation and not as co-decided acts. The Directives on harmful pests of potato will be replaced by secondary acts under now proposed Regulation, without changing their substance. The Directives on carnation leaf rollers and San José scale will not be replaced.

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on protective measures against pests of plants

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
HAVE ADOPTED THIS REGULATION:

Chapter I **General provisions**

Article 1

Subject matter and scope

1. This Regulation lays down rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products (hereinafter “pests”) and measures to reduce those risks to an acceptable level.
2. For the purpose of this Regulation, the territories listed in Annex I shall not be considered as belonging to the territory of the Union.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, amending Annex I by adding one or more territories that are referred to in Article 355(1) of the Treaty on the Functioning of the European Union and are not situated in Europe.

Article 2

Definitions

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

1. 'plants' means living plants and the following living parts of plants:
 - (a) seeds, in the botanical sense, other than those not intended for planting;
 - (b) fruits, in the botanical sense;
 - (c) vegetables;
 - (d) tubers, corms, bulbs, rhizomes, roots, rootstocks, stolons;
 - (e) shoots, stems, runners;

- (f) cut flowers;
- (g) branches with foliage;
- (h) cut trees retaining foliage;
- (i) leaves, foliage;
- (j) plant tissue cultures, including cell cultures, germplasm, meristem tips, chimaeric clones, micro-propagated material;
- (k) live pollen;
- (l) buds, bud-wood, cuttings, scions, grafts.

2. 'plant products' means products of plant origin, unprocessed or having undergone simple preparation, in so far as these are not plants and they may present a plant health risk.

Except where otherwise provided, wood shall only be considered as a 'plant product' if it complies with one or more of the following points:

- (a) it retains all or part of its natural round surface and has not undergone processing involving the use of glue, heat or pressure or a combination thereof;
- (b) it is in the form of sawn wood, chips, particles, sawdust, wood waste, shavings or scrap;
- (c) it is used as packaging material.

3. 'plants for planting' means plants, which are capable of and intended for producing entire plants, and which are destined to be planted or replanted or remain planted;

4. 'other object' means any material or object, other than plants or plant products, capable of harbouring or spreading pests, including soil or growing medium;

5. 'competent authority' means a competent authority as defined in Article 2(2)(b) of [revised Reg. 882/2004];

6. 'lot' means a number of units of a single commodity, identifiable for phytosanitary purposes by its homogeneity of composition and origin, forming part of a consignment;

7. 'operator' means any person, governed by public or private law, involved professionally in one or more of the following activities concerning plants, plant products and other objects:

- (a) planting;
- (b) growing;
- (c) production;

- (d) movement into, within and out of the Union;
- (e) marketing;
- 8. 'final user' means any person acting for purposes which are outside its trade, business or profession, who receives for its own use small quantities of plants or plant products;
- 9. 'test' means an official examination, other than visual, to determine if pests are present or to identify pests;
- 10. 'treatment' means a procedure for the killing, inactivation or removal of pests, or for rendering those pests infertile or for their devitalisation;
- 11. 'certificate' means a certificate as defined in Article 2(1)(p) of [revised Reg. 882/2004].

Chapter II Quarantine pests

SECTION 1 UNION QUARANTINE PESTS

Article 3

Prohibition of introduction and movement of Union quarantine pests

- 1. A pest shall not be introduced into or moved within the Union if it fulfils all of the following conditions:
 - (a) its identity is sufficiently characterised, in accordance with point (1) of Section 1 of Annex II;
 - (b) it is not present in the Union territory, or, if present, only distributed to a limited extent within the Union territory, in accordance with point (2) of Section 1 of Annex II;
 - (c) it is capable to enter into the Union territory, perpetuate its presence for the foreseeable future after its entry into the Union territory (hereinafter: 'to establish') and spread within the Union territory, or in those parts of it where it is not present, in accordance with point (3) of Section 1 of Annex II;
 - (d) its entry, establishment and spread would, in accordance with point (4) of Section 1 of Annex II, have an unacceptable economic, environmental or social impact for the entire Union; and
 - (e) feasible and effective measures are available to prevent the entry, establishment and/or spread of that pest and mitigate its phytosanitary risks and impacts, in accordance with point (5) of Section 1 of Annex II.

Such a pest is referred to as 'a Union quarantine pest'.

2. No action shall be taken which may contribute deliberately to the establishment and spread within the Union of a Union quarantine pest.
3. The Commission shall, by means of an implementing act, establish a list of Union quarantine pests.

That list shall include the pests listed in Part A of Annex I and Section I of Part A of Annex II to Directive 2000/29/EC.

Pests which are officially recognised to be indigenous to any part of the territory of the Union, whether naturally or due to their introduction from outside the territory of the Union, shall be marked in that list as pests known to occur in the territory of the Union.

Pests which are not officially recognised to be indigenous to any part of the territory of the Union shall be marked in that list as pests not known to occur in the territory of the Union.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).

4. The Commission shall amend the implementing act referred to in paragraph 3 where a pest not listed in that act fulfils the conditions set out in paragraph 1 or where a pest listed in that implementing act no longer fulfils one or more of those conditions.

That implementing act shall be amended in accordance with the examination procedure referred to in Article 83(3).

5. The Commission shall amend the implementing act referred to in paragraph 3 by amending the scientific name of a pest, if justified so by the scientific developments.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 83(2).

Article 4 **Priority pests**

1. A Union quarantine pest is referred to as 'priority pest' insofar as:
 - (a) it is absent from the Union territory or from most of the area in the Union territory, where the plants which may host that pest (hereinafter: 'host plants') are grown or are present naturally, as set out in point (1) of Section 2 of Annex II;
 - (b) it is capable to enter, establish and spread in most of the area in the Union territory where the respective host plants are grown or are present naturally, as set out in point (2) of Section 2 of Annex II;
 - (c) its potential economic, environmental or social impact are most severe for the Union as set out in point (3) of Section 2 of Annex II.

2. The Commission shall list, by means of implementing acts, the priority pests in accordance with the criteria set out in Section 2 of Annex II. The number of the pests of that list shall not exceed 10% of the number of the Union quarantine pests listed pursuant to Article 3(3).

Those implementing acts shall be adopted and, where applicable amended, in accordance with the examination procedure referred to in Article 83(3).

On duly justified imperative grounds of urgency relating to a serious risk to plant health, the Commission shall, in accordance with the procedure referred to in Article 83(4), adopt immediately applicable implementing acts listing Union quarantine pests as priority pests.

Article 5

Amendment of Section 1 and Section 2 of Annex II

The Commission shall be empowered to adopt delegated acts in accordance with Article 82 amending Sections 1 and 2 of Annex II on criteria for the qualification of pests according to their risk to the Union, as regards the criteria concerning the identity of the pest, its presence, the probability of its entry, establishment and spread, its potential economic, social and environmental consequences as well as the availability of feasible and effective measures against it, taking into account the developments of technical and scientific knowledge, and development in international standards.

Article 6

Pests used for scientific purposes, trials, varietal selections and exhibitions

1. By way of derogation from Article 3(1), Union quarantine pests used for scientific purposes, trials, varietal selections or exhibitions may be introduced into the Union.
2. The spread of those pests shall be obviated by applying the following measures:
 - (a) the activities for which the material of the pest is to be introduced into or moved within the Union shall have been approved by the competent authorities and shall be carried out in a quarantine facility designated as such by the competent authorities.

That approval shall be granted only if a risk assessment, carried out by the competent authorities, has shown that the risk of spread of the pest concerned is adequately mitigated by the restrictions imposed by the competent authorities conditional to the approval.

That risk assessment shall concern the identity, biology and means of dispersal of the pest, the activity envisaged, the interaction with the environment and other relevant factors relating to the risk posed by the material of the pest concerned;

- (b) the material of the pest shall be limited to an amount that is adequate for the approved activities and does not exceed the capacity of the designated quarantine facility. It shall be introduced into or moved within the Union only

if accompanied by a permit issued by the competent authorities and shall be kept in storage facilities approved by the competent authorities;

- (c) the scientific and technical qualifications of the personnel by whom the activities are to be undertaken shall have been examined and approved by the competent authorities;
 - (d) compliance with the conditions referred to in point (a) to (c) is monitored by the competent authorities and remedial action is ensured upon non-compliance.
3. The Commission may, by means of implementing acts, lay down harmonised procedures for specific Union quarantine pests concerning:
- (a) the assessment and approval referred to in paragraph 2(a);
 - (b) the issuance and approval referred to in paragraph 2(b);
 - (c) the examination and approval referred to in paragraph 2(c);
 - (d) the monitoring and remedial action referred to in paragraph 2(d);
 - (e) the exchange of information between Member States and the Commission concerning the introduction into and movement within the Union of the pests concerned; and
 - (f) the notification of non-compliance with the conditions referred to in paragraph 2(a) to (c).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

Article 7

Notification of Union quarantine pests to the competent authorities

1. Where anyone becomes aware of, or suspects, the presence of a Union quarantine pest, that person shall immediately notify the competent authority concerned.
2. If so requested by the competent authority concerned, the person referred to in paragraph 1 shall provide that authority with the relevant information which is in its possession.
3. An operator shall submit the notification referred to in paragraph 1 within ten calendar days after it became aware of the presence of the Union quarantine pest concerned, or had its suspicion confirmed.

Article 8

Notification of Union quarantine pests to the Commission and the other Member States

1. A Member State shall notify the Commission and the other Member States, in case one of the following points is fulfilled:

- (a) it has officially confirmed the presence in its territory of a Union quarantine pest not known to be present in the Union;
 - (b) it has officially confirmed the presence in its territory of a Union quarantine pest known to be present in the Union, if that pest is found to be present in a part of its territory where it was previously not present;
 - (c) it has officially confirmed the presence in its territory of a Union quarantine pest in a consignment of plants, plant products or other objects introduced into or moved within the Union.
2. The notifications referred to in paragraph 1 shall be submitted within three working days following the date of the official confirmation by the Member State of the presence of the respective Union quarantine pest.

Article 9

Measures in case of suspicion of the presence of a Union quarantine pest

1. Where competent authorities suspect the presence of a Union quarantine pest, in a part of the territory of the respective Member State where that pest was previously not known to be present, it shall immediately take any measures necessary to officially confirm whether that pest is present or not.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, laying down that the notification obligations referred to in Article 8(1) shall also apply to the suspected presence of specific Union quarantine pests, which has not yet been officially confirmed. Those delegated acts may also determine the time limit within which those notifications shall be submitted.

Article 10

Information on Union quarantine pests provided to operators by the competent authorities

Where the conditions of one of the points of Article 8(1) are fulfilled, the competent authorities concerned shall ensure that operators, whose plants, plant products or other objects may be affected, are immediately informed of the presence of the Union quarantine pest concerned.

Article 11

Information on priority pests provided to the public by the competent authorities

Where the presence of a priority pest is officially confirmed for the first time in the territory of the Member State, or in parts of a Member State where it was not known to be present, the competent authority concerned shall inform the public. The information provided shall contain the measures taken by that Member State and by any person concerned.

Article 12

Notification of imminent dangers

1. In case a Union quarantine pest is not yet present in the Union territory or parts of it, and a Member State has evidence that there is an imminent danger of the entry of

that pest into, or its establishment or spread within, the Union territory or in parts of that territory where it is not yet present, that Member State shall immediately and in writing notify the Commission and the other Member States of that evidence.

2. The operators concerned shall immediately notify the competent authorities of any evidence they may have concerning an imminent danger as referred to in paragraph 1 concerning Union quarantine pests.

Article 13

Measures to be taken immediately by operators

1. Where an operator becomes aware that a Union quarantine pest is present in plants, plant products or other objects which are under its control, it shall, immediately, and in co-ordination with the competent authority concerned, take the phytosanitary measures necessary to eliminate that pest from its premises, plants, plant products and other objects concerned and prevent its spread.

That competent authority may request the operator concerned to withdraw the respective plants, plant products and other objects from the market.

2. Where the plants, plant products or other objects referred to in paragraph 1 have left the control of the operator concerned, that operator shall, immediately and in co-ordination with the competent authority concerned, inform the persons in the trade chain from whom those plants, plant products and other objects had been obtained and to whom those plants, plant products and other objects had been supplied, of the presence of the respective pest. That information shall be provided, where appropriate, through direct contacts with the persons concerned or by electronic means.

That competent authority may request the operator concerned to recall the respective plants, plant products and other objects from the market and, where the plants, plant products and other objects may have reached the consumer, to recall them from those consumers.

3. In the cases of paragraph 1 and 2, the operator concerned shall provide all information which is relevant for the public to the competent authority concerned. That authority shall inform the public in case action needs to be taken with regards to the respective plants, plant products and other objects.

Article 14

Eradication of Union quarantine pests

1. If a competent authorities officially confirms the presence of a Union quarantine pest, included in the list referred to in Article 3(3), in its territory for the first time or in a part of its territory where it was not present before, it shall immediately take all necessary measures to eliminate that pest in the area concerned and to prevent its spread out of that area (hereinafter: 'to eradicate'). Those measures shall be one or more of the measures listed in Section 1 of Annex IV, and shall be taken in accordance with the principles set out in Section 2 of that Annex.

2. Where the presence of the Union quarantine pest concerned may be related to movements of plants, plant products or other objects, the competent authorities shall investigate to identify the source of the infestation and possible further infestations through those movements.

Article 15

Establishment of restricted areas

1. If a competent authority officially confirms the presence of a Union quarantine pest, included in the list referred to in Article 3(3), in its territory for the first time or in a part of its territory where it was not present before, it shall immediately establish a restricted area consisting of an infested zone, as provided for in paragraph 2, and a buffer zone, as provided for in paragraph 3 (hereinafter: 'the restricted area').

The establishment of that restricted area shall take place in addition to the measures referred to in Article 14(1).

2. The infested zone referred to in paragraph 1 shall contain:
 - (a) all plants known to be infested by the pest concerned;
 - (b) all plants showing signs or symptoms indicating possible infestation by that pest;
 - (c) all other plants liable to be infested by that pest due to close proximity to or common origin with infested plants, or plants grown from them.

It is referred to as 'the infested zone'.

3. The buffer zone referred to in paragraph 1 shall be adjacent to the infested zone and shall surround it.

Its size shall be appropriate in view of the risk of the pest concerned spreading out of the infested zone naturally or by human activities in the infested zone and its surroundings.

It is referred to as 'the buffer zone'.

Where there is no such risk, no buffer zone need, however, be established.

4. By way of derogation from paragraph 1, where upon first sight, in view of the nature of the pest concerned and the location where it was found, there is no risk of its spreading out of that location, the Member State concerned shall carry out a survey establishing whether any plants or plant products have been infested. On the basis of that survey, the competent authority concerned shall determine whether there is a need to establish a restricted area. The competent authority concerned shall notify to the Commission and the other Member States the conclusions of that survey.
5. Where in accordance with paragraphs 1, 2 and 3 a restricted area is to extend into the territory of another Member State, the Member State of the location where the pest concerned was found to be present shall immediately contact the Member State into

whose territory the restricted area is to extend in order to allow that Member State to take all appropriate actions, as referred to in paragraphs 1 to 4.

Article 16

Surveys and modifications of restricted areas, and lifting of restrictions

1. Member States shall carry out an annual survey of each restricted area as regards the development of the presence of the pest concerned. Those surveys shall be carried out in accordance with sound scientific and technical principles and at appropriate times with regard to the possibility to detect the pest concerned.
2. Where during an annual survey a Member State finds a presence of the pest concerned in the buffer zone, it shall immediately notify that presence to the Commission and the other Member States.
3. Member States shall extend or reduce infested zones, buffer zones and restricted areas, where appropriate, in view of the results of the surveys referred to in paragraph 1.
4. Member States may decide to remove the status of a restricted area, provided that during the surveys referred to in paragraph 1 no presence of the pest concerned has been found in that restricted area for a sufficiently long period. When deciding whether no presence has been found for a sufficiently long period, the Member State concerned shall take into account the biology of the pest concerned, the presence of host plants, the eco-climatic conditions and the likelihood of the eradication measures having been successful.

Article 17

Additional protective measures outside restricted areas

1. Where an assessment of the phytosanitary risk posed by the Union quarantine pests, for which restricted areas have been established pursuant to Article 15(1), requires so, competent authorities shall take additional protective measures and carry out intensified surveys in certain areas, outside those restricted areas, to ensure the protection of the Union territory.
2. Those measures shall be adopted in accordance with Section 1 of Annex IV, taking into account the principles set out in Section 2 of Annex IV.

Article 18

Reports on measures taken in accordance with Articles 14, 15, 16 and 17

Member States shall submit to the Commission and the other Member States, at their request, an annual report on the measures taken in accordance with Articles 14, 15, 16 and 17.

Article 19
Amendment of Annex IV

The Commission shall be empowered to adopt delegated acts in accordance with Article 82, amending Sections 1 and 2 of Annex IV on measures and principles for the management of the risks of quarantine pests, as regards the measures targeting prevention and elimination of infestation of cultivated and wild plants, measures targeting consignments of plants, plants products and other objects, measures targeting other pathways for quarantine pests and principles for the management of the risks of pests, taking into account the developments of technical and scientific knowledge, and development in international standards.

Article 20
Pest surveys

1. Member States shall conduct surveys over defined periods of time to check for any presence of pests in areas in which they were not known to be present. Those surveys shall be based on sound scientific and technical principles, and shall be carried out at appropriate times with regard to the possibility to:
 - (a) detect the potential presence of the pests concerned; and
 - (b) allow the issuance of official statements concerning the status of the presence or absence of quarantine pests at a particular point of time in a particular area, including where appropriate their distribution in those areas.

This Article shall not apply to protected zone quarantine pests.

2. Member States shall establish multi-annual programmes, setting out the content of the surveys to be carried out to ensure a systematic and transparent planning and implementation of surveys. Those programmes shall also include the collection and recording of scientific and technical publications and other data on the presence of the pests concerned.

Those programmes shall set out following elements: the objectives of the surveys, their spatial and temporary scope, the pests, plants and commodities targeted, the survey methodology and quality management including a description of inspection, sampling and testing procedures and their rationale, the timing, frequency and numbers of scheduled inspections, samples and tests, the methods of recording of the data collected and their reporting.

3. Member States shall notify the programmes referred to in paragraph 2 to the Commission and the other Member States at their initiation. Annual reports of the results of those surveys shall be notified to the Commission and the other Member States by 30 April of the following year.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, amending the elements to be included in the programmes referred to in the second subparagraph of paragraph 2.

Article 21
Surveys for priority pests

1. In addition to the surveys provided for in Article 20(1), Member States shall carry out specific surveys on their territories for each priority pest, on an annual basis. Those surveys shall, compared to the surveys referred to in Article 20(1), include an increased number of inspections, samples and tests, as appropriate for the relevant pests.
2. Member States shall report to the Commission and the other Member States by 30 April of each year the results of the surveys referred to in paragraph 1, which have been carried out in the preceding year.

Article 22
Contingency plans for priority pests

1. Each Member State shall draw up and keep up to date, for each priority pest which may enter into and establish in its territory, a separate plan containing information concerning the actions to be taken and procedures to be followed in case of a confirmed or suspected presence of such a pest to ensure a high level of awareness, preparedness and rapid response, hereinafter ‘the contingency plan’.
2. The contingency plan shall cover, where appropriate in the form of instruction manuals, at least the following matters:
 - (a) the roles and responsibilities of the bodies involved in those actions, the chain of command and co-ordination procedures to ensure a rapid and effective decision-making process at Member State, regional and local level, including co-ordination with neighbouring Member States and neighbouring third countries and territories, where appropriate;
 - (b) access to facilities, laboratories, equipment, personnel, emergency funds and all other appropriate materials and resources necessary for the rapid and effective eradication and/or containment of the priority pests concerned;
 - (c) the availability of external expertise, including specialists and scientific institutions, to assist the competent authority concerned;
 - (d) procedures concerning the communication of any presence of the priority pest and respective measures to the Commission, the other Member States, the operators concerned and the public;
 - (e) procedures concerning recording of findings of the presence of the priority pest concerned;
 - (f) the available risk assessments for the priority pest concerned;
 - (g) a description of the available measures concerning the eradication of the priority pest concerned, in accordance with Section 1 of Annex IV, and the procedures to be followed;

- (h) principles for the geographical demarcation of restricted areas;
 - (i) procedures concerning laboratory testing; and
 - (j) the appropriate training of personnel of the competent authorities.
3. Member States shall regularly evaluate and review their contingency plans to keep them up to date.
 4. Where so requested, Member States shall communicate their contingency plans to the Commission and to the other Member States.

Article 23

Simulation exercises

1. The Member States shall regularly carry out simulation exercises to verify the functionality of one or more of the contingency plans provided for in Article 22(1). Those contingency plans shall be subject to simulation exercises within a reasonable period of time.
2. Where feasible and appropriate, Member States shall carry out simulation exercises in close collaboration with the competent authorities of neighbouring Member States and third countries and territories.
3. Member States shall make available on request a report on the main results of the simulation exercises to the Commission and to the other Member States.
4. When appropriate and necessary to ensure a uniform application of the simulation exercises provided for in paragraph 1, the Commission shall, by means of implementing acts, identify means for the practical implementation of simulation exercises on:
 - (a) the frequencies, contents and format of simulation exercises;
 - (b) simulation exercises covering more than one priority pest;
 - (c) collaboration between Member States and with third countries and territories.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

Article 24

Eradication programmes for priority pests

1. In the case of confirmation of the presence of a priority pest in the territory of a Member State pursuant to Article 9, the competent authority concerned shall immediately determine and specify, through an eradication programme, the precise measures it intends to take pursuant to Articles 14, 15, 16 and 17 to eradicate the pest concerned, within a specific time schedule. That programme shall also include a description of the design and organisation of surveys and the planned number of inspections, samples to be taken and laboratory tests to be carried out.

2. Member States shall notify to the Commission and the other Member States the eradication programmes referred to in paragraph 1 at their request.

Article 25

Union measures for specific Union quarantine pests

1. The Commission may specify, by means of implementing acts, harmonised measures concerning specific Union quarantine pests and the plants, plant products and other objects which may host them, as regards the following provisions:
 - (a) Article 13 concerning measures to be taken immediately by operators;
 - (b) Article 14 concerning eradication of Union quarantine pests;
 - (c) Article 15 concerning establishment of restricted areas;
 - (d) Article 16 concerning surveys, modifications of restricted areas and lifting of restrictions;
 - (e) Article 17 concerning additional protective measures outside of restricted areas;
 - (f) Article 20 concerning pest surveys;
 - (g) Article 21 concerning surveys for priority pests, as regards the number of inspections, samples and tests for particular priority pests;
 - (h) Article 22 concerning contingency plants for priority pests;
 - (i) Article 23 concerning simulation exercises;
 - (j) Article 24 concerning eradication programmes for priority pests.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

2. In the case the Commission concludes, on the basis of the surveys referred to in Article 16 or any other evidence, that the eradication of the concerned pest is not possible in certain restricted areas, the implementing acts referred to in paragraph 1 may set out measures with the single purpose to prevent the spread of those pests out of those areas (hereinafter: 'to contain' those pests).
3. The measures referred to in paragraphs 1 and 2 shall be taken in accordance with Section 1 of Annex IV, taking into account the principles set out in Section 2 of Annex IV, the specific risks of the respective pests and the need to implement the necessary risk mitigation measures in a harmonised manner at Union level.
4. On duly justified imperative grounds of urgency to address a serious risk to plant health, the Commission may adopt immediately applicable emergency measures, by means of implementing acts, in accordance with the procedure referred to in Article 83(4).

Article 26

Temporary measures by Member States

1. Where a Member State becomes aware of the presence in its territory of a pest which may qualify as a Union quarantine pest, but which is not listed as such pursuant to Article 3(3), it shall immediately carry out a preliminary assessment of the phytosanitary risk posed by that pest. That assessment shall take place in accordance with the criteria set out in Section 3 of Annex II.
2. In the case the Member State concludes, on the basis of the assessment referred to in paragraph 1, that the pest concerned is likely to qualify as a Union quarantine pest, it shall immediately take temporary eradication measures in accordance with Section 1 of Annex IV, taking into account the principles set out in Section 2 of Annex IV. Articles 14, 15, 16 and 17 shall apply accordingly for those measures.

The Member State concerned shall immediately notify the presence of that pest, the preliminary assessment referred to in paragraph 1, the measures taken and the evidence justifying those measures, to the Commission and the other Member States.

3. The Member State concerned shall carry out a full assessment of the phytosanitary risk posed by that pest, in accordance with the criteria set out in Section 1 of Annex II. It shall notify that assessment to the Commission within a reasonable period of time, given the available technical and scientific information, which shall be no longer than 24 months.

Article 27

Union emergency measures

1. Following the notifications referred to in Article 26(2) and (3), or any other relevant evidence concerning the presence in, or imminent danger for entry into, the Union territory of an pest which is likely to qualify as a Union quarantine pest, but which is not listed as such pursuant to Article 3(3), the Commission shall preliminarily assess the phytosanitary risk posed by that pest for the Union territory. That assessment shall take place in accordance with the criteria set out in Section 3 of Annex II.
2. In the case the Commission concludes, on the basis of the assessment referred to in paragraph 1, that the pest concerned is likely to qualify as a Union quarantine pest, it shall adopt, by means of implementing acts, temporary measures restricted to a specific time period to mitigate the respective phytosanitary risks (hereinafter: 'emergency measures'). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

The emergency measures shall concern, as appropriate, the notification of the presence of the quarantine pest concerned, the measures imposed on operators, eradication, establishment and modification of restricted areas, the surveys to be carried out, additional protective measures to be carried out outside of restricted areas, contingency plans and eradication programmes for that pest and, where applicable, plants, plant products and other objects which may host it.

3. In the case the Commission concludes, on the basis of surveys or any other evidence, that the eradication of the pest concerned is not possible in certain restricted areas,

the implementing acts referred to in paragraph 2 may set out measures with the single purpose to contain those pests.

4. The measures referred to in paragraphs 2 and 3 may include, as appropriate, one or more of the measures listed in Section 1 of Annex IV, taking into account the specific risks of the respective pests, the risk management principles set out in Section 2 of Annex IV and the need to implement the necessary risk mitigation measures in a harmonised manner at Union level.
5. The implementing acts referred to in paragraph 2 may provide that the measures taken by the Member States pursuant to Article 26 are to be repealed or amended. Until a measure has been adopted under the aforesaid procedure, the Member State may maintain the measures that it has employed.
6. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable emergency measures, by means of implementing acts, in accordance with the procedure referred to in Article 83(4).

Article 28

More stringent requirements adopted by Member States

1. Member States may apply within their territories more stringent measures than the measures adopted pursuant to Article 25(1) and Article 27(2), if so justified by the objective of phytosanitary protection and in accordance with the principles set out in Section 2 of Annex IV.

Those measures shall not impose any prohibitions or restrictions on the movement within the Union of plants, plant products and other objects, other than those imposed by the provisions of Articles 37 to 48 and the provisions of Articles 58 to 79.

2. Member States shall notify the Commission and the other Member States of those measures.

Article 29

Amendment of Section 3 of Annex II

The Commission shall be empowered to adopt delegated acts in accordance with Article 82 amending Section 3 of Annex II on criteria for the qualification of pests according to their risk to the Union, as regards the criteria concerning the identity of the pest, its presence, the probability of its entry, establishment and spread, its potential economic, social and environmental consequences as well as the availability of feasible and effective measures against it, taking into account the developments of technical and scientific knowledge, and development in international standards.

SECTION 2 PROTECTED ZONE QUARANTINE PESTS

Article 30

Recognition of protected zones with respect to specified protected zone quarantine pests

1. On the request of a Member State, protection may be granted to its territory, or part of its territory, against certain pests which meet the criteria provided in Section 1 of Annex II (hereinafter: 'quarantine pests'), but do not qualify as a Union quarantine pest as they are present in the Union and their potential economic, social and environmental consequences for the entire Union are not unacceptable. The Member State territory, or part of its territory, to which protection is granted is referred to as 'a protected zone'.

That protection shall only be granted against quarantine pests which meet the criteria provided in Section 1 of Annex II as regards those protected zones. Such a quarantine pest is referred to as 'a protected zone quarantine pest'.

2. A protected zone quarantine pest shall not be introduced into or moved within the respective protected zone.

No action shall be taken which may contribute deliberately to the establishment and spread within a protected zone of the respective protected zone quarantine pest.

3. The Commission shall, by means of an implementing act, recognise the protected zones recognised by Regulation (EC) No 690/2008 and establish a list of the respective protected zone quarantine pests. That list shall include the pests listed in Part B of Annex I and Part B of Annex II to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).

4. Where a Member State so requests, the Commission may recognise, by means of implementing acts, additional protected zones with respect to certain quarantine pests and amend the list of protected zone quarantine pests referred to in paragraph 3. That amendment shall take place in accordance with the criteria set out in paragraph 1 concerning the recognition of protected zones and the identification of protected zone quarantine pests. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

That recognition may only take place if it is concluded, on the basis of the assessment by the Commission of the available evidence, that the requirements of paragraph 1 are fulfilled. That evidence shall include reports from surveys during the three previous years concerning the absence of the relevant quarantine pest from the proposed protected zone. Those surveys shall have been carried out at appropriate times with regards to the possibility to detect the potential presence of the concerned quarantine pest and have been based on sound scientific and technical principles.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones.

Article 31

General obligations concerning protected zones

1. The obligations laid down in Articles 7 to 10 concerning the confirmation, notification and information of the presence of Union quarantine pests, in Article 13 concerning measures to be taken by the operators in relation to Union quarantine pests and in Articles 14, 15 and 16 concerning the eradication of Union quarantine pests, the establishment and modification of restricted areas and surveys in those restricted areas shall apply accordingly for the protected zone quarantine pests with regard to the respective protected zones.
2. The restricted areas established within a protected zone and the eradication measures taken in those areas pursuant to paragraph 1 shall be immediately notified to the Commission and the other Member States.

Article 32

Surveys on protected zone quarantine pests

1. Competent authorities shall carry out surveys in the respective protected zones concerning the presence of the respective protected zone quarantine pests on an annual basis. Those surveys shall be based on sound scientific and technical principles and shall be carried out at appropriate times with regards to the possibility to detect the potential presence of the pests concerned.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, laying down detailed rules for surveys to be carried out for purposes of this paragraph.

2. Member States shall notify the Commission and the other Member States, by 30 April of each year, of the results of the surveys referred to in paragraph 1, which have been carried out in the preceding year.

Article 33

Revocation or amendment of the protected zones

1. The Commission shall revoke, upon the request of the Member State concerned, the recognition of a protected zone.

The Commission shall revoke the recognition of a protected zone in case the surveys referred to in Article 31 have not been carried out in accordance with Article 32(1).

The Commission shall revoke the recognition of a protected zone, in case the respective protected zone quarantine pest has been found present in that zone and one of the following conditions is fulfilled:

- (a) no restricted area has been designated, in accordance with Article 31(1), within three months after the presence of that pest was confirmed;

- (b) the eradication measures taken in a restricted area pursuant to Article 31(1) have not been successful within 24 months after the presence of that pest was confirmed;
- (c) information at the disposal of the Commission demonstrates major negligent reaction to the presence of that pest in the concerned protected zone.

By derogation to point 3(b), the boundaries of the protected zone may be modified, on the request of the Member State concerned, to exclude that restricted area. In that case, the Member State concerned shall notify the Commission, the other Member States and, via the internet, the operators of the amended boundaries of that protected zone, including maps.

In case paragraphs 1, 2, 3 or 4 apply, the Commission shall, by means of implementing acts, revoke, or where applicable modify the boundaries of, the protected zone concerned, by means of an implementing act. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

Chapter III

Quality pests

Article 34

Prohibition of the presence of Union quality pests on plants for planting

1. The presence of a pest on particular plants for planting shall be prohibited, if that pest fulfils all of the following criteria:
 - (a) its identity is sufficiently characterised, in accordance with point (1) of Section 4 of Annex II;
 - (b) it is present in the Union and it does not qualify as a Union quarantine pest, in accordance with point (2) of Section 4 of Annex II;
 - (c) it is transmitted mainly through specific plants for planting, in accordance with point (3) of Section 4 of Annex II;
 - (d) its presence on those plants for planting has unacceptable economic impacts on the intended use of those plants for planting, in accordance with point (4) of Section 4 of Annex II;
 - (e) feasible and effective measures are available to prevent the presence of that pest on the plants for planting concerned, in accordance with point (5) of Section 4 of Annex II.
 - (f) Such a pest is referred to as 'a Union quality pest'.
2. By way of derogation from paragraph 1, the presence of Union quality pests on certain plants for planting shall only be prohibited where that presence exceeds

certain thresholds, established in accordance with the risk management principles set out in Section 2 of Annex IV, and only if all of the following conditions are fulfilled:

- (a) the presence of those Union quality pests on the specified plants for planting is economically acceptable only below those thresholds;
 - (b) it is possible to ensure that the presence of those Union quality pests on the specified plants for planting does not exceed those thresholds by measures concerning the area or place of production of those plants for planting, their parent stock or the lots of those plants for planting; and
 - (c) it is possible to verify that the threshold set is not exceeded in lots of those plants for planting.
3. The Commission shall establish, by means of an implementing act, a list of Union quality pests and the respective plants for planting. Where applicable, that list may also include specific prohibitions or thresholds concerning the presence of quality pests on one or more of the following categories of plants for planting in the meaning of Article 11 of [PRM Regulation]:
- (a) pre-basic material;
 - (b) basic material;
 - (c) certified material;
 - (d) standard material.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).

4. The list referred to in paragraph 3 shall include the pests, and where applicable the thresholds, and the respective plants for planting listed in the following acts:
- (a) Section II of Part A of Annex II of Directive 2000/29/EC;
 - (b) Annex I, points (3) and (6), and Annex II, point (3), to Council Directive 66/402/EEC on the marketing of cereal seed;
 - (c) the Annex of Directive 93/48/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by fruit plant propagating material and fruit plants intended for fruit production, pursuant to Council Directive 92/34/EEC;
 - (d) the Annex of Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC;
 - (e) Annex II, point (b) of Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed;
 - (f) Annex I, point 6 and Annex II, point B of 2002/56/EC of 13 June 2002 on the marketing of seed potatoes;

(g) Annex I, point 4 and Annex II, point 5, of Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants.

5. The Commission shall amend the implementing act referred to in paragraph 3 where a pest not listed in that act fulfils the conditions set out in paragraph 1 or where a pest listed in that implementing act no longer fulfils one or more of those conditions.

That implementing act shall be amended in accordance with the examination procedure referred to in Article 83(3).

6. The Commission shall amend the implementing act referred to in paragraph 3 by amending the scientific name of a pest, if justified so by the technical and scientific developments.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 83(2).

Article 35

Amendment of Section 4 of Annex II

The Commission shall be empowered to adopt delegated acts in accordance with Article 82 amending Section 4 of Annex II on criteria for the qualification of pests according to their risk to the Union, as regards the criteria concerning the identity of the pest, its relevance, the probability of its spread, its potential economic, social and environmental consequences as well as the availability of feasible and effective measures against it, taking into account the developments of technical and scientific knowledge, and development in international standards.

Article 36

Exception for scientific purposes, trials or varietal selections

The prohibition referred to in Article 34(1) and the thresholds referred to in Article 34(2) shall not apply to quality pests when used for scientific purposes, trials, varietal selections or exhibitions.

Chapter IV

Measures concerning plants, plant products and other objects

SECTION 1

MEASURES RELATING TO THE ENTIRE UNION TERRITORY

Subsection 1

Permanent measures

Article 37

Plants, plant products and other objects subject to specific requirements

1. Plants, plant products and other objects which are likely to host Union quarantine pests, shall be subject, when introduced into or moved within the Union territory, to specific requirements, if they pose a phytosanitary risk which may only be reduced to an acceptable level by the application of those requirements.
2. The Commission shall establish, by means of an implementing act, a list of the plants, plant products and other objects, and the respective requirements referred to in Annex IV, Part A to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).
3. The implementing act referred to in paragraph 2 may be amended in accordance with the examination procedure referred to in Article 83(3). Those amendments shall include the listing of the plants, plant products and other objects, and the respective requirements for their introduction into and movement within the Union, as referred to in paragraph 1.

Those amendments shall take place in accordance with the risk management principles set out in Section 2 of Annex IV, while taking into account the scientific and technical developments. Those requirements shall include one or more of the measures listed in Section 1 of Annex IV. Where appropriate, they may require the attestation of compliance of the plants, plant products and other objects concerned with the respective requirements, and the examinations and the controls required for that attestation.

That implementing act may restrict the application of those requirements to plants, plant products and other objects originating in specific third countries, where the concerned pests are known to be present.

Where appropriate, those requirements may include approvals of:

- (a) areas in third countries or Member States as free from certain quarantine pests;
- (b) methods to verify compliance of plants, plant products and other objects with the requirements of Article 61(2);
- (c) treatment methods or treatment products;

- (d) seed production methods.
4. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 83(4).

Article 38

Equivalent phytosanitary measures of third countries

1. The Commission may recognise, by means of implementing acts, phytosanitary measures adopted by a third country for export to the Union as equivalent to certain requirements, laid down pursuant to Article 37(2), concerning the introduction into the Union of those plants, plant products and other objects, where the following conditions are fulfilled:
- (a) the third country concerned objectively demonstrates that its measures achieve the Union's appropriate level of phytosanitary protection for those plants, plant products and other objects concerned; and
 - (b) the scientific and technical justification of that demonstration is confirmed by a risk assessment.

The Commission may investigate that demonstration in the country of origin of those plants, plant products or other objects in accordance with Article [72 of revised Regulation 882].

2. The implementing acts referred to in paragraph 1 shall be adopted, and where applicable amended or repealed, in accordance with the examination procedure referred to in Article 83(3).

Article 39

Plants, plant products and other objects the introduction of which into the Union shall be prohibited

1. The introduction into the Union of plants, plant products and other objects which are likely to host Union quarantine pests shall be prohibited if they pose a phytosanitary risk which cannot be reduced to an acceptable level by any specific requirements.
2. The Commission shall establish, by means of an implementing act, a list of the plants, plant products and other objects, and the respective third countries of origin and prohibitions referred to in Annex III, Part A of Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).
3. The implementing act referred to in paragraph 2 may be amended in accordance with the examination procedure referred to in Article 83(3). Those amendments shall include the listing of the plants, plant products and other objects, and the respective third countries of origin to which the prohibitions referred to in the paragraph 1 apply.

Those amendments shall take place in accordance with the risk management principles set out in Section 2 of Annex IV, while taking into account the scientific and technical developments.

4. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 83(4).

Article 40

Derogations from requirements or prohibitions

1. The Commission may decide, by means of implementing acts, to provide for derogations from certain requirements, laid down pursuant to Article 37(2), and certain prohibitions, laid down pursuant to Article 39(2), concerning the introduction into the Union of plants, plant products and other objects from certain third countries, where the following conditions are fulfilled:
 - (a) the risk of the introduction into the Union territory of Union quarantine pests is eliminated by alternative measures adopted, in accordance with the provisions of Annex IV, concerning the origin of those plants, plant products or other objects, their treatment or special precautions for their use;
 - (b) the scientific and technical justification of the elimination of that risk is confirmed by a risk assessment, where appropriate supplemented by investigations by the Commission in accordance with [Article 72 of Regulation 882] in the country of origin of those plants, plant products or other objects; and
 - (c) the compliance with those alternative measures is attested on the phytosanitary certificate accompanying those plants, plant products and other objects.
2. The implementing acts referred to in paragraph 1 shall be adopted, and where applicable amended or repealed, in accordance with the examination procedure referred to in Article 83(3).

Article 41

Exception from requirements or prohibitions for frontier zones

1. Provided that there is no risk of quarantine pests spreading, any requirements or prohibitions adopted pursuant to Articles 37(2) and (3) and Article 39(2) and (3) concerning introduction into the Union shall not apply to plants, plant products and other objects which are grown, produced or used in the immediate frontier zones of Member States with third countries and are introduced into the Union in order to be worked in nearby locations in the respective frontier zone. Those plants, plant products and other objects shall only move into and within those locations under the official control of the competent authorities. They shall not move outside those locations and within the other parts of the Union.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, setting out the width of frontier zones and distance of locations from the

border and setting out the procedures concerning the authorisation of trans-border movements in accordance with paragraph 1.

3. The Commission may lay down, by means of implementing acts, specific conditions for the introduction into the Union of particular plants, plant products and other objects, and specific third countries, which are subject to this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

Subsection 2 **Temporary measures**

Article 42

Plants for planting presenting new risks

1. Plants for planting from particular third countries which are likely to pose previously unidentified or newly emerging phytosanitary risks, and for which there is limited experience with trade, may be subject to temporary measures concerning their introduction into the Union. The Commission may adopt, by means of implementing acts, such temporary measures for those plants, plant products and other objects, in accordance with the examination procedure referred to in Article 83(3).
2. The measures referred to in paragraph 1 shall be adopted on the basis of preliminary evidence that the plants for planting concerned are likely to host Union quarantine pests, in accordance with the criteria set out in Annex III. Taking account of the risk management principles set out in Section 2 of Annex IV, the measures shall be one of the following:
 - (a) physical checks for quarantine pests of each lot of the introduced plants, plant products or other objects, on the basis of an intensified sampling and testing regime;
 - (b) imposition of a quarantine period to verify the absence in those plants, plant products and other objects of quarantine pests, in case this absence cannot be reliably confirmed through checks at the introduction of the plant, plant product or other object concerned into the Union territory;
 - (c) prohibition of introduction into the Union.

In addition, those measures may set out that specific plants for planting shall be subject to certification requirements, where this would be necessary to prevent the entry into, and establishment and spread within the Union, of the pests concerned.

3. The measures referred to in paragraph 1 shall have a duration of a maximum of two years. This period may be only once prolonged for two further years, if the circumstances referred to in paragraph 1 remain and justify such a prolongation. In this case, the measures referred to in paragraph 1 may be amended as appropriate.
4. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable emergency

measures, by means of implementing acts, in accordance with the procedure referred to in Article 83(4).

SECTION 2

MEASURES RELATING TO PROTECTED ZONES

Article 43

Plants, plant products and other objects subject to specific requirements for protected zones

1. Plants, plant products and other objects which are likely to host protected zone quarantine pests shall be subject, when introduced into or moved within the respective protected zones, to specific requirements, if they pose a phytosanitary risk to those protected zones which may only be reduced to an acceptable level by the application of those requirements.
2. The Commission shall establish, by means of an implementing act, a list of the plants, plant products and other objects, the respective protected zones and the respective requirements referred to in Annex IV, Part B to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).
3. The implementing act referred to in paragraph 2 shall be amended in accordance with the examination procedure referred to in Article 83(3). Those amendments may include the listing of plants, plant products and other objects, and the respective requirements for their introduction into and movement within the respective protected zones. Those acts may restrict the application of those requirements to plants, plant products and other objects originating in specific areas, where the pests concerned are known to be present.

Those amendments shall take place in accordance with the risk management principles set out in Section 2 of Annex IV, while taking into account the scientific and technical developments.

Article 44

Prohibition of introduction of plants, plant products and other objects into protected zones

1. The introduction into specified protected zones of plants, plant products and other objects which are likely to host the respective protected zone quarantine pests shall be prohibited, if they pose a phytosanitary risk to those protected zones which cannot be reduced to an acceptable level by any specific requirements.
2. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, the respective areas of origin, and the respective prohibitions referred to in Annex III, Part B to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 83(2).
3. The implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 83(3). Those amendments shall take

place in accordance with the risk management principles set out in Section 2 of Annex IV, while taking into account the scientific and technical developments.

Article 45

Derogations and equivalence

The provisions of Article 38 concerning the recognition of equivalent measures, and the provisions of Article 40 concerning derogations from requirements or prohibitions with regards to the introduction into and movement within the Union of plants, plant products and other objects, may accordingly apply for the protected zones for which requirements and prohibitions have been adopted pursuant to Articles 43 and 44.

Article 46

Exception from requirements or prohibitions for frontier zones

The provisions in Article 41 concerning the exceptions from requirements or prohibitions for frontier zones with regards to the introduction into and movement within the Union of plants, plant products and other objects, may accordingly apply for the protected zones for which requirements and prohibitions have been adopted pursuant to Articles 43 and 44.

SECTION 3

OTHER MEASURES CONCERNING PLANTS, PLANT PRODUCTS AND OTHER OBJECTS

Article 47

Exceptions for scientific purposes, trials, varietal selection and exhibitions

1. The requirements and prohibitions of Articles 37, 39 and 42 shall not apply to the introduction into and movement within the Union of the plants, plant products and other objects referred to in those Articles, if used for scientific purposes, trials, varietal selections or exhibitions.

The requirements and prohibitions of Articles 43 and 44 shall not apply on the introduction into and movement within the respective protected zones of the plants, plant products and other objects referred to in those Articles, if used for scientific purposes, trials, varietal selections or exhibitions.

2. The spread of pests through those plants, plant products and other objects shall be obviated by applying the following measures:
 - (a) the activities for which the plants, plant products or other objects are to be introduced into or moved within the Union shall have been approved by the competent authorities and shall be carried out in a quarantine facility designated as such by the competent authorities.

That approval shall be granted only if a risk assessment, carried out by the competent authorities, has shown that the risk of spread of quarantine pests that could be carried on those plants, plant products or other objects is adequately mitigated by the restrictions imposed by the competent authorities conditional to the approval.

That risk assessment shall concern the identity, biology and means of dispersal of quarantine pests that could be carried on those plants, plant products or other objects, the activities envisaged, the interaction with the environment and other relevant factors relating to the risk posed by the those plants, plant products or other objects;

- (b) the plants, plant products or other objects shall be limited to an amount that is adequate for the approved activities and does not exceed the capacity of the designated quarantine facility. They shall be introduced into or moved within the Union only if accompanied by a permit issued by the competent authorities and shall be kept in storage facilities approved by the competent authorities;
 - (c) the scientific and technical qualifications of the personnel by whom the activities are to be undertaken shall have been examined and approved by the competent authorities;
 - (d) compliance with the conditions referred to in point (a) to (c) is monitored by the competent authorities and remedial action is ensured upon non-compliance.
3. The Commission may, by means of implementing acts, lay down harmonised procedures for specific Union quarantine pests concerning:
- (a) the assessment and approval referred to in paragraph 2(a);
 - (b) the issuance and approval referred to in paragraph 2(b);
 - (c) the examination and approval referred to in paragraph 2(c);
 - (d) the monitoring and remedial action referred to in paragraph 2(d);
 - (e) the exchange of information between Member States and the Commission concerning the introduction into and movement within the Union of the pests concerned; and
 - (f) the notification of non-compliance with the conditions referred to in paragraph 2(a) to (c).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(3).

Article 48

General requirements for vehicles, packaging and documentation

1. Packaging used or, where appropriate, the vehicles transporting plants, plant products or other objects moving into or through the Union territory, or where relevant to the territory of a protected zone, shall be free from quarantine pests, and of such nature as to ensure that there is no risk of quarantine pests spreading.
2. Immediately after packaging, the packaging or, where appropriate, the vehicles transporting the plants, plant products or other objects shall be secured to ensure that, during transportation through the relevant territory, there is no risk of quarantine pests spreading in the Union territory or, where relevant the territory of the protected

zone, that the identity of the products will remain unchanged and that they remain secured.

Article 49

Quarantine facilities

1. If so required by acts adopted pursuant to Articles 25 and 27 concerning eradication measures, or Articles 37, 38, 40 or 42 concerning specific requirements, Member States shall designate quarantine facilities in their territory or authorise the use of designated quarantine facilities in other Member States.
2. Quarantine facilities shall be designated by the competent authorities at the request of any person or on the initiative of the competent authorities, provided that the conditions in paragraphs 3 to 6 are fulfilled.
3. Quarantine facilities shall meet the following technical biosecurity standards:
 - (a) physical isolation of the plants from other areas, including offices used by personnel, and adequate safeguards to ensure plants cannot be accessed or removed from the station without appropriate authorisation;
 - (b) provision of suitable growing conditions conducive for the development on those plants of signs and symptoms of quarantine pests;
 - (c) surfaces constructed of smooth and impervious material for cleaning and effective decontamination and resistant to deterioration and to attack by insects and other arthropods;
 - (d) irrigation, sewage and ventilation systems prohibiting transmission or escape of quarantine pests;
 - (e) systems for sterilisation, decontamination or destruction of waste, including infested plants and materials, and equipment before removal from the station;
 - (f) protective clothing and shoe covering to be worn by all personnel and visitors and removed on exit from the stations and if appropriate decontamination of personnel upon exit of the station.
4. Quarantine facilities shall have access to the necessary diagnostic expertise.
5. Quarantine facilities shall keep records of their activities, the staff authorised to enter the facility, visitors having entered the facility, the consignments of plants kept in the facility, their place of origin and reports of the observations and findings made on those plants, and completion of the required quarantine periods.
6. Quarantine facilities shall have systems in place for monitoring for the presence of quarantine pests in the facilities and their vicinity, the notification of findings of the presence of those pests to the competent authorities and action in case of those findings.
7. Plants shall be released from the quarantine facilities, by the competent authorities, only if they are found to be free from quarantine pests after completion of a

quarantine period, the duration of which shall be based on technical-scientific evidence.

8. The competent authorities shall supervise the quarantine facilities and carry out audits on a regular basis to ensure that the facilities meet the requirements referred to in paragraphs 3 to 7. In case it is concluded, on the basis of the results of those audits, that those requirements are no longer met, the competent authorities shall ensure immediate action to restore compliance or revoke the designation of the quarantine facility.
9. Member States shall communicate a list of the designated quarantine facilities in their territory to the Commission and the other Member States upon the request of one of them.

Article 50

Notifications of non-compliance

Member States shall notify to the Commission and the other Member States any case of non-compliance with the provisions of Sections 1 and 2 of this Chapter, and the measures taken.

Article 51

Export from the Union

1. The operators and the Member States shall take the appropriate measures to ensure that export and re-export from the Union to a third country, or a Union territory listed in Annex I, of plants, plant products and other objects takes place in accordance with the relevant rules for movement of plants, plant products and other objects within the Union territory laid down in accordance with this Chapter, while taking into account the phytosanitary status of the third country of destination, or the Union territory listed in Annex I, with regard to pests as referred to in Article 4.
2. However, if requested by the authorities of the importing country, or the Union territory listed in Annex I, or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in the importing country, or the Union territory listed in Annex I, export and re-export may take place in accordance with those provisions.
3. Where the provisions of a bilateral agreement concluded between the Union and a third country are applicable, plants, plant products and other objects exported from the Union to that third country shall comply with the said provisions.

Article 52

Amendment of Annex III

The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, amending Annex III on criteria to identify plants for planting which are likely to pose previously unidentified phytosanitary risks for the Union territory, as regards the characteristics and origin of plants for planting, taking into account the developments of technical and scientific knowledge, and development in international standards.

Chapter V

Registration of operators and traceability

Article 53

Official register of operators

1. Competent authorities shall keep and update a register of all operators whose professional activities bring along risks for plant health (hereinafter 'register'), to ensure effective controls concerning the implementation of this Regulation.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, setting out that certain operators referred to in paragraph 1 shall not be subject to this Article. Those delegated acts may specify particular requirements for the registration of certain categories of operators.

2. The register shall include all operators as defined in accordance with Article 3(4) of [PRM Regulation].
3. Paragraphs 1 and 2 shall not apply to operators exclusively supplying small quantities of plants, plant products and other objects to final users.

Article 54

Procedure for inclusion in the register

1. Operators referred to in Article 53(1 and 2) shall submit an application to the competent authorities for inclusion in the register.
2. The competent authorities shall adopt a decision, on the basis of the application of the operator, concerning its inclusion in the register.
3. The competent authorities shall revoke the registration if the operator so requests, or they conclude that the operator does not fulfil the criteria of Article 2(g) of this Regulation or, where applicable, of Article 3(4) of [PRM Regulation].

Article 55

Content of the register

The register shall contain:

- (a) name and address of the operator, including the contact details;
- (b) address of the premises involved in the activities, including, where applicable, collective warehouses or dispatching centres in the respective production areas;
- (c) official registration number and the code indicated in norm ISO 3166-1 for the Member State in which the operator is registered;
- (d) the activities exercised, as referred to in Article 2(g) with a statement whether the operator concerned issues plants passports or applies the mark referred to in

accordance with Annex II to the FAO International Standard for Phytosanitary Measures No 15 on *Regulation of wood packaging material in international trade*⁵, or carries out imports, exports and/or sales through distance contracts;

- (e) a specification, if relevant, where an operator produces and/or markets plant reproductive material in the meaning of [PRM Regulation] or issues official labels pursuant to Article 20 of that Regulation;
- (f) main plant genera and species concerned by the activities of the operator.

Article 56

Availability of information of official registers

1. The information contained in the official registers shall be made available to competent authorities or the Commission at their request.
2. The information contained in Article 55 (a, c and e) shall be made available to any operator at its request.

Article 57

Traceability

1. Operators shall ensure that plants, plant products and other objects under their control that are subject to requirements or prohibitions pursuant to Articles 37, 38, 39, 40, 42, 43, 44 and 45 are traceable at all stages of production, movement into or within and export from the Union.
2. For the purpose of paragraph 1, operators shall keep information allowing them to identify the operators supplying them with those plants, plant products and other objects. On request, they shall make such information available to the competent authorities.
3. For the purpose of paragraph 1, operators shall keep information allowing them to identify the persons whom they have supplied with the plants, plant products and other objects concerned, with the exception of final users. On request they shall make such information available to the competent authorities.
4. Operators shall keep records of the supplies referred to in paragraphs 2 and 3 for at least three years since the plants, plant products and other objects concerned have been respectively supplied to or by them.

⁵ Food and Agriculture Organisation of the United Nations, Rome, 2011. International Standard for Phytosanitary Measures 15: Regulation of wood packaging material in International trade (2009).

Chapter VI

Certification of plants, plant products and other objects

SECTION 1

PHYTOSANITARY CERTIFICATES REQUIRED FOR PLANTS, PLANT PRODUCTS AND OTHER OBJECTS

Article 58

Plants, plant products and other objects for which phytosanitary certificates are required

1. The introduction into the Union of certain plants, plant products and other objects, which are likely to pose a phytosanitary risk to the Union territory, shall only be allowed if they are accompanied by a phytosanitary certificate or a phytosanitary certificate for re-export (hereinafter 'phytosanitary certificate') assuring that the respective risk is eliminated or reduced to an acceptable level.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, listing the plants, plant products and other objects, and the respective third countries, for which phytosanitary certificates are required for their introduction into the Union.

Those lists shall include at least:

- (a) plants for planting, other than seeds;
- (b) the plants, plant products and other objects listed in Annex V, Part B (I) of Directive 2000/29/EC, other than the plants for planting referred to in point (a);
- (c) other plants, plant products and other objects listed pursuant to Articles 37(2), or subject to the measures referred to in Articles 38(1) and 40(1);
- (d) seeds listed pursuant to Article 34(3);
- (e) plants, plant products and other objects for which measures have been adopted pursuant to Article 25(1) concerning their introduction into the Union.

Those lists may also include plants, plant products and other objects, other than the ones referred to in this paragraph, if their movement into the Union is likely to contribute to the introduction of Union quarantine pests into the Union.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, listing the plants, plant products and other objects, and the respective third countries, for which phytosanitary certificates are only required for their introduction into certain protected zones.

Those lists shall include at least:

- (a) the plants, plant products and other objects listed in Part B(II) of Annex V of Directive 2000/29/EC;

- (b) other plants, plant products and other objects listed pursuant to Articles 43(2), or, pursuant to Article 45, subject to the measures referred to in Articles 38(1) and 40(1).

Those lists may also include plants, plant products and other objects, other than the ones referred to in this paragraph, if their introduction into the respective protected zones is likely to contribute to the introduction of protected zone quarantine pests into those zones.

- 4. The phytosanitary certificate referred to in paragraph 1 shall attest, as applicable, compliance with the provisions of the Articles referred to in paragraphs 2 and 3, as well as with the provisions of Articles 3(1,2) and 30(2).
- 5. The delegated acts referred to in paragraphs 2 and 3 may exempt particular plants, plant products and other objects referred to in paragraph 2(c) and 3(b) from the requirement referred to in paragraph 1.
- 6. This Article shall apply without prejudice to any derogations and exceptions adopted pursuant to Articles 36, 38, 40, 41, 45, 46 and 47.

Article 59

Conditions for validity of phytosanitary certificate

- 1. In the case of a third country which is party to the IPPC, the phytosanitary certificates shall only be valid if they have been issued by representatives of the official national plant protection organisation of that third country or, under their responsibility, by other public officers who are technically qualified and duly authorised by the concerned official national plant protection organisation.

In the case of a third country which is not party to the IPPC, the phytosanitary certificates shall only be valid if they have been issued by authorities empowered to this effect on the basis of laws or regulations of the third country concerned, and only if the concerned third country has notified these authorities to the Commission. The Commission shall inform the Member States of the received notifications.

- 2. In addition to the requirements referred to in paragraph 1, the phytosanitary certificates shall only be valid if they have been issued pursuant to the following requirements:
 - (a) they have been issued in at least one of the official languages of the Union;
 - (b) they have been issued in compliance with the provisions of the IPPC;
 - (c) they are addressed to the Union or one of its Member States;
 - (d) they have been issued no more than 14 days before the date on which the plants, plant products or other objects covered by them have left the third country in which they were issued;
 - (e) where applicable they specify, under the heading ‘Additional Declaration’ and in accordance with the implementing acts adopted pursuant to Articles 37(2)

and 43(2), which special requirement out of those listed as alternatives in the relevant provision of those acts have been complied with. This specification shall be given through reference to the relevant provision of those acts;

- (f) where applicable, they attest compliance with the phytosanitary measures recognised pursuant to Article 38(1);
 - (g) they contain information in accordance with the relevant models specified in the Annex to the IPPC.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, specifying the conditions for the validity of phytosanitary certificates by third countries which are not a party to the IPPC.
 4. The Commission may adopt, by means of implementing acts, the format of the phytosanitary certificates issued by third countries. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 83(2).
 5. Electronic phytosanitary certificates shall only be valid when provided through the computerised information management system referred to in Article [80 of revised Regulation 882/2004].

Article 60

Cancellation of phytosanitary certificate

In the case the competent authority concludes that the conditions for validity referred to in Article 58 are not fulfilled, it shall invalidate the phytosanitary certificate and ensure that it does not accompany any longer the plants, plant products or other objects concerned.

SECTION 2

PLANT PASSPORTS REQUIRED FOR THE MOVEMENT OF PLANTS, PLANT PRODUCTS AND OTHER OBJECTS WITHIN THE UNION

Article 61

Plants, plant products and other objects for which a plant passport is required

1. The movement within the Union of certain plants, plant products and other objects, which are likely to pose a phytosanitary risk to the Union territory, shall only be allowed if they are accompanied by an official label [attesting compliance with certain phytosanitary requirements of this Regulation] (hereinafter: 'plant passport'). [assuring that the respective risk is eliminated or reduced to an acceptable level.]
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, listing the plants, plant products and other objects, for which plant passports are required for their movement within the Union.

Those lists shall include at least:

- (a) plants for planting, other than seeds;

- (b) the plants, plant products and other objects listed in Annex V, Part A (I) of Directive 2000/29/EC, other than the plants for planting referred to in point (a);
- (c) other plants, plant products and other objects listed pursuant to Articles 37(2), or subject to the measures referred to in Articles 38(1) and 40(1);
- (d) seeds listed pursuant to Article 34(3);
- (e) plants, plant products and other objects for which measures have been adopted pursuant to Article 25(1) concerning their movement within the Union.

Those lists may also include plants, plant products and other objects, other than the ones referred to in this paragraph, if their movement within the Union is likely to contribute to the spread of Union quarantine pests within the Union.

3. The movement into and within protected zones of certain plants, plant products and other objects shall only be allowed if they are accompanied by a plant passport valid for those protected zones.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, listing the plants, plant products and other objects, for which plant passports are only required for their movement into and within certain protected zones.

Those lists shall include at least:

- (a) the plants, plant products and other objects listed in Annex V, Part A (II) of Directive 2000/29/EC;
- (b) other plants, plant products and other objects listed pursuant to Articles 43(2), or, pursuant to Article 45, subject to the measures referred to in Articles 38(1) and 40(1).

Those lists may also include plants, plant products and other objects, other than the ones referred to in this paragraph, if their introduction into the respective protected zones is likely to contribute to the introduction of protected zone quarantine pests into those zones.

5. The plant passport referred to in paragraphs 1 and 3 shall attest, as applicable, compliance with the provisions of the Articles referred to in paragraphs 2 and 4, as well as with the provisions of Articles 3(1, 2) and 30(2).
6. The delegated acts referred to in paragraphs 2 and 4 may exempt particular plants, plant products and other objects referred to in paragraphs 2(c) and 4(b) from the requirement referred to in paragraph 1.
7. This Article shall apply without prejudice to any derogations and exceptions adopted pursuant to Articles 36, 38, 40, 41, 45, 46 and 47.

Article 62
Exception for final users

No plant passport shall be required for the movement of a plant, plant product or other objects to a final user.

Article 63
Exceptions for local movements

1. No plant passport shall be required for the following movements, provided that there is no risk of spreading of quarantine pests:
 - (a) the local movement of plants, plant products and other objects within specific limited parts of a Member State, originating from small operators whose entire production and sale of plants, plant products and other objects are destined for final users on the local market;
 - (b) the movements of plants, plant products and other objects between the premises of the same operator over short distances.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 82 setting out specified limits for the sizes of small operators, local markets and short distances.

Article 64
Logo and information items

1. The plant passport shall contain, as a logo, the flag of the Union, together with the following information:
 - (a) the botanical name of the concerned plant species, in case of plants and plant products;
 - (b) the code indicated in norm ISO 3166-1 for the Member State in which the operator which issued the plant passport is registered;
 - (c) the registration number of the registered operator;
 - (d) the lot number of the concerned plant or plant product.
2. The lot number referred to in point (d) of paragraph 1 may be replaced by a reference to a unique traceability data carrier, such as barcode, hologram or chip.

Article 65
Form and format

1. The plant passport referred to in Article 61(1) and 61(3) shall contain the indication 'Plant Passport'.

The plant passports referred to in Article 61(4) shall in addition contain the indication 'ZP' (Zona Protecta) and the scientific name of the pest relevant to the concerned protected zones and shall have a different colour than the plant passport referred to in the first subparagraph.

2. The plant passports referred to in Article 61(1), 61(2) and 61(4) shall be issued in the form of a distinct label, which may be printed in any legible size on any suitable substrate, provided that the plant passport is kept separate from the other information on that label.

The information referred to in Article 64(1) and in paragraph 1 shall be provided in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

3. The format of the plant passports referred to in Article 61(1), 61(2) and 61(4) shall be harmonised for the entire Union.

The Commission shall adopt, by means of an implementing act, a harmonised format for the plant passports referred to in subparagraph 1. That act shall set out the size and colour of the plant passports, the logo referred to in Article 64(1) as well as the font and font size to be used. Different sizes may be specified for specific types of plants, plant products or other objects.

That act shall be adopted within one year after the entry into force of this Regulation, in accordance with the advisory procedure referred to in Article 83(2).

4. Plant passports shall be affixed to the plants, plant products and other objects concerned when they are moved within the Union. Where such plants, plant products or other objects are moved in a package, bundle or container, the plant passport shall be affixed to that package, bundle or container.

Article 66

Official label of plant reproductive material

In the case of plants for planting marketed, or produced with a view to be marketed, as pre-basic, basic or certified material in the meaning of, and in accordance with, [PRM Regulation], the plant passport and the official label produced in accordance with Article 20 of that Regulation shall be combined in a single document.

Article 67

Issuance by operators and competent authorities

1. Plant passports shall only be issued by registered operators, authorised by the competent authorities to issue plant passports, hereinafter 'authorised operators', under the official control of the competent authorities.
2. Plant passports may, however, be issued by the competent authorities where the operator requests so.

Article 68

Examinations of plants, plant products, other objects for the issuance of plant passports

1. Plant passports for the entire Union territory shall be issued provided that the concerned plants, plant products and other objects and their packaging are meticulously examined, either in their entirety or by representative samples of the plants, plant products and other objects concerned and it is concluded that:
 - (a) they are free from Union quarantine pests;
 - (b) they comply with the provisions of Article 34(1), (2) concerning the presence of quality pests on plants for planting;
 - (c) they comply with the requirements adopted concerning plants, plant products and other objects in accordance with Articles 37(2); and
 - (d) where applicable, they comply with the provisions of 38(1) and 40(1).

2. Plant passports for protected zones shall be issued provided that the concerned plants, plant products and other objects and their packaging are meticulously examined, either in their entirety or by representative samples of the plants, plant products and other objects concerned and it is concluded that:
 - (a) they are free from the respective protected zone quarantine pests;
 - (b) (they comply with the provisions of Articles 34(1), (2) concerning the presence of quality pests on plants for planting;
 - (c) they comply with the requirements concerning plants, plant products and other objects adopted in accordance with Article 43(2); and
 - (d) where applicable, they comply with the provisions of Articles 38(1) and 40(1) pursuant to Article 45.

3. The examinations of the plants, plant products and other objects referred to in paragraphs 1 and 2 shall be carried out by the operators, or where applicable by the competent authorities, who issue the plant passports pursuant to Article 67. Those examinations shall be carried out in accordance with the following conditions:
 - (a) they shall be carried out regularly, at appropriate times and on the basis of the related risk;
 - (b) they shall be carried out in the premises of the operators and in their immediate vicinity;
 - (c) they shall extend to the relevant plants for planting or plant products grown, produced or used by the producer, or otherwise present on its premises, as well as to the growing medium used there; and
 - (d) they shall be made at least by visual observation, without prejudice to any specific examination requirements or measures adopted in accordance with Article 25(1), 27(2), 37(2), 38(1), 40(1), 42(1) and 43(2).

4. The Commission may adopt, by means of implementing acts, modalities concerning the methods for and frequency and timing of the examinations referred to in paragraph 3, with regard to specific plants, plant products and other objects, and on the basis of the particular phytosanitary risks they may present. Those implementing acts shall take into account the technical and scientific knowledge and developments. Those implementing acts shall be adopted, and where appropriate amended, in accordance with the examination procedure referred to in Article 83(3).

Article 69

Examinations as parts of certification schemes for plants for planting

1. The Commission may adopt, by means of implementing acts, specific modalities for the examination methods during the production of certain plants for planting and, where appropriate, their number of generations, hybrids or subdivision of categories into grades satisfying different conditions. Those modalities may include the methods referred to in Article 68(4) and shall take into account the technical and scientific knowledge and developments.

Those implementing acts shall be adopted, and where appropriate amended, in accordance with the examination procedure referred to in Article 83(3).

2. Where the acts referred to in paragraph 1 require that certain plants for planting are subject to examination requirements to ensure the absence of certain quality pests or quarantine pests, and those plants for planting are subject to certification schemes pursuant to Article 21(2)(3) of [PRM Regulation], the respective examinations shall be combined in a single examination scheme.

Article 70

Conditions for authorisation of operators to issue plant passports

1. Operators shall be authorised by the competent authorities to issue plant passports only where they comply with the following conditions:
 - (a) they possess the necessary knowledge to carry out the examinations referred to in Article 68 and 69 concerning the quarantine and quality pests that could affect the relevant plants, plant products and other objects and their signs and symptoms;
 - (b) they shall possess the necessary knowledge concerning the means to prevent the presence and spread of those pests, the means to eradicate them and provide the relevant training to their personnel;
 - (c) they identify and monitor the critical points of the production process as concerns compliance of those plants with the provisions referred to in Article 68(1, 2), and keep records of this;
 - (d) they ensure that the risks of infestation by the pests concerned are adequately mitigated;

- (e) they have in place systems and procedures enabling them to fulfil their obligations concerning traceability pursuant to Article 57, immediately and on a permanent basis.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, setting out qualification and training requirements to be fulfilled by the operators in order for them to comply with the conditions of paragraph 1(a) and (b).

Article 71

Movements of plants, plant products and other objects within operators' premises

1. Registered operators shall have in place systems and procedures to allow identification of the movements of their plants, plant products and other objects within their own premises.
2. The information on the supplies as contained in those systems and procedures shall be made available to the competent authorities on request.

Article 72

Withdrawal of authorisation

1. Competent authorities shall immediately investigate any actual or suspected non-compliance by authorised operators with the conditions in Article 70 and impose corrective measures on those operators as necessary.
2. Competent authorities shall without delay withdraw the authorisation referred to in Article 70(1) of an authorised operator if it no longer complies with the conditions set out in that Article and does not apply the corrective measures imposed by the competent authorities within the requested period of time.
3. Competent authorities shall without delay withdraw the authorisation referred to in Article 70(1) to issue plant passports for the entire Union territory, if an authorised operator is located within a restricted area as referred to in Article 15. That withdrawal shall only concern the plants, plant products and other objects likely to host the Union quarantine pest for which the restricted area was established.
4. Competent authorities shall without delay withdraw the authorisation referred to in Article 70(1) to issue plant passports for certain protected zones, if an authorised operator is located within a restricted area as referred to in Article 31(1). That withdrawal shall only concern the plants, plant products and other objects likely to host the protected zone quarantine pest for which the restricted area was established.
5. By way of derogation to paragraphs 3 and 4, the respective withdrawals may not take place, or may be revoked, where the competent authorities ensure by intensified control and appropriate measures that the provisions concerning examinations referred to in Article 68(1, 2) are complied with.

Article 73
Replacing a plant passport

1. In case a lot of plants, plant products or other objects, for which a plant passport has been issued, is divided up, or several of such units or parts thereof are combined into a single lot, the concerned registered operator shall replace the plant passport through the issuance of another plant passport (replacing plant passport).
2. The replacing plant passport shall only be issued if the unaltered identity and origin of the product concerned is guaranteed and it is concluded that that product, since dispatch by the producer, continues complying with the provisions referred to in Article 68(1, 2).

Article 74
Plant passports replacing phytosanitary certificates

In the case where plants, plant products and other objects, introduced into the territory of the Union from a third country accompanied with a phytosanitary certificate, require a plant passport for movement within the Union pursuant to Article 61(2, 4), that plant passport shall be issued to replace the phytosanitary certificate.

That issuance shall take place on the condition that the checks at introduction into the territory of the Union have been completed and the plants, plant products and other objects concerned have been found, where applicable, in compliance with the provisions referred to in Article 68.

Article 75
Prohibition of use of plant passport

1. The operator shall remove the plant passport from the plants, plant products and other objects concerned, in case it is proven that the requirements of Articles 64 and 65 concerning the logo, information items, form or format of the plant passport, or the requirements referred to in Article 68(1, 2, 3, 4) are not fulfilled.

The operator shall subsequently invalidate that plant passport and retain it for at least three years.

2. In case the operator fails to implement the provisions of paragraph 1, the competent authorities shall themselves remove and invalidate the plant passport concerned.

SECTION 3
MARK FOR WOOD PACKAGING MATERIAL REQUIRED FOR INTRODUCTION OF WOOD PACKAGING MATERIAL INTO, AND ITS MOVEMENT WITHIN, THE UNION

Article 76
Certification of wood packaging material

1. Requirements adopted pursuant to Articles 25(1), 27(2), 37(2), 38(1), 40(1) and 43(2) may concern the application of a mark in accordance with Annex II to the FAO

International Standard for Phytosanitary Measures No 15 on Guidelines for regulating wood packaging material in international trade⁶, certifying that wood packaging material has been treated in accordance with the specifications in Annex II to that standard. In that case, that mark shall only be placed by operators registered in accordance with Article 54.

2. The Commission shall be empowered, in accordance with Article 82, to adopt delegated acts setting out requirements for the authorisation, supervision and withdrawal of authorisation by the competent authorities of operators applying that mark.

SECTION 4

PHYTOSANITARY CERTIFICATES REQUIRED FOR THE EXPORT OF PLANTS, PLANT PRODUCTS AND OTHER OBJECTS FROM THE UNION

Article 77

Phytosanitary certificates for export and re-export

1. Where a third country requires phytosanitary certificates for export or re-export at import of plants, plant products or other objects from the Union, those certificates shall be issued by the competent authorities, at the request of the operator concerned. Those certificates shall be in compliance with the provisions of IPPC and shall contain information in accordance with the relevant models specified to the Annex of IPPC.

Competent authorities shall issue those certificates only where the official information available is sufficient to guarantee compliance with the requirements of the third country of destination.

2. The Commission may adopt, by means of implementing acts, the format of the phytosanitary certificates for export and re-export. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 83(2).
3. Electronic phytosanitary certificates shall only be valid when provided through the computerised information management system referred to in Article [80 of revised Regulation 882/2004].

Article 78

Pre-export certificates

1. The Member State from which the plants, plant products and other objects referred to in Article 77(1) are exported from the Union and the Member State where the plants, plant products and other objects originated shall exchange information as necessary to ensure that the export certification is completed without delay.

⁶ Secretariat of the International Plant Protection Convention (2009), International Standard for Phytosanitary Measures 15: Regulation of wood packaging material in International trade.

That exchange shall take place in the form of a harmonised document (hereinafter 'pre-export certificate'), in which the Member State where the plants, plant products and other objects originated officially attests compliance of those plants, plant products or other objects with certain phytosanitary requirements of third countries. That attestation shall be based on official technical information concerning the phytosanitary status or the origin of the plants, plants products or other objects concerned and, where applicable, the phytosanitary procedures applied.

2. The Member State where the plants, plant products and other objects originated shall issue the pre-export certificate on request of the registered operator concerned, where applicable taking account of the export destination of the plans, plant products and other objects specified by the operator concerned. That pre-export certificate shall be completed in such a way that the Member State of export is able to declare with confidence in its phytosanitary certificate, based on the pre-export certificate, that the plants, plant products or other objects meet specific requirements of the third country to which they are exported.
3. The pre-export certificate shall accompany the plants, plant products and other objects concerned during their movement within the Union, unless the information contained in it is officially exchanged between the Member States concerned by electronic means.
4. The Commission shall adopt, by means of implementing acts, a harmonised format for the pre-export certificate. That format may concern pre-export certificates issued on paper and phytosanitary pre-export certificates issued by electronic certification.

Those implementing acts shall be adopted, and where appropriate amended, in accordance with the examination procedure referred to in Article 83(3).

SECTION 5

DOCUMENTS FOR TRANSIT OF PLANTS, PLANT PRODUCTS AND OTHER OBJECTS THROUGH THE UNION

Article 79

Phytosanitary transit

1. Plants, plant products and other objects may be moved in phytosanitary transit through the Union territory provided that the following conditions are met:
 - (a) they are packed and moved in such a way that there is no risk of spreading of quarantine pests during their transit;
 - (b) they are accompanied by a signed attestation of the operator that those plants, plant products or other objects originate outside the Union territory, are destined for a third country and are packed and moved in such a way that there is no risk of spreading of quarantine pests during their transit;
 - (c) they are moved under official control by the competent authorities.

2. The provisions in paragraph 1 concerning the transit of plants, plant products and other objects through the Union territory shall apply accordingly to their transit through protected zones.
3. Without prejudice to Article 51, plants, plant products and other objects that do not comply with the provisions referred to in Article 68(1, 2, 3, 4) may be exported to third countries, or Union territories listed in Annex I, provided that the following conditions are met:
 - (a) they are packed and moved in such a way that there is no risk of spreading of quarantine pests during their transit until the point of exit from the Union territory;
 - (b) they are accompanied by a signed attestation of the operator that those plants, plant products or other objects originate inside the Union territory, do not comply with the Union phytosanitary requirements, are destined for third countries and are packed and moved in such a way that there is no risk of spreading of quarantine pests during their transit;
 - (c) they are moved under official control by the competent authorities.
4. The Commission shall be empowered, in accordance with Article 82, to adopt delegated acts setting out the contents of, and a harmonised format for, the attestation referred to in paragraph 1.

Chapter VII

Measures supporting the implementation of this Regulation

Article 80

Establishment of a team of Union phytosanitary experts

The Commission shall establish a team of Union phytosanitary experts to provide assistance to the competent authorities in the implementation of this Regulation.

Article 81

Establishment of application system for notification and reporting

The Commission shall establish an electronic application system for the notifications and reporting of the presence of pests referred to in Articles 8, 26 and 31 and the notification of non-compliance with the provisions set out in Chapters III, IV and VI. That system shall be connected to and compatible with the computerised information system referred to in Article 80(1) of Regulation [official controls].

Member States shall notify those notifications and reports through that electronic application system.

Chapter VIII

Final provisions

Article 82

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in Articles 1(2), 5, 9(2), 19, 20(4), 23(4), 29, 30(5), 35, 41(2), 52, 53(1), 58(2), 58(3), 59(3), 61(2), 61(4), 63(2), 70(2), 76(2), 79(4) and 85(3) shall be conferred on the Commission for an indeterminate period of time from the entry into force of this Regulation.
3. The delegation of power referred to in this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to this Regulation shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 83

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.

5. Any references in Directive 2000/29/EC, Council Directive 69/464/EEC, Council Directive 93/85/EEC, Council Directive 98/57/EC and Council Directive 2007/33/EC to the Standing Committee on Plant Health, and the acts adopted in accordance with the provisions of those Directives, shall be construed as references to the Standing Committee referred to in paragraph 1.

Article 84

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

The Member States shall notify these provisions to the Commission within one year after the entry into force of this Regulation and shall notify without delay any subsequent amendments of those provisions.

Article 85

Repeals

1. Council Directive 2000/29/EC and the acts referred to in Annex V are repealed.
2. References to the repealed Directives and Regulations shall be construed as references to this Regulation and shall be read in accordance to the correlation table set out in Annex V.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 82, setting out that one or more of the acts referred to in Annex V shall be repealed at a specific date after the date from which this Regulation shall apply. In case of conflict between the provisions of those acts and the provisions of this Regulation, the provisions of this Regulation shall prevail.

Article 86

Entry into force and application

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

This Regulation shall apply from 36 months after its entry into force.

...

ANNEX I

Territories which, for the purpose of this Regulation, are not considered as belonging to the territory of the Union as referred to in Article 1(2)

The geographical territories of:

1. Guadeloupe
2. French Guiana
3. Martinique
4. Reunion
5. Saint Barthelemy
6. Saint-Martin
7. [Mayotte – Annex II of TFEU, status change requested by FR and supported by COM for 2014]
8. Ceuta
9. Melilla
10. The Canary Islands
11. [Bonaire (NL) – Annex II of TFEU (since 2010 formally a municipality of NL)]
12. [Saba (NL) – Annex II of TFEU (idem)]
13. [Sint Eustatius (NL) – Annex II of TFEU (idem)]

ANNEX II

Criteria for the qualification of pests according to their risk to the Union

SECTION 1

CRITERIA TO IDENTIFY PESTS WHICH QUALIFY AS A QUARANTINE PEST FOR THE UNION TERRITORY, OR SPECIFIC PARTS OF THE UNION TERRITORY, AS REFERRED TO IN ARTICLES (1), 26(3) AND 30(1)

(1) Identity of the pest

The taxonomic identity of the pest shall be clearly defined or, alternatively, the pest shall have been shown to produce consistent symptoms and to be transmissible.

The taxonomic identity of the pest shall be defined at species level or, alternatively, a higher or lower taxonomic level if supported by a scientifically sound rationale, including evidence demonstrating that the taxonomic level concerned is appropriate based on factors such as virulence, host range or vector relationships.

(2) Presence of the pest in the Union

The pest shall be absent from the Union territory or, in case it is or distributed within the Union to a limited extent, from specific part(s) of the Union territory.

(3) Probability of entry, establishment and spread of the pest in the Union territory, or the specific part(s) of the Union territory where it is not present

(a) *Probability of entry into the Union territory*

The pest shall be capable of entry into the Union, or the specific part(s) of the Union territory where it is not present (hereinafter: 'endangered area'), because:

- (i) it is associated, spatially or temporally, with the entry pathway at origin of the concerned plant, plant product or other object;
- (ii) it survives during transport or storage;
- (iii) it may be transferred to a suitable host plant, plant product or other object in the Union territory.

(b) *Probability of establishment in the Union territory*

The pest shall be capable of perpetuating its presence for the foreseeable future (hereinafter: 'establishment') in the Union, or the specific part(s) of the Union territory where it is not present, because:

- (i) suitable hosts, alternate hosts and/or vectors of the pest are sufficiently available;

- (ii) factors in the environment (for example suitability of climate, soil, pest and host competition) that are critical to the development of the pest, its host and if applicable its vector, and its ability to survive periods of climatic stress and complete its life cycle are favourable;
- (iii) cultural practices and control measures applied in the Union are favourable;
- (iv) the survival methods, reproductive strategy, genetic adaptability of the pest and its minimum viable population size support its establishment.

(c) *Probability of spread within the Union*

The pest shall be capable of territorial spread in the Union, or the specific part(s) of the Union territory where it is not present, due to one or more of the following factors:

- (i) the natural and/or managed environment is suitable for natural spread of the pest;
- (ii) insufficient barriers to natural spread of the pest are present;
- (iii) commodities or conveyances allow for movement of the pest, and their intended use supports further natural spread;
- (iv) potential hosts and/or vectors of the pest are present;
- (v) insufficient natural enemies and/or antagonists of the pest are present.

(4) Potential economic, social and environmental consequences of the pest

The entry, establishment and spread of the pest in the Union, or the parts of the Union where the pest is not present, shall have unacceptable economic, social and/or environmental impacts for the Union in one or several of the following areas:

- (a) Direct effects on potential hosts in the endangered area:
 - crop losses in terms of yield and quality;
 - costs of control measures;
 - costs of replanting and losses due to the necessity of growing substitute crops;
 - effects on existing production practices;
 - effects on street trees, parks and public and private green;
 - reduction, displacement or elimination of keystone plant species, plant species that are major components of ecosystems and endangered native plant species;
 - capacity of the pest to act as a vector for other pests.

Those effects shall be assessed taking account of the range of the host plants, and on the basis of the types, amount and frequency of the damage suffered by those host plants.

(b) Indirect effects within and outside the endangered area:

- changes to producer costs or input demands, including control costs and costs of eradication and containment;
- effects on producer profits that result from changes in production costs, yields or price levels;
- changes to domestic or foreign consumer demand for a product resulting from quality changes;
- effects on domestic and export markets and prices paid, including effects on export market access and likelihood of phytosanitary restrictions imposed by trading partners;
- resources needed for additional research and advice;
- environmental and other undesired effects of control measures;
- effects on plant communities and biodiversity;
- effects on designated environmentally sensitive or protected areas;
- changes in ecological processes and the structure, stability or processes of an ecosystem, including further effects on plant species, erosion, water table changes, fire hazards, nutrient cycling;
- costs of environmental restoration;
- effects on food security;
- effects on employment;
- effects on water quality, recreation, tourism, animal grazing, hunting, fishing.

(5) Availability of measures against the pest

Feasible and effective measures shall be available to prevent the entry, establishment and/or spread of the pest and mitigate its phytosanitary risks and impacts.

SECTION 2

CRITERIA TO IDENTIFY QUARANTINE PESTS WHICH QUALIFY AS A PRIORITY PEST AS REFERRED TO IN ARTICLE 4(1,2)

(1) Presence of the quarantine pest in the Union

The pest shall be absent from the Union territory or from most of the area in the Union territory where the respective host plants are grown or occur naturally.

(2) Probability of entry, establishment and spread in the Union of the quarantine pest

The pest shall be capable to enter, establish and spread in most of the area in the Union territory where the respective host plants are grown or occur naturally.

(3) Potential economic, social and environmental consequences of the quarantine pest

The pest shall be considered to have most severe economic, social and/or environmental impacts for the Union, if its entry, establishment and spread have one or several of the following impacts:

- (a) Economic impacts: the pest shall have the potential to cause major losses in terms of the direct and indirect effects referred to in point (4)(b) of Section I for crops with a total annual production value for the Union of at least EUR 1 billion.
- (b) Social impacts: the pest shall have the potential to cause one or more of the following effects:
 - (i) a significant employment decrease in the agriculture, horticulture of forestry sector concerned;
 - (ii) risks to food security;
 - (iii) the disappearance of or permanent large-scale damage to certain main tree species growing or cultivated in the Union.
- (c) Environmental impacts:
 - (i) reduction, displacement or elimination of keystone plant species, plant species that are major components of ecosystems and endangered native plant species in relation to protected areas covered under the provisions of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora⁷ and Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds⁸;
 - (ii) major and permanent increases of the use of plant protection products on the crops concerned.

⁷ OJ L 206, 22.7.1992, p. 7.

⁸ OJ L 20, 26.1.2010, p. 7.

SECTION 3

CRITERIA TO IDENTIFY PESTS WHICH PROVISIONALLY QUALIFY AS A QUARANTINE PEST REQUIRING TEMPORARY MEASURES AS REFERRED TO IN ARTICLES 26(1) AND 27(1)

- (1) Identity of the pest

The pest shall meet the criterion defined in point (1) of Section 1.

- (2) Presence of the pest in the Union

The pest shall be likely absent from the Union territory or from specific part(s) of the Union territory.

- (3) Probability of entry, establishment and spread of the pest in the Union territory, or the specific part(s) of the Union territory where it is not present

The pest shall likely meet the criteria defined in point (3) of Section 1.

- (4) Potential economic, social and environmental consequences of the pest

The pest shall likely have unacceptable economic, social and/or environmental impacts for the Union, if it would enter, establish and spread in the Union, as concerns one or several of the areas defined in point (4) of Section 1.

Those impacts shall include at least the direct effects listed under point (3)(a) of Section 1.

As regards the temporary measures referred to in Article 26(1) and Article 27(1), those impacts shall concern the impacts for, respectively, the concerned Member State territory and the Union territory.

- (5) Availability of measures against the pest

Feasible and effective measures shall be available to prevent the entry, establishment and/or spread of the pest and mitigate its phytosanitary risks and impacts.

SECTION 4

CRITERIA TO IDENTIFY PESTS WHICH QUALIFY AS A QUALITY PEST AS REFERRED TO IN ARTICLE 34(1)

- (1) Identity of the pest

The taxonomic identity of the pest shall be clearly defined or, alternatively, the pest shall have been shown to produce consistent symptoms and to be transmissible.

The taxonomic identity of the pest shall be defined at species level or, alternatively, a higher or lower taxonomic level if supported by a scientifically sound rationale, including evidence demonstrating that the taxonomic level concerned is appropriate based on factors such as virulence, host range or vector relationships.

(2) Relevance of the pest to the Union territory

The pest shall be present in the Union territory and shall not qualify as a Union quarantine pest.

(3) Probability of spread in the Union of the pest

The pest shall be transmitted mainly via specific plants for planting, taking account of the life cycle of the pest and its host(s), the epidemiology of the pest and sources of infestation with the pest.

The assessment shall include as appropriate the following aspects:

- the number of life cycles of the pest on the concerned host;
- the biology, epidemiology and survival of the pest;
- possible natural, human-assisted or other pathways for transmission of the pest to the concerned host and pathway efficiency, including mechanisms of dispersal and dispersal rate;
- secondary infestation and transmission of the pest from the concerned host to other plants and vice versa;
- climatological factors;
- cultural practices before and after harvest;
- soil types;
- susceptibility of the concerned host and relevant stages of host plants;
- presence of vectors for the pest;
- presence of natural enemies and antagonists of the pest;
- presence of other hosts susceptible to the pest;
- prevalence of the pest in the Union;
- intended use of the plants.

(4) Potential economic, social and environmental consequences of the pest

Infestations of the plants for planting referred to in point (3) with the pest shall have an economically unacceptable impact on the intended use of those plants in one or several of the following areas:

(a) Direct effects:

- crop losses in terms of yield and quality;
- extra costs of control measures;

- extra costs of harvesting and grading;
- costs of replanting;
- losses due to the necessity of growing substitute crops;
- effects on existing production practices;
- effects on other host plants at the place of production;
- capacity of the pest to act as a vector for other pests.

Those effects shall be assessed on the basis of the types, amount and frequency of the respective damage.

(b) Indirect effects:

- effects on producer profits that result from changes in production costs, yields or price levels;
- changes to domestic or foreign consumer demand for a product resulting from quality changes;
- effects on domestic and export markets and prices paid;
- effects on employment.

(5) Availability of measures against the pest

Feasible and effective measures shall be available to prevent the presence of the pest on the plants for planting concerned.

ANNEX III

Criteria to identify plants for planting which are likely to pose previously unidentified phytosanitary risks for the Union territory, as referred to in Article 42(2)

Plants for planting from third countries are likely to pose previously unidentified phytosanitary risks for the Union territory where those plants for planting fulfil several of the following conditions:

- (1) Characteristics of the plants for planting
 - (a) They belong to a plant genus or family known to commonly host pests regulated as quarantine pests in the Union or in third countries;
 - (b) They belong to a plant genus or family known to commonly host polyphagous pests, or monophagous pests known to have major impact to plant species grown in the Union territory which have major economic, social or environmental importance to the Union;
 - (c) They are grown outdoors in the third countries of origin;
 - (d) They are not treated with generic pesticides prior to or during shipment;
 - (e) They are not subject to export inspection and certification in the third country of origin;
 - (f) They are not shipped in closed containers or packaging, or when shipped in such a way, the shipments because of their size cannot be opened in closed premises for import inspection purposes;
 - (g) Signs and symptoms of pests on those plants for planting are likely to be missed during import inspection, without recourse to sampling and testing or submission to quarantine procedures, because of latent infections and infestations with those pests.
- (2) Origin of the plants for planting
 - (a) They originate from or are shipped from a third country which is the source of frequent notifications of interceptions of quarantine pests;
 - (b) They originate from or are shipped from a third country where quarantine pests potentially associated with those plants for planting are known to be present;
 - (c) They originate from or are shipped from a third country with which there is limited phytosanitary experience with trade in plants for planting;
 - (d) They originate from a third country which is not a member of the IPPC.

ANNEX IV

Measures and principles for the management of the risks of quarantine pests

SECTION 1

MEASURES TO MANAGE THE RISKS OF QUARANTINE PESTS AS REFERRED TO IN ARTICLES 14(1), 17(2), 25(3), 26(2), 27(4), 37(3) AND 40(1)

The management of the risks of quarantine pests shall consist of one or more, as appropriate, of the following measures:

- (1) Measures targeting prevention and elimination of infestation of cultivated and wild plants
 - (a) Restrictions on the identity, nature, origin, ancestry, provenance and production history of cultivated plants;
 - (b) Restrictions on the cultivation, harvesting and use of plants;
 - (c) Restrictions on the use of plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects;
 - (d) Surveillance, inspection, sampling and laboratory testing of plants, plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects for the presence of quarantine pests;
 - (e) Surveillance for breakdown or change in the effectiveness of a resistant plant species or plant variety which relates to a change in the composition of the quarantine pest or its biotype, pathotype, race or virulence group;
 - (f) Physical, chemical and biological treatment of plants, plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects, infested or potentially infested with quarantine pests;
 - (g) Destruction of plants, plant products and other objects, infested or potentially infested with quarantine pests or for preventive purposes;
 - (h) Information, data recording, communication and reporting obligations.

For the purpose of point (b), those measures may include requirements with regard to the testing of plant species and plant varieties for resistance to the quarantine pest concerned and the listing of plant species and plant varieties found to be resistant to the quarantine pest concerned.

For the purpose of point (f), those measures may include requirements with regard to:

- (a) the registration, authorisation and official supervision of operators applying the treatment concerned;

- (b) the issuance of a phytosanitary certificate, plant passport, label or other official attestation for the treated plants, plants products or other objects and the placing of the mark referred to in Article 76(1) following the application of the treatment concerned.

(2) Measures targeting consignments of plants, plants products and other objects

- (a) Restrictions on the identity, nature, origin, provenance, ancestry, production history and traceability of plants, plant products and other objects;
- (b) Restrictions on the introduction, movement, use, handling, processing, packaging, storage, distribution and destination of plants, plant products and other objects;
- (c) Surveillance, inspection, sampling, laboratory testing of plants, plant products and other objects for the presence of quarantine pests, including through subjection to quarantine procedures;
- (d) Physical, chemical and biological treatment and where appropriate destruction of plants, plant products and other objects, infested or potentially infested with quarantine pests;
- (e) Information, data recording, communication and reporting obligations.

For the purpose of points (a) to (d), those measures may include requirements with regard to:

- (a) the issuance of a phytosanitary certificate, plant passport, label or other official attestation, including the placing of the mark referred to in Article 76(1) to attest compliance with the provisions referred to in point (a) to (d);
- (b) the registration, authorisation and official supervision of operators applying the treatment referred to in point (d).

(3) Measures targeting other pathways for quarantine pests

- (a) Restrictions on the introduction and movement of quarantine pests as a commodity;
- (b) Surveillance, inspection, sampling and laboratory testing and where appropriate destruction of commodities of quarantine pests;
- (c) Restrictions on plants, plant products and other objects carried by travellers;
- (d) Surveillance, inspection, sampling and laboratory testing and where appropriate treatment or destruction of plants, plant products and other objects carried by travellers;
- (e) Restrictions on vehicles, packaging and other objects used in transport of commodities;

- (f) Surveillance, inspection, sampling and laboratory testing and where appropriate treatment or destruction of vehicles, packaging and other objects used in transport of commodities;
- (g) Information, data recording, communication and reporting obligations.

SECTION 2

PRINCIPLES FOR THE MANAGEMENT OF THE RISKS OF PESTS AS REFERRED TO IN ARTICLES 14(1), 17(2), 25(3), 26(2), 27(4), 28(1), 34(2), 37(3), 39(3), 40(1), 42(2), 43(3) AND 44(3)

The management of the risks of quarantine pests and quality pests shall respect the following principles:

(1) **Necessity**

Risk management measures shall be applied only where such measures are necessary to prevent the introduction and/or spread of pests.

(2) **Proportionality**

Risk management measures shall be consistent with the risk posed by the concerned pest and the level of protection that is required.

(3) **Minimal impact**

Risk management measures shall represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.

(4) **Non-discrimination**

Risk management measures shall not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade. They shall be no more stringent for third countries than measures applied to the same pests if present within the Union territory, if third countries can demonstrate that they have the same phytosanitary status and apply identical or equivalent phytosanitary measures.

(5) **Technical justification**

Risk management measures shall be technically justified on the basis of conclusions reached by using an appropriate risk analysis or, where applicable, another comparable examination and evaluation of available scientific information. Risk management measures should reflect, and where appropriate should be modified or removed to reflect, new or updated risk analysis or relevant scientific information.

(6) **Feasibility**

Risk management measures should be such as to allow that the objective of those measures is likely achieved.

ANNEX V

Repealed acts referred to in Article 85(1)

1. Council Directive 74/647/EEC on control of carnation leaf rollers;
2. Council Directive 69/466/EEC on control of San Jose Scale;
3. Council Directive 69/464/EEC on control of Potato Wart Disease;
4. Council Directive 93/85/EEC on control of Potato Ring Rot;
5. Council Directive 98/57/EC on control of *Ralstonia solanacearum*;
6. Council Directive 2007/33/EC on the control of potato cyst nematodes and repealing Directive 69/465/EC;
7. Commission Regulation (EC) No 690/2008 recognising protected zones exposed to particular plant health risks in the Community;
8. Commission Directive 93/51/EEC establishing rules for movements of certain plants, plant products or other objects through a protected zone;
9. Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products and other objects are subject and establishing details for their registration;
10. Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement;
11. Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, Part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register;
12. Commission Decision 91/261/EEC of 2 May 1991 recognizing Australia as being free from *Erwinia amylovora* (Burr.) Winsl. Et al.;
13. Commission Decision 2002/360/EC of 13 May 2002 establishing the amendments to be made to the measures taken by Austria to protect itself against the introduction of *Anoplophora glabripennis* (Motschulsky);
14. Commission Directive 2004/105/EC of 15 October 2004 determining the models of official phytosanitary certificates or phytosanitary certificates for re-export accompanying plants, plant products or other objects from third countries and listed in Council Directive 2000/29/EC;
15. Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants,

plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement;

16. Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, Part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register;
17. Commission Regulation (EC) No 1040/2002 of 14 June 2002 establishing detailed rules for the implementation of the provisions relating to the allocation of a financial contribution from the Community for plant-health control and repealing Regulation (EC) No 2051/97.

ANNEX VI

Correlation table

[to be completed]