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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on protective measures against pests of plants**

{SWD(2013) 168 final}

{SWD(2013) 169 final}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

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. Plant health is also important for the protection of biodiversity and ecosystem services.

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 foreign pests. The main tool hereby is Council Directive 2000/29/EC<sup>1</sup>, which also reflects international trade agreements in this area. The EU phytosanitary (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.

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<sup>1</sup> OJ L 169, 10.7.2000, p. 1.

## Problem analysis

An evaluation of the regime (2010)<sup>2</sup> 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 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 professional operators and Member States, so as to use the resources available to the phytosanitary authorities for true Union priorities. In the meanwhile,

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<sup>2</sup> [http://ec.europa.eu/food/plant/plant\\_health\\_biosafety/rules/index\\_en.htm](http://ec.europa.eu/food/plant/plant_health_biosafety/rules/index_en.htm)

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 result in reduced burden for professional 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 professional operators with the Union phytosanitary legislation, as are currently present in Directive 2000/29/EC. Those controls are now being positioned exclusively in the proposal concerning official controls (replacing Regulation (EC) 882/2004<sup>3</sup>). 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 food and feed expenditure, which concerns the management of Union expenditures relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

The proposal will be complementary to the proposal concerning Invasive Alien Species foreseen under the EU Biodiversity Strategy.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS**

### Consultation process

The Council on 21 November 2008 invited the Commission to proceed to an evaluation of the EU plant health regime and to consider possible modifications to the existing legal framework and the impact of such modifications<sup>4</sup>. The Commission initiated a comprehensive evaluation of the regime from the introduction of the internal market (1993)<sup>5</sup> and contracted the necessary study out to an external consultant<sup>6</sup>. Member State experts participated in the Inter-Service Steering Group for the evaluation. A conference took place on 23-24 February 2010 to inform the stakeholders and MS on the progress of the evaluation and to consult them on the provisional options for the future developed by the consultant. The input received framed the final options and recommendations. The report of the evaluation<sup>7</sup> was presented in a second conference on 28 September 2010 including stakeholders, the

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<sup>3</sup> OJ L 191, 28.5.2004, p. 1.

<sup>4</sup> Council of the European Union, 2906th Economic and Financial Affairs / Budget, 21 November 2008. Council Conclusions on the Review of the EU Plant Health Regime. Document no. 104228.

<sup>5</sup> Taking account of a previous evaluation of the financial aspects of the regime, completed in 2008.

<sup>6</sup> Food Chain Evaluation Consortium (FCEC), consisting of Civic Consulting, Agra CEAS Consulting (project leader), Van Dijk Management Consultants and Arcadia International.

<sup>7</sup> [http://ec.europa.eu/food/plant/plant\\_health\\_biosafety/rules/index\\_en.htm](http://ec.europa.eu/food/plant/plant_health_biosafety/rules/index_en.htm)

general public, and representatives of MS and third countries. Linked to this conference was a public consultation on the recommendations from the evaluation and the scope of the subsequent impact assessment.

In preparation for the impact assessment, the options recommended by the external consultant were discussed with the Member States in Council with the Chief Officers for Plant Health (COPHs) in many rounds of meetings and, as concerns the coherence with the Plant Reproductive Material (PRM) regime, the Heads of Service for that regime and the relevant Working Party. Five task forces with Member State experts and Commission were convened to further discuss the main areas of change.

Stakeholders (industry association representatives and NGOs) were consulted from the very start of the review process, prior to the initiation of the evaluation, during the evaluation study and again during the preparation of the impact assessment. An ad-hoc Working Group on Plant Health was set up under the Advisory Group on the Food Chain, Animal and Plant Health. The progress was presented and discussed in several meetings of the aforementioned Advisory Group, in other Advisory Groups<sup>8</sup> and on invitation in meetings of COPA-COGECA, EUROPATAT, ESA and UNION FLEURS. Stakeholder consultation was a key element of the evaluation study and the supplementary economic study contracted out to an external consultant. The consultation concerned changes of the EU plant health regime itself as well as elements of the regime to be transferred to or from the plant reproductive material regime and the EU regime on official controls on food and feed, animal health and welfare, plant health and plant reproductive material.

The conferences organised during the review process ensured stakeholders' input and views concerning the recommendations and the scope of the impact assessment, both orally at the conferences and through the linked public consultation. A consultation on the technical change proposals was linked to the meeting of the Working Group on Plant Health on 18 February 2011 and targeted the preferred way forward for the changes with major impact. Consultations were additionally published on the dedicated web page<sup>9</sup> of DG SANCO. A final consultation on the strategic options was launched on 13 May 2011.

#### Data collection

The collection of data commenced with a comprehensive evaluation of the regime by the external consultant from 2009 to 2010. The evaluation included an *ex post* analysis of the regime for the period 1993-2008, the collection of economic data on costs and administrative burden for competent authorities and stakeholders stemming from the regime, as well as the development *ex ante* of options and recommendations for the future. The evaluation report was delivered in May 2010.

The internal process to develop the IA was further supported by a second contract with the consultant. This contract concerned a study on the quantification of costs and benefits of amendments to the regime, supplementary to the data that had been collected during the evaluation. The study consisted of modules addressing the *ex*

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<sup>8</sup> Advisory Groups on Seeds, Advisory Group on Cotton, Advisory Group on Floriculture and Ornamentals, Advisory Group on Citrus, Advisory Group on Potato.

<sup>9</sup> [http://ec.europa.eu/food/plant/plant\\_health\\_biosafety/rules/index\\_en.htm](http://ec.europa.eu/food/plant/plant_health_biosafety/rules/index_en.htm)

*ante* assessment of the economic impact of specific technical options for the revision of the legislation. The scope of the issues to be addressed had been subject to stakeholder consultation. The modules were set up in such a way that aggregation was possible to potential overall policy options. In July 2011, the final report of the study was delivered by the consultant. Where necessary further information was gathered from the literature, study reports and queries to assess the key impacts the change in policy would have. Furthermore, the social and environmental impacts of the policy options were assessed by Commission's services.

### Impact assessment

Four options were developed to improve the regime:

*Option 1: Improve only the legal form and clarity of the regime.* The legislation would be converted from a Directive into a Regulation, and simplified and clarified. The status quo would be maintained in terms of substance.

*Option 2: Prioritise, modernise and step up prevention.* Additional to Option 1, prioritisation would be improved by transforming the current Annexes I and II, which list regulated pests according to technical features irrespective of their priority for the Union, into lists based on intervention logic and priority. The plant passport and protected zone systems would be modernised (responsibility sharing with professional operators) and upgraded (plant passport scope, format, mandatory cost-recovery based plant passport fees as already exist for import controls, rules for surveillance and outbreak eradication in protected zones). The coherence between the PHR and the plant reproductive material regime would be improved to increase effectiveness and reduce costs for professional operators. Prevention would be reinforced by introducing a new provision concerning high-risk plant reproductive materials (plants for planting) that are not authorised for introduction into the Union or subject to specific enhanced physical controls until completion of a risk analysis, and by removing exemptions for passenger luggage (to be subject to low frequency controls to minimise the cost impacts).

*Option 3: Prioritise, modernise, step up prevention and reinforce actions against outbreaks.* Additional to Option 2, obligations would be introduced for surveillance and contingency planning. In analogy with the arrangements in the animal health regime, EU co-financing would be made available for surveillance and, in certain cases, for financial compensation of direct losses of professional operators. The legal instruments for eradication and containment would be further developed. The exclusion of natural spread related measures would be removed.

*Option 4: Prioritise, modernise, step up prevention, reinforce actions against outbreaks and expand the scope to invasive plants.* Additional to Option 3, the regime would also cover invasive plants, in terms of legal provisions for measures and EU co-financing. Invasive plants (other than parasitic plants) would not be covered in Options 1, 2 and 3.

The assessment of the impacts of the four options revealed that Option 3 provided the best way forward to achieve the objectives with the best cost-benefit level and an optimal balance of inputs from Member States, professional operators and the Union. Option 3 should have a significant positive impact on profitability and economic

growth of the sectors involved; it was also the closest reflection of the outcome of the stakeholder and MS consultation.

The EU budget necessary to implement Option 3 was secured in the Commission proposal for the Multi-Annual Financial Framework (MFF) for 2014-2020. The corresponding legal provisions are included in the legal proposal for a Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

#### Small and medium-sized enterprises and micro-enterprises

The nature of the plant health regime requires that small and medium-sized enterprises (SME) are not exempted from the obligations of this Regulation. The majority of the enterprises affected by the regime are SME and exempting them *a priori* would fundamentally jeopardise the regime's objectives. However, the proposal exempts enterprises selling plants and plant products exclusively to the local market from the obligation to issue plant passports, which will moreover not be required for sales to final non-professional consumers anyhow. For micro-enterprises, special arrangements concerning potential refunding of fees for plant health controls, within the framework of State Aid rules, will be made possible under the new Regulation concerning official controls.

#### Fundamental rights

This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter on Fundamental rights of the European Union. It should be applied by the Member States in accordance with those rights and principles, implemented as appropriate in their national legislation. Certain provisions of this Regulation nevertheless limit particular rights under the Charter, however only to the extent strictly necessary for protecting the general interest of the Union concerned by this Regulation and conserving the essence of the rights at stake.

Eradication of outbreaks of foreign pests can only be successful if all sources of infestation are removed. Apart from outbreaks of quarantine pests on the premises of professional operators, outbreaks may also take place in public or private green. In those cases, the eradication measures need to include the infested and potentially infested plants in that public and private green in order to be successful at all (any remaining infested plants will act as a source of new infestations elsewhere). This implies that, in certain cases, competent authorities of Member States need to be given access to private premises for official controls, possibly followed by the imposition of treatment or eradication measures or certain restrictions or prohibitions on the use of plants. This is a limitation of Articles 7 and 17 of the Charter on Fundamental Rights concerning, respectively, the Respect for Private and Family Life and the Right to Property. That limitation is necessary to achieve an objective of general interest, being the protection of plant health in the Union. The limitation is proportionate because the objective of general interest cannot be achieved without ensuring that phytosanitary measures are respected equally by all (refraining from destruction of infested plants in private gardens would annihilate the benefits of eradication measures imposed on professional operators and carried out in public-owned green). It will be the responsibility of the Member States to provide fair

compensation to affected citizens in good time for the suffered loss. The essence of the Right to Property is thus conserved.

Anybody who is aware of the presence of a quarantine pest will be obliged to notify the presence of that quarantine pest to the competent authorities, accompanied with the information concerning the origin and the nature of the material concerned. This will also apply to laboratories and research organisation encountering pests in samples provided to them. This may in some cases constitute a limitation of Article 8 of the Charter, concerning the Right to Protection of Personal Data. That limitation is necessary to achieve the public interest objective of plant health in the Union, as findings of quarantine pests need to be made known to the competent authorities in order to ensure the immediate eradication of outbreaks. The limitation is proportionate because personal data are subject to the provision only to the extent that they are indispensable for the competent authorities to locate the outbreaks and take the necessary action. The essence of the Right to Protection of Personal Data is thus conserved.

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### Chapter I: Subject matter, scope and definitions

The territorial scope of the regime does not include any non-European outermost regions of Member States, as those regions 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 region 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 enhanced financial support from the Union for the required actions. Criteria to decide

whether a 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.

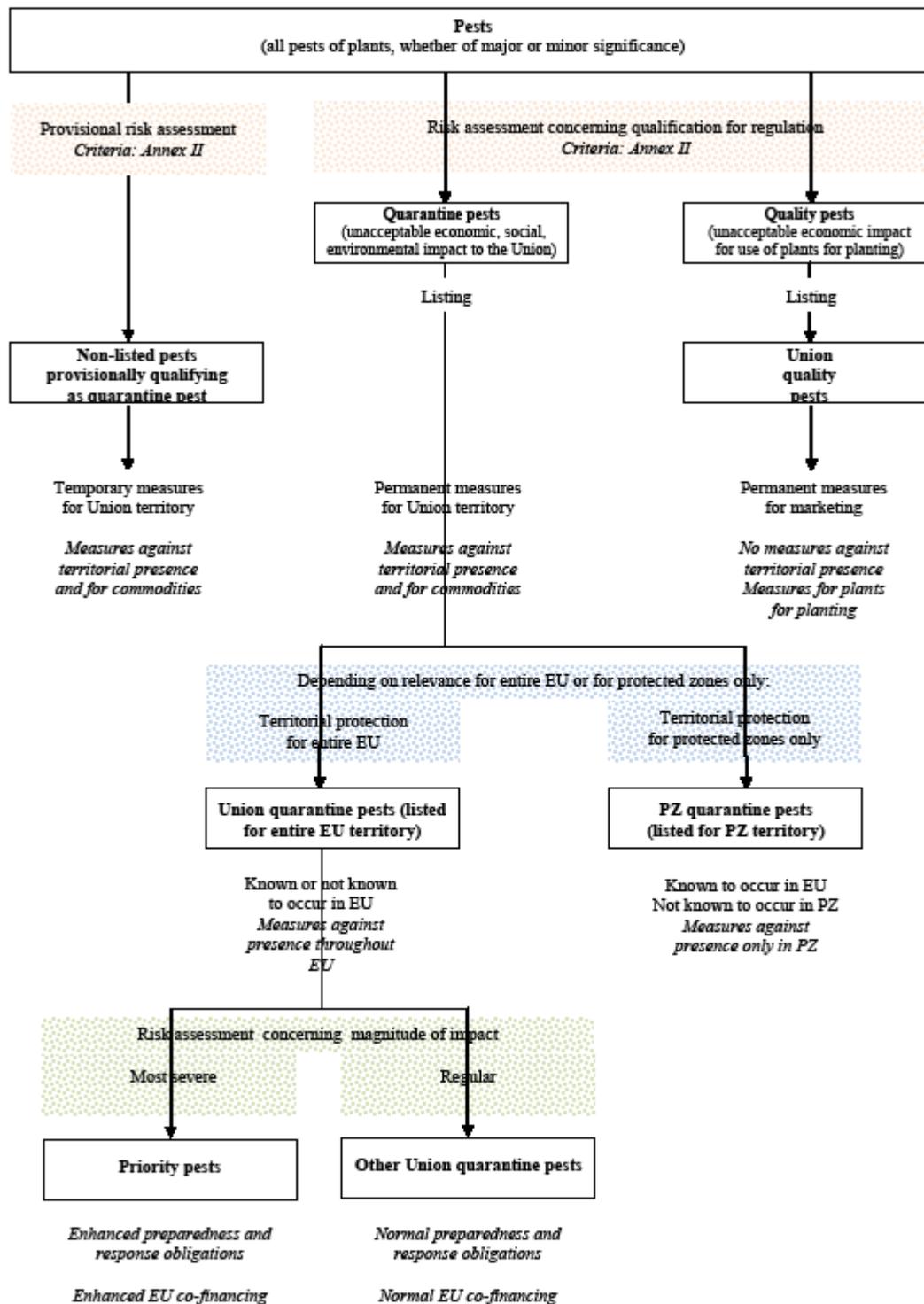
This chapter furthermore sets out detailed rules on notification of the presence of quarantine pests, measures to be taken for the eradication of those pests including the restriction of areas subject to eradication measures, surveys to be carried out for the presence of pests and the establishment of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

### Chapter III: Quality pests

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 categorises them all as Union quality pests. It sets out the conceptual nature of such pests and subsequently lists them through implementing acts. Criteria to decide whether a pest qualifies as a Union quality pest are provided in Annex II. Quality pests will not be regulated under the legal proposal for Plant Reproductive Material, other than their inclusion, where appropriate, in certification schemes.



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

#### 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 for planting from certain third countries which require precautionary measures. Listed plant materials will require intensified visual examination 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 phytosanitary 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 professional operators and traceability

The proposal requires the relevant professional operators to be registered, in a register which will also contain the professional operators required to be registered under the proposed Regulation concerning plant reproductive material. This should reduce burden for professional 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 professional 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 professional 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 the certification schemes created under the proposed Regulation concerning plant reproductive material shall be used. This should preclude that double schemes are set up, which would result in double costs for professional 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 proposed Regulation concerning plant reproductive material, the plant passport and the certification label shall be combined in a single document. This should preclude double costs for professional operators, where the issuance is done by the competent authorities.

Rules are foreseen concerning the authorisation and supervision of professional 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 the Regulation

The proposal foresees the establishment of an electronic notification 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 foresees amendments to the Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, which is foreseen to be adopted in advance of the current legal proposal. Those amendments include the possibility for the Union to co-finance measures concerning priority pests (a pest category created in the current proposal) and compensation to operators for the foregone value of plant material that is destroyed as part of eradication measures concerning priority pests.

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 leafrollers 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 pests of potato will be replaced by secondary acts under now proposed Regulation, without changing their substance. The Directives on carnation leafrollers and San José scale will not be replaced.

### **4. BUDGETARY IMPLICATION**

The financial provisions and appropriations for implementing the Regulation up to 31 December 2020 will be presented in the forthcoming legal proposal for a Regulation on the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material. The current proposal does not imply any expenditures which will not be part of the financial statement of the legal proposal for that Regulation and it does not require additional human resources.

Proposal for a

**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,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>10</sup>,

Having regard to the opinion of the Committee of the Regions<sup>11</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community<sup>12</sup> sets out a plant health regime.
- (2) On 21 November 2008, the Council invited the Commission to proceed to an evaluation of that plant health regime<sup>13</sup>.
- (3) In the light of the outcome of that evaluation and the experience gained from the application of Directive 2000/29/EC, that Directive should be replaced. To ensure uniform application of the new rules, the act replacing that Directive should take the form of a Regulation.
- (4) Plant health is very important for plant production, public and private green, natural ecosystems, ecosystem services and biodiversity in the Union. Plant health is threatened by species injurious to plants and plant products, hereinafter 'pests'. To fight that threat, it is necessary to adopt measures concerning the determination of the

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<sup>10</sup> OJ C , , p. .

<sup>11</sup> OJ C , , p. .

<sup>12</sup> OJ L 169, 10.7.2000, p. 1.

<sup>13</sup> Council of the European Union, 2906th Economic and Financial Affairs / Budget, 21 November 2008. Council Conclusions on the Review of the EU Plant Health Regime. Document no. 104228.

phytosanitary risks posed by those pests and the reduction of those risks to an acceptable level.

- (5) The need for such measures has long been recognised. They have formed the subject of international agreements and international conventions, including the International Plant Protection Convention (IPPC) of 6 December 1951 concluded at the United Nations Food and Agricultural Organisation (FAO) and its new revised text approved by the Food and Agriculture Organisation Conference in November 1997 at its 29th session. The Union is party to the IPPC.
- (6) It has appeared that for the determination of the scope of this Regulation it is important to take into account bio-geographical factors to avoid that pests not present in the European territory of the Union spread to that territory. Consequently, non-European territories (outermost regions) of Member States referred to in Article 355(1) TFEU should be excluded from the territorial scope of this Regulation. Those territories should be listed. Where the status of such a territory or a territory referred to in Article 355(2) TFEU is amended pursuant to Article 355(6) TFEU, that list should be amended to ensure that the territorial scope of this Regulation remains confined to the European part of the Union territory. References to third countries should be read as references also to the territories included in that list.
- (7) Directive 2000/29/EC sets out rules concerning official controls to be carried out by the competent authorities as regards protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. Such rules are presently set out by Regulation (EU) No .../.... on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...]/2013 [*Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)<sup>14</sup> [*Office of Publications, please insert number of Regulation on Official Controls and, in the footnote, the reference to the Official Journal*] and therefore should not be part of this Regulation.
- (8) Criteria should be set out in order to allow pests to be identified for which it is necessary to adopt measures of control for the entire Union territory. Such pests are referred to as 'Union quarantine pests'. Criteria should also be set out for the identification of pests for which it is necessary to adopt measures of control only as regards one or more parts of that territory. Such pests are referred to as 'protected zone quarantine pests'.
- (9) In order to allow efforts for the control of Union quarantine pests to concentrate on pests whose economic, environmental or social impact is most severe for the Union

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<sup>14</sup> OJ L ..., ....., p. ...

territory as a whole, a restricted list of such pests, hereinafter 'priority pests', should be established.

- (10) It is appropriate to provide for exemptions from the prohibition of introduction into and movement within the Union territory of Union quarantine pests for scientific purposes, trials, varietal selections, breeding and exhibitions.
- (11) In order to ensure effective and timely action in case of the presence of a Union quarantine pest, notification obligations should apply to the public, professional operators and to the Member States.
- (12) Where those notification obligations imply that personal data of natural or legal persons should be disclosed to the competent authorities, this may constitute a limitation of Article 8 (Protection of Personal Data) of the Charter on Fundamental Rights. However that limitation would be necessary and proportionate to achieve the public interest objective of this Regulation.
- (13) A professional operator becoming aware of the presence of a Union quarantine pest in a plant, plant product or other object which is or was under its control should be under an obligation to take all measures that may be appropriate as regards the elimination of the pest, the withdrawal or recall of the plants, plant products or other objects concerned and the information of the competent authority, other persons in the trade chain and the public.
- (14) Member States should take all necessary measures to eradicate Union quarantine pests, when found present in their territories. It is appropriate to set out measures which may be taken by Member States in such a case and the principles based on which they are to decide what measures to take. Those measures should include the establishment of restricted areas, consisting of an infested zone and a buffer zone.
- (15) In certain cases, Member States should impose measures for the eradication of quarantine pests on plants in private premises, because eradication of pests can only be successful if all sources of infestation are removed. For this purpose, the competent authorities of Member States should have legal access to those premises. This may constitute a limitation of Article 7 (Respect for Private and Family Life) and Article 17 (Right to Property) of the Charter on Fundamental Rights. That limitation is necessary and proportionate to achieve the public interest objective of the regime, in so far as Member States ensure fair compensation in good time for the loss of private property.
- (16) Early detection of the presence of pests is extremely important for timely and effective eradication. Member States should therefore conduct surveys for the presence of Union quarantine pests in the areas where those pests were not known to be present. In view of the number of Union quarantine pests and the time and resources required to carry out those surveys, Member States should establish multi-annual survey programmes.
- (17) The Commission should be empowered to adopt measures in case of the suspected or confirmed presence of specific Union quarantine pests, concerning in particular their eradication and containment, and the establishment of restricted areas, surveys, contingency plans, simulation exercises and eradication plans as regards those pests.

- (18) In order to ensure swift and effective action against pests which are no Union quarantine pests but which Member States consider may fulfil the conditions for inclusion in the list of Union quarantine pests, provision should be made for measures to be taken by Member States in case they become aware of the presence of such a pest. Similar provisions should be set out for the Commission.
- (19) Under certain conditions Member States should be allowed to adopt more stringent eradication measures than required by Union legislation.
- (20) Special provisions should apply to priority pests as regards the information of the public, surveys, contingency plans, eradication plans and co-financing of measures by the Union, in particular.
- (21) Quarantine pests which are present in the Union territory but absent from specific parts of that territory designated as 'protected zones', and whose presence would have unacceptable economic, social or environmental impacts only for those protected zones, should be specifically identified and listed as 'protected zone quarantine pests'. The introduction into, movement within, and release into the respective protected zones of protected zone quarantine pests should be prohibited.
- (22) Rules should be set out concerning the recognition, modification or revocation of recognition of protected zones, survey obligations for protected zones, and actions to be taken in case protected zone quarantine pests are found present in the respective protected zones. In case of findings of the presence of the protected zone quarantine pest inside the respective protected zone, strict rules should apply for the amendment and revocation of those protected zones.
- (23) A pest, which is no Union quarantine pest, should be referred to as a 'Union quality pest' in case that pest is mainly transmitted through specific plants for planting, its presence on those plants for planting has an unacceptable economic impact as regards the intended use of those plants and it is listed as a Union quality pest. To limit the presence of such pests their introduction into or movement within the Union territory on the plants for planting concerned should be prohibited unless provided otherwise in that list.
- (24) Certain plants, plant products and other objects pose an unacceptable phytosanitary risk by their likelihood to host a Union quarantine pest. For some of those, acceptable risk mitigation measures are available, while not for others. Depending on the availability of acceptable risk mitigation measures, their introduction into, and movement within, the Union territory should be either prohibited or subject to special requirements. Those plants, plant products and other objects should be listed.
- (25) Derogations from the prohibitions or special requirements as regards the introduction of plants, plant products and other objects into the Union territory should be provided for. The Commission should be empowered to recognise certain measures of third countries as equivalent to the requirements for the movement within the Union territory of plants, plant products and other objects concerned.
- (26) Those prohibitions or requirements should neither apply to small quantities of plants, plant products and other objects, other than plants for planting, for non-commercial and non-professional purposes nor to the introduction into and movement within frontier zones of plants, plant products and other objects. Nor should they apply to the

introduction into and movement within the Union territory of plants, plant products and other objects for scientific purposes, trials, varietal selection, breeding and exhibitions. Proper safeguards should be set and information should be provided to those concerned.

- (27) A derogation from the Union rules for introduction into and movement within the Union territory should be provided for plants, plant products and other objects in transit.
- (28) The international trade of plants for planting with which there is limited phytosanitary experience can involve serious risks of the establishment of quarantine pests for which no measures have been adopted pursuant to this Regulation. In order to ensure swift and effective action against newly identified risks associated with plants for planting which are not subject to permanent requirements or prohibitions, but may qualify for such permanent measures, the Commission should have the possibility to adopt temporary measures in accordance with the precautionary principle.
- (29) It is necessary to set out prohibitions and special requirements, similar to those set out for the Union territory, in respect of the introduction into and movement within protected zones of plants, plant products and other objects that would pose a phytosanitary risk of an unacceptable level by their likelihood to host the respective protected zone quarantine pest.
- (30) General requirements should be adopted concerning vehicles and packaging material of plants, plant products and other objects to ensure that they are free from quarantine pests.
- (31) Member States should designate quarantine stations. Requirements concerning the designation, operation and supervision of those quarantine stations as well as the release of plants, plant products or other objects from those stations should be set out. Where those requirements include the maintenance of lists of staff and visitors entering the stations, this may constitute a limitation of Article 8 (Protection of Personal Data) of the Charter on Fundamental Rights. However that limitation would be necessary and proportionate to achieve the public interest objective of this Regulation.
- (32) Where so required by a bilateral agreement concluded by the Union with a third country, or by the legislation of a third country, plants, plant products and other objects moved out of the Union territory to the third country concerned should comply with those rules.
- (33) Where, as regards certain plants, plant products or other objects moved out of the Union territory to third countries, no bilateral phytosanitary agreement concluded by the Union with a third country and no phytosanitary legislation of a third country applies, protection should be offered to third countries against Union quarantine pests because of their acknowledged harmful nature, except where a Union quarantine pest is officially known to be present in the third country concerned and not under official control, or where it can be reasonably assumed that that Union quarantine pest does not meet the criteria to qualify as a quarantine pest for the third country concerned.
- (34) In order to ensure effective implementation of this Regulation, professional operators subject to obligations under this Regulation should be registered in registers set up by

the Member States. In order to reduce administrative burden, those registers should also include professional operators falling within the ambit of Regulation (EU) No .../.... on .....<sup>15</sup> [*Office of Publications to insert number, title and, in a footnote, the OJ reference for the Regulation on plant reproductive material*].

- (35) Professional operators operating at more than one premise should be given the possibility to register separately for each of those premises.
- (36) To facilitate the detection of the source of an infestation by a quarantine pest, it is appropriate to require professional operators to keep records in respect of the plants, plant products and other objects supplied to them by professional operators and supplied by them to other professional operators. In view of the latency periods of some quarantine pests, and the time required for the detection of the source of infestation, records should be kept for three years.
- (37) Professional operators should also have in place systems and procedures to allow identification of the movements of their plants, plant products and other objects within their own premises.
- (38) A phytosanitary certificate should be required for the introduction from third countries into the Union territory, and into protected zones, of certain plants, plant products and other objects. Those plants, plant products and other objects should be listed in the interest of clarity.
- (39) Those phytosanitary certificates should comply with the requirements of the IPPC and attest compliance with the requirements and measures established pursuant to this Regulation. In order to ensure the credibility of the phytosanitary certificates, rules should be established concerning the conditions of their validity and cancellation.
- (40) The movement within the Union territory, and into and within protected zones, of certain plants, plant products and other objects should only be permitted if accompanied by a plant passport, attesting compliance with the requirements and measures established pursuant to the provisions of this Regulation. Those plants, plant products and other objects should be listed in the interest of clarity.
- (41) Plant passports should not be required for plants, plant products and other objects intended for final users.
- (42) In order to ensure the credibility of the plant passports, rules should be established concerning their contents.
- (43) Plant passports should generally be issued by the professional operator. Where professional operators do not have the resources to issue plant passports, the possibility should exist that, upon their request, plant passports are issued by the competent authorities.
- (44) Rules should be set out for the issuance of plant passports, the examinations required for issuance, the authorisation and supervision of professional operators issuing plant

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<sup>15</sup> OJ L ..., ....., p. ...

passports, the obligations of authorised operators and the withdrawal of that authorisation.

- (45) In order to reduce the burden of authorised operators, examinations for issuing plant passports should be combined with the examinations required under Regulation (EU) No .../.... [*Office of Publications to insert number of Regulation on plant reproductive material law*], where appropriate.
- (46) Authorised operators should possess the necessary knowledge concerning pests.
- (47) Certain operators may desire to establish a phytosanitary risk management plan, ensuring and demonstrating a high level of competence and awareness as regards phytosanitary risks as regards critical points in their professional activities and justifying special control arrangements with the competent authorities. Union rules should be established concerning the contents of those plans.
- (48) It is appropriate to provide for the replacement of plant passports and of phytosanitary certificates.
- (49) In cases of non-compliance with the Union rules, plant passports should be removed, invalidated and, for reasons of traceability, kept.
- (50) FAO International Standard for Phytosanitary Measures No 15 requires that wood packaging material is marked with a specific mark, applied by duly authorised and supervised professional operators. This Regulation should set out the model and contents of that mark and the authorisation and supervision of professional operators in the Union territory applying that mark.
- (51) Where so required by a third country, the respective plants, plant products or other objects should move from the Union territory to that third country with a phytosanitary certificate for export or re-export. In respect of the relevant provisions of IPPC, those certificates should be issued by the competent authorities, respecting the contents of the model certificates for export and re-export set out by the IPPC.
- (52) Where a plant, plant product or other object is moved through more than one Member States before it is exported to a third country, it is important that the Member State in which the plants, plant product or other objects were produced or processed exchanges information with the Member State which issues the phytosanitary certificate for export. This exchange of information is important to enable attestation of compliance with the requirements of the third country. Therefore, a harmonised 'pre-export certificate' should be established to ensure that the exchange of that information takes place in a uniform manner.
- (53) The Commission should establish an electronic system for the notifications required in accordance with this Regulation.
- (54) In order to ensure that the exceptions for Union quarantine pests used for scientific purposes, trials, varietal selections, breeding or exhibitions are implemented in a manner that does not pose any phytosanitary risk to the Union territory or parts of it, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning the exchange of information between Member States and the Commission as regards the introduction into and movement

within the Union territory of the pests concerned, the respective assessments and authorisation, and the monitoring of compliance, the action in case of non-compliance and the notification thereof.

- (55) In order to ensure an effective system of notifications, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning notification obligations concerning the suspected presence of particular Union quarantine pests which has not yet been officially confirmed.
- (56) In order to take into account the technical and scientific developments concerning surveys on the presence of pests, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules amending or supplementing the elements to be covered by the multi-annual survey programmes.
- (57) In order to ensure the effective functioning of simulation exercises, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the frequencies, contents, format and other provisions on simulation exercises.
- (58) In order to ensure that protected zones are established and function in a reliable manner, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules on surveys to be carried out for purposes of the recognition of protected zones and on whether protected zones comply with the respective requirements.
- (59) In order to ensure a proportionate and restricted application of the exemptions concerning the movement of plants, plant products or other objects into or within frontier zones, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning the maximum width of third country frontier zones and Member State frontier zones, the maximum distance of the movement of the plants, plant products and other objects concerned within the third country frontier zones and Member State frontier zones and the procedures concerning the authorisation of the introduction into and movement within the Member State frontier zones of plants, plant products and other objects.
- (60) In order to avoid phytosanitary risks during transit of plants, plant products or other objects, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the contents of a declaration concerning the passing of plants, plant products or other objects through the Union territory for the purpose of moving to a third country.
- (61) In order to ensure that the registration of professional operators is proportionate to the objective of controlling phytosanitary risk, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out categories of, and conditions for, professional operators to be exempted from the obligation to register in a register.
- (62) In order to ensure the credibility of phytosanitary certificates of third countries which are not parties to the IPPC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules supplementing the conditions for acceptance of phytosanitary certificates from those third countries.

- (63) In order to minimise the phytosanitary risks of plants, plant products or other objects moved within the Union territory, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the maximum figure for small quantities of particular plants, plant products or other objects to be exempted from plant passports.
- (64) In order to ensure the reliability of examinations of plants, plant products and other objects carried out for the issuance of plant passports, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules on visual examination, sampling and testing and the use of certification schemes.
- (65) In order to enhance the credibility of plant passports, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out qualification requirements to be fulfilled by the professional operators in order for them to be authorised to issue plant passports.
- (66) In order to enhance the scope and utility of the phytosanitary risk management plan, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules supplementing or amending the elements covered by such plan.
- (67) In order to take into account the development of international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning attestations for commodities of a specific nature, other than wood packaging material, which would require the application of a specific attestation of compliance with the rules of this Regulation.
- (68) In order to ensure the utility and reliability of official attestations and pre-export certificates, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the contents of official attestations, the authorisation and supervision of professional operators issuing those attestations, and the contents of the pre-export certificate.
- (69) In order to adapt to the technical and scientific developments, and to adapt to a decision of the European Council pursuant to Article 355(6) TFEU, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules amending the Annexes of this Regulation.
- (70) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (71) In order to ensure uniform conditions for the implementation of this Regulation with respect to establishing a list of Union quarantine pests, establishing a list of the priority pests, setting out measures against specific Union quarantine pests, adopting measures for a limited time as regards the phytosanitary risks posed by pests provisionally qualifying as Union quarantine pests, recognising the protected zones recognised in accordance with the first subparagraph of Article 2(1)(h) of Directive 2000/29/EC and establishing a list of the respective protected zone quarantine pests,

amending or revoking protected zones, amending the list of those protected zones, listing of Union quality pests and the plants for planting concerned, listing the plants, plant products and other objects whose introduction into and movement within the Union territory is to be prohibited, and the third countries concerned, listing the plants, plant products and other objects, and the requirements for their introduction into and movement within the Union territory, setting out equivalent requirements of third countries to the requirements for movement within the Union territory of plants, plant products or other objects, setting out specific conditions or measures concerning the introduction of particular plants, plant products and other objects into frontier zones of Member States, adoption of temporary measures as regards the introduction into and movement within the Union territory of plants for planting from third countries, listing of plants, plant products and other objects, whose introduction into, and movement within, particular protected zones is to be prohibited, listing requirements for the introduction into, and movement within, particular protected zones of plants, plant products and other objects, listing of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is to be required for their introduction into the Union territory, listing of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is to be required for their introduction into certain protected zones from those third countries, listing of the plants, plant products and other objects, for which a plant passport is to be required for their movement within the Union territory, listing of the plants, plant products and other objects, for which a plant passport is to be required for their introduction into certain protected zones, and setting out the format of the plant passport, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>16</sup>.

- (72) The advisory procedure should be used for the adoption of the initial list of Union quarantine pests given that that initial list should merely contain, without any modifications, the pests listed in Part A of Annex I to Directive 2000/29/EC and Section I of Part A of Annex II to that Directive, for the amendment of the scientific name of a pest, where such an amendment is justified on the basis of the development of scientific knowledge, for the adoption of the initial list of protected zones and the respective protected zone quarantine pests given that that initial list should merely contain, without any modifications, the protected zones recognised in accordance with the first subparagraph of Article 2(1)(h) of Directive 2000/29/EC and the protected zone quarantine pests listed in Part B of Annex I and Part B of Annex II to Directive 2000/29/EC, for the amendment and revocation of protected zones, for the adoption of the initial list of Union quality pests given that that initial list should merely contain, without any modifications, the pests listed in certain Directives on the production and marketing of seeds and propagating material, for the adoption of the initial list of plants, plant products and other objects whose introduction into and movement within the Union territory is to be prohibited given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the prohibitions and the third countries concerned, as set out in Part A of Annex III to

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<sup>16</sup> OJ L 55, 28.2.2011, p. 13.

Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of plants, plant products and other objects whose introduction into and movement within the Union territory is to be subject to special requirements given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the requirements and the third countries concerned, as set out in Part A of Annex IV to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of plants, plant products and other objects whose introduction into certain protected zones is to be prohibited given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the prohibitions and the third countries concerned, as set out in Part B of Annex III to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of plants, plant products and other objects whose introduction into, and movement within, certain protected zones is to be subject to special requirements given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the requirements, as set out in Part B of Annex IV to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required for their introduction into the Union territory, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point I of Part B of Annex V to Directive 2000/29/EC, for the adoption of the initial list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required for their introduction into certain protected zones, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point II of Part B of Annex V to Directive 2000/29/EC, for the adoption of the initial list of the plants, plant products and other objects, for which a plant passport is required for their movement within the Union territory, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point I of Part A of Annex V to Directive 2000/29/EC, and for the adoption of the initial list of the plants, plant products and other objects, for which a plant passport is required for their introduction into certain protected zones, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point II of Part A of Annex V to Directive 2000/29/EC.

- (73) Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers<sup>17</sup> and Council Directive 69/466/EEC of 8 December 1969 on control of San José Scale<sup>18</sup> set out measures on the control of the respective pests. Following the entry into force of those Directives, the concerned pests have become widely spread throughout the Union territory, thus their containment is not feasible any more. Those Directives should therefore be repealed.
- (74) Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease<sup>19</sup>, Council Directive 93/85/EEC of 4 October 1993 on control of Potato Ring

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<sup>17</sup> OJ L 352, 28.12.1974, p. 41–42.

<sup>18</sup> OJ L 323, 24.12.1969, p. 5–6.

<sup>19</sup> OJ L 323, 24.12.1969, p. 1–2.

Rot<sup>20</sup>, Council Directive 98/57/EC of 20 July 1998 on control of *Ralstonia solanacearum* (Smith) Yabuuchi et al.<sup>21</sup> and Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EC<sup>22</sup> should be repealed, as new measures on the pests concerned should be adopted in accordance with the provisions of this Regulation. In view of the time and resources required to adopt those new measures, those acts should be repealed by 2021.

- (75) Regulation (EU) No .../2013 on .....<sup>23</sup> [Office of Publications, please insert number and title of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material and, in the footnote, the reference to the Official Journal] sets out that grants for measures against pests are to concern certain pests listed in the Annexes to Directive 2000/29/EC, and certain pests not listed in those Annexes but subject to temporary Union measures adopted with regard to them. This Regulation establishes the category of priority pests. It is appropriate that certain measures taken by the Member States as regards priority pests are to be eligible for Union grants, including compensation paid to professional operators for the value of plants, plant products and other objects, subject to destruction pursuant to the eradication measures set out in this Regulation. Regulation (EU) No XXX/2013 should therefore be amended.
- (76) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to protective measures against pests of plants, cannot be sufficiently achieved by the Member States and can therefore, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not exceed what is necessary in order to achieve that objective.
- (77) For small and medium enterprises, this Regulation does not create disproportionate administrative burden or economic impact. Under this Regulation, based on consultation with stakeholders, the special situation of small and medium enterprises has been taken into account where possible. A potential universal exemption for micro-enterprises, which make up the majority of companies, has not been considered, in view of the public policy objective(s) to protect plant health.
- (78) This Regulation respects the IPPC, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the guidelines set out under these.
- (79) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably respect for private and family life, the right to property, the protection of personal data, freedom to conduct business and the freedom of art and science. This Regulation should be applied by the Member States in accordance with those rights and principles,

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<sup>20</sup> OJ L 259, 18.10.1993, p. 1–25.

<sup>21</sup> OJ L 235, 21.8.1998, p. 1–39.

<sup>22</sup> OJ L 156, 16.6.2007, p. 12–22.

<sup>23</sup> OJ L ..., ....., p. ....

HAVE ADOPTED THIS REGULATION:

# Chapter I

## Subject matter, scope and definitions

### *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 purposes of this Regulation references to third countries shall be read as references to third countries and to the territories listed in Annex I.

For the purposes of this Regulation, references to the Union territory shall be read as references to the Union territory without the territories listed in Annex I.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Annex I to ensure that the scope of this Regulation is confined to the European part of the Union territory. That amendment shall be either of the following:

- (a) an addition to Annex I of one or more territories that are referred to in Article 355(1) of the Treaty;
- (b) a removal from Annex I of one or more territories that are referred to in Article 355(2) of the Treaty.

### *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, meristems, chimaeric clones, micro-propagated material;
  - (k) live pollen;
  - (l) buds, budwood, 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.

Except where otherwise provided, wood shall only be considered as a 'plant product' if it has not undergone processing eliminating the phytosanitary risks, and complies with one or more of the following points:

- (a) it retains all or part of its natural round surface, with or without bark;
  - (b) it has not retained its natural round surface due to sawing, cutting or cleaving;
  - (c) it is in the form of chips, particles, sawdust, wood waste, shavings or scrap, and has not undergone processing involving the use of glue, heat or pressure or a combination thereof to produce pellet, briquettes, plywood or particle board;
  - (d) it is, or is intended to be, used as packaging material or dunnage, whether or not it is actually in use for transport of goods;
- (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(5) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*];
- (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) 'professional 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) introduction into, and movement within, and out of the Union territory;
- (e) making available on the market;
- (8) 'final user' means any person, acting for purposes which are outside its trade, business or profession, who acquires for its own use 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.

## **Chapter II Quarantine pests**

### **SECTION 1 QUARANTINE PESTS**

#### *Article 3*

#### **Definition of quarantine pests**

A pest shall be referred to as a 'quarantine pest', with respect to a defined territory, if it fulfils all of the following conditions:

- (a) its identity is established, within the meaning of point (1) of Section 1 of Annex II;
- (b) it is not present in that territory, within the meaning of point (2)(a) of Section 1 of Annex II, or, if present, only distributed to a limited extent within that territory, within the meaning of points (2)(b) and (c) of Section 1 of Annex II;
- (c) it is capable of entering into that territory, of perpetuating its presence in that territory for the foreseeable future after its entry into it (hereinafter: 'to establish') and of spreading within that territory, or, if present, those parts of it where it is distributed to a limited extent, in accordance with point (3) of Section 1 of Annex II;
- (d) its entry, establishment and spread would, within the meaning of point (4) of Section 1 of Annex II, have an unacceptable economic, environmental or social impact for that territory, or, if present, those parts of it where it is distributed to a limited extent; and
- (e) feasible and effective measures are available to prevent the entry into, establishment or spread of that pest within that territory, and mitigate its phytosanitary risks and impacts.

## SECTION 2 UNION QUARANTINE PESTS

### *Article 4*

#### **Definition of Union quarantine pests**

A quarantine pest shall be referred to as a Union quarantine pest if the defined territory as referred to in the introductory words of Article 3 is the Union territory and it is included in the list referred to in Article 5(2).

### *Article 5*

#### **Prohibition of introduction and movement of Union quarantine pests**

1. A Union quarantine pest shall not be introduced into or moved within the Union territory.

No action shall be taken intentionally which may contribute to the introduction into, and establishment and spread within, the Union territory of a Union quarantine pest.

2. The Commission shall, by means of an implementing act, establish a list of pests fulfilling the conditions referred to in Article 3(b), (c) and (d) in respect of the Union territory, referred to as 'list of Union quarantine pests'.

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

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

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

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission shall amend the implementing act referred to in paragraph 2, where an assessment shows that a pest not listed in that act fulfils the conditions referred to in Article 3(b), (c) and (d) in respect of the Union territory, or a pest listed in that act no longer fulfils one or more of those conditions. In the first case it shall add the pest concerned to the list referred to in paragraph 2, in the second case it shall delete the pest concerned from that list.

The Commission shall make that assessment available to the Member States.

The implementing acts amending the implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 99(3). The same procedure shall apply to a repeal or a replacement of the implementing act referred to in paragraph 2.

4. The Commission shall amend the implementing act referred to in paragraph 2 by amending the scientific name of a pest, where such an amendment is justified by the development of scientific knowledge.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

#### *Article 6* **Priority pests**

1. A Union quarantine pest is a 'priority pest' if it fulfils all of the following conditions:
  - (a) it fulfils, as regards the Union territory, the condition set out in point (a) or in point (b) of point (2) of Section 1 of Annex II;
  - (b) its potential economic, environmental or social impact is most severe for the Union territory as set out in Section 2 of Annex II;
  - (c) it is listed in accordance with paragraph 2.
2. The Commission shall, by means of an implementing act, establish and amend a list of the priority pests, hereinafter: 'list of priority pests'.

Where the results of an assessment show that a Union quarantine pest fulfils the conditions referred to in paragraph 1, or a pest no longer fulfils one or more of those conditions, the Commission shall amend the implementing act referred to in the first subparagraph by adding the pest concerned to, or removing it from, that list.

The Commission shall make that assessment available to the Member States.

The number of priority pests shall not exceed 10% of the number of the Union quarantine pests listed pursuant to Article 5(2) and (3). Where the number of priority pests has exceeded 10% of the number of the Union quarantine pests listed pursuant to Article 5(2) and (3), the Commission shall amend the implementing act referred to in the first subparagraph by accordingly adjusting the number of pests in that list, on the basis of their potential economic, environmental or social impact as set out in Section 2 of Annex II.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

On duly justified imperative grounds of urgency relating to a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4), listing Union quarantine pests as priority pests.

#### *Article 7* **Amendment of Section 1 and Section 2 of Annex II**

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 1 of Annex II on criteria to identify pests which qualify

as a quarantine pest, as regards the identity of the pest, its presence, its capability of entry, establishment and spread, and its potential economic, social and environmental impact, taking into account the developments of technical and scientific knowledge.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 2 of Annex II on criteria to identify Union quarantine pests which qualify as a priority pest, as regards their potential economic, social and environmental impact, taking into account the developments of technical and scientific knowledge.

#### *Article 8*

#### **Union quarantine pests used for scientific purposes, trials, varietal selections, breeding or exhibitions**

1. By way of derogation from Article 5(1), Member States may, on application, authorise the introduction into, and the movement within, their territory of Union quarantine pests for use for scientific purposes, trials, varietal selections, breeding or exhibitions if all of the following requirements are fulfilled:
  - (a) the introduction, movement and use of the pest concerned do not result in the establishment or spread of that pest within the Union territory if adequate restrictions are imposed;
  - (b) the storage facilities in which that pest is to be kept and the quarantine stations, as referred to in Article 56, in which that pest is to be used are appropriate;
  - (c) the scientific and technical qualifications of the personnel by whom the activity involving that pest is to be carried out are appropriate.
2. The competent authority shall assess the risk of establishment and spread of the pest concerned, as referred to in paragraph 1(a), taking into account 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 that pest.

It shall assess the storage facilities in which that pest is to be kept, as referred to in paragraph 1(b), and the scientific and technical qualifications of the personnel by whom the activity involving the pest is to be carried out, as referred to in paragraph 1(c).

On the basis of those assessments the competent authority shall authorise introduction of the pest into, or movement within, the Union territory if the requirements set out in paragraph 1 are fulfilled.
3. Where an authorisation is granted, it shall include all of the following conditions:
  - (a) the pest is to be kept in storage facilities found to be appropriate by the competent authorities and referred to in the authorisation;
  - (b) the activity involving the pest is to be carried out in a quarantine station designated in accordance with Article 56 by the competent authority and referred to in the authorisation;

- (c) the activity involving the pest is to be carried out by personnel whose scientific and technical qualifications are found to be appropriate by the competent authority and referred to in the authorisation;
  - (d) the pest is to be accompanied by the authorisation when introduced into or moved within the Union territory.
4. The authorisation shall be limited to the amount that is adequate for the activity concerned and shall not exceed the capacity of the designated quarantine station.
- It shall include the restrictions necessary to adequately mitigate the risk of establishment and spread of the Union quarantine pest concerned.
5. The competent authority shall monitor compliance with the conditions referred to in paragraph 3 and the limitation and the restrictions referred to in paragraph 4 and take the necessary action in case those conditions, that limitation or those restrictions are not complied with. Where appropriate, that action shall be the revocation of the authorisation referred to in paragraph 1.
6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules concerning:
- (a) the exchange of information between Member States and the Commission concerning the introduction into, and movement within, the Union territory of the pests concerned;
  - (b) the assessments and authorisation referred to in paragraph 2; and
  - (c) the monitoring of compliance, the action in case of non-compliance and the notification thereof, as referred to in paragraph 5.

#### *Article 9*

##### **Notification of Union quarantine pests to the competent authorities**

1. Where anyone becomes aware of the presence of a Union quarantine pest or has reason to suspect such a presence, that person shall notify, in writing, the competent authority within ten calendar days.
2. If so requested by the competent authority, the person referred to in paragraph 1 shall provide that authority with the information concerning that presence which is in its possession.

#### *Article 10*

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

Where a competent authority 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.

#### Article 11

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

1. A Member State shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States, in case one of the following points is fulfilled:
  - (a) its competent authority has received a diagnosis of an official laboratory, as referred to in Article 36 of Regulation (EU) No .../.... [*Office of Publications, please insert the number of the Regulation on Official Controls*], confirming (hereinafter: 'officially confirming') the presence in its territory of a Union quarantine pest not known to be present in that Member State;
  - (b) its competent authority has officially confirmed the presence in its territory of a Union quarantine pest, if that pest is found to be present in a part of its territory where it was previously not present;
  - (c) its competent authority 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, intended to be introduced into or moved within the Union territory.
2. The notifications referred to in paragraph 1 shall be submitted within three working days following the date of the official confirmation by the competent authority of the presence of the respective Union quarantine pest.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down that the notification obligations referred to in paragraph 1 shall also apply to the suspected presence of particular 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 12

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

Where the conditions of one of the points of Article 11(1) are fulfilled, the competent authority concerned shall ensure that professional operators, whose plants, plant products or other objects may be affected, are immediately informed of the presence of the Union quarantine pest concerned.

#### Article 13

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

Where the conditions of one of the points of Article 11(1)(a) or (b) are fulfilled as regards a priority pest, the competent authority shall inform the public about the measures taken and to be taken by that competent authority and, where applicable, to be taken by particular professional operators or other persons.

#### *Article 14*

### **Notification of imminent dangers**

1. Where a Member State has evidence that there is an imminent danger of the entry of a Union quarantine pest into the Union territory or into a part 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. Professional operators 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 15*

### **Measures to be taken immediately by professional operators**

1. Where a professional 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 after informing and consulting with the competent authority concerned, take the phytosanitary measures necessary to eliminate that pest from the plants, plant products or other objects concerned and from its premises, where applicable, and prevent the spread of that pest.

That professional operator shall, immediately and after informing and consulting with the competent authority concerned, inform the persons in the trade chain from whom those plants, plant products or other objects had been obtained.

That competent authority shall, where appropriate, ensure that the professional operator concerned withdraws from the market the plants, plant products and other objects in which that pest may be present.

2. Where the plants, plant products or other objects referred to in paragraph 1 have left the control of the professional operator concerned, that professional operator shall, immediately and after informing and consulting with the competent authority concerned, inform the persons in the trade chain from whom those plants, plant products or other objects had been obtained and to whom those plants, plant products and other objects had been supplied, of the presence of the pest.
3. The competent authority shall, where appropriate, ensure that the professional operator concerned recalls from the market the plants, plant products and other objects in which the pest may be present and, where the plants, plant products and other objects may have reached the final user, to recall them from those final users.
4. Where paragraph 1 or 2 applies, the professional 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 regard to the plants, plant products or other objects in which the respective pest may be present.

#### *Article 16*

### **Eradication of Union quarantine pests**

1. Where the presence of a Union quarantine pest is officially confirmed, the competent authority 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 adopted in accordance with Annex IV on measures and principles for the management of the risks of pests.
2. Where the presence of the Union quarantine pest concerned may be related to movements of plants, plant products or other objects, the competent authority shall investigate the source of that presence and the possibility that the pest concerned has been spread to further plants, plant products or other objects by those movements.
3. Where the measures referred to in paragraph 1 concern the introduction into, or movement within, the Union territory of plants, plant products and other objects, the Member State concerned shall immediately notify those measures to the Commission and the other Member States.
4. Private premises of citizens shall not be exempted from the measures, referred to in paragraph 1, and the investigations, referred to in paragraph 2.

#### *Article 17*

### **Establishment of restricted areas**

1. Following the official confirmation referred to in Article 11(1)(a), the competent authority shall immediately establish an area where the measures referred to in that Article are to be taken (hereinafter: 'restricted area').

The restricted area shall consist of an infested zone, as provided for in paragraph 2, and a buffer zone, as provided for in paragraph 3.

2. The infested zone 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 their susceptibility to that pest and their close proximity to infested plants, or common source of production, if known, with infested plants, or plants grown from them.
3. The buffer zone 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, and shall be decided in accordance with the principles set out in Section 2 of Annex IV on measures and principles for the management of the risks of pests.

However, where any risk of the pest spreading out of the infested zone is sufficiently mitigated through natural or artificial barriers, no buffer zone need be established.

4. By way of derogation from paragraph 1, where upon first sight the competent authority concludes, in view of the nature of the pest concerned and the site where it was found, that the pest concerned can be eliminated immediately, the competent authority may decide not to establish a restricted area.

In that case, it shall carry out a survey to determine whether any further plants or plant products have been infested. On the basis of that survey, the competent authority 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 2 and 3 a restricted area is to extend into the territory of another Member State, the Member State 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.
6. By 31 March of each year, Member States shall notify to the Commission and the other Member States the number and locations of the restricted areas established, the pests concerned, and the respective measures taken during the preceding year.

#### *Article 18*

#### **Surveys and modifications of restricted areas, and lifting of restrictions**

1. Competent authorities shall annually carry out a 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 the provisions on surveys as set out in Article 21(1) and (2).

2. Where as a result of an annual survey a competent authority finds a presence of the pest concerned in the buffer zone, the Member State concerned shall immediately notify that presence to the Commission and the other Member States specifying that the pest was found present in a buffer zone.
3. Competent authorities shall modify the boundaries of infested zones, buffer zones and restricted areas, where appropriate, in view of the results of the surveys referred to in paragraph 1.
4. Competent authorities may decide to abolish a restricted area and terminate the respective eradication measures, 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.
5. When deciding on the modifications referred to in paragraph 3 or the abolition of the restricted area referred to in paragraph 4, the competent authority concerned shall at least take into account the biology of the pest and the vector concerned, the presence

of host plants, the eco-climatic conditions and the likelihood of the eradication measures having been successful.

#### *Article 19*

#### **Reports on measures taken in accordance with Articles 16, 17 and 18**

Member States shall prepare a report on the measures taken in accordance with Articles 16, 17 and 18.

Where those measures are taken by a Member State in an area adjacent to the border with another Member State, that report shall be submitted to the latter Member State.

That report shall be submitted, on request, to the Commission and the other Member States.

#### *Article 20*

#### **Amendment of Annex IV**

The Commission shall be empowered to adopt delegated acts in accordance with Article 98, amending Section 1 of Annex IV on measures to manage 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, plant products and other objects, measures targeting other pathways for quarantine pests, and amending Section 2 of that Annex on principles for the management of the risks of pests, as regards principles for the management of the risks of pests, taking into account the developments of technical and scientific knowledge.

#### *Article 21*

#### **Surveys on Union quarantine pests and pests provisionally qualifying as Union quarantine pest**

1. Member States shall conduct surveys, over specific periods of time, checking for the presence of any Union quarantine pest, and signs or symptoms of any pest provisionally qualifying as Union quarantine pest, pursuant to Section 3 of Annex II, in all areas where that pest was not known to be present.
2. Those surveys shall consist, at least, of visual examinations by the competent authority, and, where appropriate, collection of samples and performance of tests. They shall be based on sound scientific and technical principles, and shall be carried out at appropriate times with regard to the possibility to detect the pest concerned.

Those surveys shall take account of scientific and technical evidence, and any other appropriate information, concerning the presence of the pests concerned.

3. 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*

### **Multi-annual survey programmes and collection of information**

1. Member States shall establish multi-annual programmes setting out the content of the surveys to be carried out pursuant to Article 21. Those programmes shall provide for the collection and recording of the scientific and technical evidence and other information as referred to in the second subparagraph of Article 21(2).

Those programmes shall set out the following elements: the specific objective of each survey, its spatial and temporary scope, the pests, plants and commodities targeted, the survey methodology and quality management including a description of the procedures for visual examination, sampling and testing and their technical justification, the timing, frequency and numbers of scheduled visual examinations, samples and tests, the methods of recording of the information collected and their reporting.

The multi-annual programmes shall be for a period of five to seven years.

2. Member States shall notify their multi-annual survey programmes upon their establishment to the Commission and the other Member States.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending or supplementing the elements to be covered by the multi-annual survey programmes, as set out in paragraph 1.

## *Article 23*

### **Surveys of priority pests**

1. For each priority pest, Member States shall annually carry out a separate survey, as set out in Article 21(1). Those surveys shall include a sufficiently high number of visual examinations, sampling and testing, as appropriate for the relevant pests, to ensure, at a high level of probability, their timely detection.
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 were carried out in the preceding year.

## *Article 24*

### **Contingency plans for priority pests**

1. Each Member State shall draw up and keep up to date, for each priority pest which is capable of entering into and establishing in its territory, or a part thereof, a separate plan containing information concerning the decision making processes, procedures and protocols to be followed, and resources to be made available, in case of a confirmed or suspected presence of the pest concerned, hereinafter 'the contingency plan'.
2. The contingency plan shall include the following:

- (a) the roles and responsibilities of the bodies involved in the execution of the plan, in case of a confirmed or suspected presence of the priority pest concerned, the chain of command and procedures for the co-ordination of actions taken by competent authorities, other public authorities, as referred to in Article 3(2) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation of Official Controls*], delegated bodies or natural persons involved, as referred to in Article 25(1) of Regulation (EU) No .../.... [*Office of Publication, please insert number of Regulation of Official Controls*], laboratories and professional operators, including co-ordination with neighbouring Member States and neighbouring third countries, where appropriate;
- (b) access of competent authorities to premises of professional operators and of natural persons, where necessary, laboratories, equipment, personnel, external expertise and resources necessary for the rapid and effective eradication or, where appropriate, containment of the priority pest concerned;
- (c) measures to be taken concerning the information of the Commission, the other Member States, the professional operators concerned and the public, as regards the presence of the priority pest concerned and the measures taken against it, in case a presence of the pest concerned is officially confirmed or suspected;
- (d) arrangements for recording findings of the presence of the priority pest concerned;
- (e) the available assessments as set out in Article 6(2), and any assessment of the Member State as regards the risk of the priority pest concerned for its territory;
- (f) the risk management measures to be implemented as regards the priority pest concerned, in accordance with Section 1 of Annex IV, and the procedures to be followed;
- (g) principles for the geographical demarcation of restricted areas;
- (h) protocols describing the methods of visual examinations, sampling and laboratory testing; and
- (i) principles concerning the training of personnel of the competent authorities.

Where appropriate, points (a) to (i) shall take the form of instruction manuals.

3. Within one year from the date of the inclusion of the pest concerned in the list of priority pests, Member States shall establish a contingency plan for the priority pest concerned.

Member States shall regularly review and, where appropriate, update their contingency plans.

4. Member States shall communicate their contingency plans to the Commission and to the other Member States on request.

## *Article 25*

### **Simulation exercises**

1. Member States shall carry out simulation exercises concerning the implementation of the contingency plans at intervals set according to the biology of the priority pest concerned and the phytosanitary risk posed by that pest.

Those exercises shall take place with regards to all priority pests concerned within a reasonable period of time.

2. As regards priority pests whose presence in one Member state could have impacts for neighbouring Member States, the simulation exercises shall be carried out together by the Member States concerned on the basis of their respective contingency plans.

Where appropriate, Member States shall carry out those simulation exercises with neighbouring third countries.

3. Member States shall, on request, make available a report on the results of each simulation exercise to the Commission and to the other Member States.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out:

- (a) the frequencies, contents and format of simulation exercises;
- (b) simulation exercises covering more than one priority pest;
- (c) co-operation between Member States, and of Member States with third countries;
- (d) contents of the reports on simulation exercises provided for in paragraph 3.

## *Article 26*

### **Eradication plans for priority pests**

1. Where the presence of a priority pest is officially confirmed in the territory of a Member State pursuant to Article 11(1)(a), the competent authority shall immediately adopt a plan setting out the measures for the eradication of the pest concerned, as provided for in Articles 16, 17 and 18, and a time schedule for the application of those measures. That plan is referred to as the 'eradication plan.

The eradication plan shall include a description of the design and organisation of the surveys to be carried out and set out the number of visual examinations, samples to be taken and laboratory tests to be carried out.

2. Member States shall notify, on request, to the Commission and the other Member States the eradication plans and an annual report on the measures taken in accordance with Articles 16, 17 and 18 under the eradication plans concerned.

## *Article 27*

### **Union measures for specific Union quarantine pests**

1. The Commission may, by means of implementing acts, set out measures against specific Union quarantine pests. Those measures shall implement, specifically for each of the pest(s) concerned, one or more of the following provisions:
  - (a) Article 10 concerning measures in case of suspicion of the presence of a Union quarantine pest;
  - (b) Article 15 concerning measures to be taken immediately by professional operators;
  - (c) Article 16 concerning eradication of Union quarantine pests;
  - (d) Article 17 concerning establishment of restricted areas;
  - (e) Article 18 concerning surveys, modifications of restricted areas and lifting of restrictions;
  - (f) Article 21 concerning surveys on Union quarantine pests and pests provisionally qualifying as Union quarantine pest;
  - (g) Article 23 concerning surveys for priority pests, as regards the number of visual examinations, samples and tests for particular priority pests;
  - (h) Article 24 concerning contingency plans for priority pests;
  - (i) Article 25 concerning simulation exercises;
  - (j) Article 26 concerning eradication plans for priority pests.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

2. Where, as regards a restricted area, the Commission concludes, on the basis of the surveys referred to in Article 18 or other evidence, that the eradication of the Union quarantine pest concerned is not possible, the Commission may adopt implementing acts, as referred to in paragraph 1, which set out measures with the single purpose of prevention of the spread of those pests out of the areas concerned. Such prevention is referred to as 'containment'.
3. In case the Commission concludes that prevention measures in locations outside restricted areas are necessary to protect the part of the Union territory where the Union quarantine pest concerned is not present, the Commission may adopt implementing acts, as referred to in paragraph 1, setting out such measures.
4. The measures referred to in paragraphs 1, 2 and 3 shall be taken in accordance with Annex IV on measures and principles for the management of the risks of pests, taking into account the specific risks of the Union quarantine pests concerned 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 1 may provide that the measures, referred to in points (a) to (j) of paragraph 1, taken by the Member States are to be repealed or amended. Until a measure has been adopted by the Commission, the Member State may maintain the measures that it has employed.
6. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).
7. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States of any cases of non-compliance by professional operators with the measures adopted pursuant to this Article.

#### *Article 28*

#### **Measures by Member States concerning pests not listed as Union quarantine pests**

1. Where the presence of a pest that is not included in the list of Union quarantine pests in the territory of a Member State is officially confirmed, and the competent authority concerned considers that that pest may fulfil the conditions for inclusion in the list of Union quarantine pests, it shall immediately assess whether that pest fulfils the criteria of Subsection 1 of Section 3 of Annex II. If it concludes that those criteria are fulfilled, it shall immediately take eradication measures in accordance with Annex IV on measures and principles for the management of the risks of pests. Articles 16 to 19 shall apply.

Where a competent authority suspects the presence in its territory of a pest fulfilling the criteria referred to in the first subparagraph, Article 10 shall apply accordingly.

2. Following the actions referred to in paragraph 1, the Member State shall assess whether the pest concerned fulfils, as regards the Union territory, the criteria for quarantine pests set out in Section 1 of Annex II.
3. The Member State concerned shall immediately notify to the Commission and the other Member States the presence of that pest, the assessment referred to in paragraph 1, the measures taken and the evidence justifying those measures.

It shall notify to the Commission the results of the assessment referred to in paragraph 2 within 24 months of the official confirmation of the presence of that pest.

Notifications of the presence of that pest shall be submitted through the electronic notification system referred to in Article 97.

#### *Article 29*

#### **Measures by the Union concerning pests not listed as Union quarantine pests**

1. Where the Commission receives the notification referred to in the first subparagraph of Article 28(3), or has other evidence concerning the presence in, or imminent danger of entry into, the Union territory of a pest which is not included in the list of Union quarantine pests and it considers that that pest may fulfil the conditions for

inclusion in that list, it shall immediately assess whether, as regards the Union territory, that pest fulfils the criteria of Subsection 2 of Section 3 of Annex II.

Where it concludes that those criteria are fulfilled, it shall immediately, by means of implementing acts, adopt measures for a limited time as regards the phytosanitary risks posed by that pest. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Those measures shall implement, specifically for each of the pests concerned, one or more of the provisions referred to in Article 27(1)(a) to (f).

2. Where the Commission concludes, on the basis of surveys referred to in Article 18 and in Article 21, or other evidence, that the eradication of the pest concerned is not possible in certain restricted areas, the implementing acts referred to in the second subparagraph of paragraph 1 may set out measures with the single purpose to contain that pest.
3. In case the Commission concludes that prevention measures in locations outside restricted areas are necessary to protect the part of the Union territory where the pest concerned is not present, the implementing acts referred to in paragraph 1 may set out such measures.
4. The measures referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with Section 1 of Annex IV on measures to manage the risks of quarantine pests and Section 2 of that Annex on principles for the management of the risks of pests, taking into account the specific risks of the pests concerned 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 1 may provide that the measures taken by the Member States pursuant to Article 28 are to be repealed or amended. Until a measure has been adopted by the Commission, the Member State may maintain the measures that it has employed.
6. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).
7. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States of any cases of non-compliance by professional operators with the measures adopted pursuant to this Article.

#### *Article 30*

### **Amendment of Section 3 of Annex II**

The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 3 of Annex II on criteria to be fulfilled by pests, as provided for in Articles 28 and 29, 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 impact, taking into account the developments of technical and scientific knowledge.

### *Article 31*

#### **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 27(1), (2) and (3) and Article 29(1), (2) and (3), if justified by the objective of phytosanitary protection and in accordance with Section 2 of Annex IV on measures and principles for the management of the risks of pests.

Those measures shall not impose, or result in, any prohibitions or restrictions on the introduction into, or movement within, the Union territory of plants, plant products and other objects, other than those imposed by the provisions of Articles 40 to 54 and the provisions of Articles 67 to 96.

2. Member States shall immediately notify the Commission and the other Member States of measures adopted by them within the ambit of paragraph 1.

Member States shall, on request, submit to the Commission and the other Member States an annual report on the measures taken in accordance with paragraph 1.

### **SECTION 3**

#### **PROTECTED ZONE QUARANTINE PESTS**

### *Article 32*

#### **Recognition of protected zones**

1. Where a quarantine pest is present in the Union territory but not present in the Member State concerned, and is not a Union quarantine pest, the Commission may, upon application of that Member State pursuant to paragraph 4, recognise the territory of that Member State as a protected zone in accordance with paragraph 3.

Where a protected zone quarantine pest is absent from a part of the territory of a Member State the same shall apply with respect to that part.

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.

Nobody shall intentionally take an action which contributes to the introduction into, and establishment and spread within, a protected zone of the respective protected zone quarantine pest.

3. The Commission shall, by means of an implementing act, establish a list of protected zones and the respective protected zone quarantine pests. That list shall include the protected zones recognised in accordance with the first subparagraph of Article 2(1)(h) of Directive 2000/29/EC and the respective 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 99(2).

The Commission may recognise additional protected zones, by amending the implementing act referred to in the first subparagraph, where the conditions provided for in paragraph 1 are fulfilled. Such an amendment shall be adopted in accordance with the examination procedure referred to in Article 99(3). The same procedure shall apply to a repeal or replacement of the implementing act referred to in the first subparagraph.

Where Article 35 applies, an implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

4. With the application referred to in paragraph 1, the Member State concerned shall submit:
  - (a) a description of the boundaries of the protected zone concerned, including maps; and
  - (b) the results of surveys showing that during the three years preceding the application, the quarantine pest concerned was not present in the territory concerned.

Those surveys shall have been carried out at appropriate times and have been of appropriate intensity with regard to the possibility to detect the presence of the quarantine pest concerned. They shall have been based on sound scientific and technical principles.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones.

### *Article 33*

#### **General obligations concerning protected zones**

1. With regard to a protected zone, the obligations set out in the following Articles shall apply accordingly to the protected zone quarantine pests:
  - (a) Articles 9 to 12 concerning the confirmation, notification and information as regards the presence of Union quarantine pests;
  - (b) Article 15 concerning measures to be taken immediately by professional operators;
  - (c) Articles 16, 17 and 18 concerning the eradication of Union quarantine pests, the establishment and modification of restricted areas and surveys in those restricted areas.
2. A plant, plant product or other object originating in a restricted area established, in accordance with Article 17, in a protected zone for the protected zone quarantine pest concerned, may not be moved within or into any protected zone established for that protected zone quarantine pest. When moved out of the protected zone concerned, that plant, plant product or other object shall be packed and moved in such a way that

there is no risk of spreading the respective protected zone quarantine pest within that protected zone.

3. The restricted areas established within a protected zone and the eradication measures taken in those areas pursuant to Articles 16, 17 and 18 shall be immediately notified to the Commission and the other Member States.

#### *Article 34*

### **Surveys on protected zone quarantine pests**

1. The competent authority shall carry out an annual survey of each protected zone as regards the presence of the protected zone quarantine pest concerned. Those surveys shall be carried out at appropriate times and be of an appropriate intensity with regard to the possibility to detect the presence of the protected zone quarantine pest concerned. They shall be based on sound scientific and technical principles.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules for those surveys to be carried out to confirm that the protected zones continue to fulfil the conditions set out in Article 32(1).

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 35*

### **Amendment and revocation of the protected zones**

1. The Commission may amend the size of the protected zone on application by the Member State whose territory is concerned.

Where the Commission amends the protected zone, the Member State concerned shall notify the Commission, the other Member States and, via the internet, the professional operators of the amendment to that protected zone, including maps.

Where that amendment concerns the extension of a protected zone, Articles 32, 33 and 34 shall apply.

2. On application by the Member State referred to in paragraph 1, the Commission shall revoke the recognition of a protected zone or shall reduce its size.
3. The Commission shall revoke the recognition of a protected zone in case the surveys referred to in Article 34 have not been carried out in accordance with that Article.
4. The Commission shall revoke the recognition of a protected zone, in case the respective protected zone quarantine pest has been found to be present in that zone and one of the following conditions is fulfilled:
  - (a) no restricted area has been designated, in accordance with Article 33(1), within three months after the presence of that pest was confirmed;

- (b) the eradication measures taken in a restricted area pursuant to Article 33(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, with regard to the application of measures pursuant, by virtue of Article 33(1)(c), to Articles 16, 17 and 18, negligent reaction to the presence of that pest in the concerned protected zone.

## **Chapter III**

### **Union quality pests**

#### *Article 36*

#### **Definition of Union quality pests**

A pest shall be referred to as a 'Union quality pest' if it fulfils the following conditions and it is included in the list referred to in Article 37:

- (a) its identity is established in accordance with point (1) of Section 4 of Annex II;
- (b) it is present in the Union territory;
- (c) it is no Union quarantine pest;
- (d) it is transmitted mainly through specific plants for planting, in accordance with point (2) of Section 4 of Annex II;
- (e) its presence on those plants for planting has an unacceptable economic impact, as regards the intended use of those plants for planting, in accordance with point (3) of Section 4 of Annex II;
- (f) feasible and effective measures are available to prevent its presence on the plants for planting concerned.

#### *Article 37*

#### **Prohibition of the introduction and movement of Union quality pests on plants for planting**

1. A Union quality pest shall not be introduced into or moved within the Union territory on the plants for planting through which it is transmitted, as specified in the list referred to in paragraph 2.
2. The Commission shall, by means of an implementing act, establish a list setting out the Union quality pests and the specific plants for planting, as referred to in Article 36(d), where appropriate with the categories referred to in paragraph 4 and thresholds referred to in paragraph 5.

That list shall include the pests, and the respective plants for planting, as set out in the following acts:

- (a) Section II of Part A of Annex II of Directive 2000/29/EC;
- (b) points (3) and (6) of Annex I to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed<sup>24</sup> and point (3) of Annex II thereto;
- (c) the Annex of Commission 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<sup>25</sup>;
- (d) the Annex of Commission 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<sup>26</sup>;
- (e) point (b) of Annex II to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed<sup>27</sup>;
- (f) point (6) of Annex I to Council Directive 2002/56/EC<sup>28</sup> of 13 June 2002 on the marketing of seed potatoes and point B of Annex II thereto;
- (g) point (4) of Annex I to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants<sup>29</sup> and point (5) of Annex II thereto.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission shall amend the implementing act referred to in paragraph 2, where an assessment shows that a pest not listed in that act fulfils the conditions referred to in Article 36, a pest listed in that implementing act no longer fulfils one or more of those conditions or where amendments to that list are necessary, as regards categories referred to in paragraph 4 or thresholds referred to in paragraph 5.

The Commission shall make that assessment available to the Member States.

4. Where Article 36(e) is only fulfilled for one or more of the categories referred to in Article 12(1) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material law*], the list referred to in paragraph 1 shall set out those categories stating that the prohibition of introduction and movement provided for in paragraph 1 only applies to those categories.
5. Where Article 36(e) is only fulfilled if the pest concerned is present above a certain threshold, the list referred to in paragraph 1 shall set out that threshold stating that the prohibition of introduction and movement provided for in paragraph 1 only applies above that threshold.

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<sup>24</sup> OJ L 125, 11.7.1966, p. 2309.

<sup>25</sup> OJ L 250, 7.10.1993, p. 1.

<sup>26</sup> OJ L 250, 7.10.1993, p. 9.

<sup>27</sup> OJ L 193, 20.7.2002, p. 33.

<sup>28</sup> OJ L 193, 20.7.2002, p. 60.

<sup>29</sup> OJ L 193, 20.7.2002, p. 74.

A threshold shall only be set if the following points are fulfilled:

- (a) it is possible to ensure by measures taken by the professional operator that the presence of that Union quality pest on those plants for planting does not exceed that threshold; and
- (b) it is possible to verify whether that threshold is not exceeded in lots of those plants for planting.

The principles for the management of the risk of pests set out in Section 2 of Annex IV shall apply.

6. For amendments to the implementing act referred to in paragraph 2 which are necessary to adapt that implementing act in view of changes to the scientific name of a pest, the advisory procedure referred to in Article 99(2) shall apply.

All other amendments to the implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 99(3). The same procedure shall apply to a repeal or a replacement of the implementing act referred to in paragraph 2.

#### *Article 38*

#### **Amendment of Section 4 of Annex II**

The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 4 of Annex II on criteria to identify pests which qualify as a Union quality pest, as regards the criteria concerning the identity of the pest, its relevance, the probability of its spread, its potential economic, social and environmental impact, taking account of the developments of technical and scientific knowledge.

#### *Article 39*

#### **Union quality pests used for scientific purposes, trials, varietal selections, breeding or exhibitions**

The prohibition provided for in Article 37 shall not apply to Union quality pests present on the plants for planting concerned, and used for scientific purposes, trials, varietal selections, breeding or exhibitions.

# Chapter IV

## Measures concerning plants, plant products and other objects

### SECTION 1

#### MEASURES RELATING TO THE ENTIRE UNION TERRITORY

#### *Article 40*

#### **Prohibition of introduction of plants, plant products and other objects into the Union territory**

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, and the prohibitions and the third countries concerned, as set out in Part A of Annex III to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, the plants, plant products and other objects shall be identified by their respective code in accordance with the classification in the Combined Nomenclature as laid down in Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff<sup>30</sup> (hereinafter: 'CN code').

2. In case a plant, plant product or other object, originating in or being dispatched from a third country, poses a phytosanitary risk of an unacceptable level by its likelihood to host a Union quarantine pest, and that risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures and principles for the management of the risks of pests, the Commission shall amend, as appropriate, the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the third countries, concerned.

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level, or it poses such a risk but that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend that implementing act, as appropriate.

The acceptability of the level of that phytosanitary risk shall be assessed in accordance with the principles set out in Section 2 of Annex IV on principles for the management of the risks of pests. Where appropriate, the acceptability of that level of phytosanitary risk shall be assessed with regards to one or more specific third countries.

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<sup>30</sup> OJ L 256, 7.9.1987, p. 1.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt those amendments by immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 shall not be introduced into the Union territory from the third country, concerned by that listing.
4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where plants, plant products or other objects have been introduced into the Union territory in violation of paragraph 3.

The third country from which the plants, plant products or other objects were introduced into the Union territory shall be notified.

#### *Article 41*

#### **Plants, plant products and other objects subject to special and equivalent requirements**

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, and the requirements and, where applicable, the third countries concerned, as set out in Part A of Annex IV to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, those plants, plant products and other objects shall be identified by their respective CN code.

2. In case a plant, plant product or other object poses a phytosanitary risk of an unacceptable level by its likelihood to host a Union quarantine pest, and that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures and principles for the management of the risks of pests, the Commission shall amend the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the measures to be applied to it. Those measures, and the requirements referred to in paragraph 1, are hereinafter referred to as 'special requirements'.

Those measures may take the form of specific requirements, adopted in accordance with Article 42(1), for the introduction into the Union territory of particular plants, plant products or other objects, which are equivalent to special requirements for the movement of those plants, plant products or other objects within the Union territory (hereinafter: 'equivalent requirements').

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level, or it poses such a risk but that risk cannot be reduced to an acceptable level by the special requirements, the Commission shall amend that implementing act.

The acceptability of the level of that phytosanitary risk shall be assessed, and the measures to reduce that risk to an acceptable level shall be adopted, in accordance with the principles set out in Section 2 of Annex IV on principles for the management of the risks of pests. Where appropriate, the acceptability of that level of phytosanitary risk shall be assessed, and those measures shall be adopted, with regards to one or more specific third countries or parts thereof.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 99(4).

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 may only be introduced into, or moved within, the Union territory if the special requirements, or equivalent requirements, are fulfilled.
4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of paragraph 3.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

#### *Article 42*

#### **Setting out of equivalent requirements**

1. Equivalent requirements, as referred to in the second subparagraph of Article 41(2) shall be set out, by means of an implementing act, on request of a particular third country, if all of the following conditions are fulfilled:
  - (a) the third country concerned ensures, through the application under its official control of one or more specified measures, a level of phytosanitary protection which is equivalent to the special requirements adopted pursuant to Article 41(1) and (2) in respect of the movement within the Union territory of plants, plant products and other objects concerned;
  - (b) the third country concerned objectively demonstrates to the Commission that the specified measures referred to in point (a) achieve the level of phytosanitary protection referred to in that point.
2. Where appropriate, the Commission shall investigate, in the third country concerned, and in accordance with Article 119 of the Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*], whether points (a) and (b) are fulfilled.
3. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 99(3).

### *Article 43*

#### **Information to be provided to travellers, clients of postal services and internet clients**

1. Member States and international transport operators shall make information available to passengers concerning the prohibitions, set out pursuant to Article 40(3), the requirements, set out pursuant to Articles 41(1) and 42(2), and the exemptions, set out pursuant to Article 70(2), as regards the introduction of plants, plant products and other objects into the Union territory.

That information shall be provided in the form of posters or brochures, which, where appropriate, shall be made available through the internet.

Where that information is made available to passengers at seaports and airports, it shall be provided in the form of posters.

The Commission shall be empowered to adopt an implementing act, setting out those posters and brochures. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

2. The information referred to in paragraph 1 shall be made available by postal services, and by professional operators involved in sales through distance contracts, to their clients through the internet.
3. Member States shall annually submit to the Commission a report summarising the information provided pursuant to this Article.

### *Article 44*

#### **Exception from prohibitions and requirements for frontier zones**

1. By way of derogation from Articles 40(3) and 41(3), Member States may authorise the introduction of plants, plant products and other objects into the Union territory, where the plants, plant products and other objects fulfil the following conditions:
  - (a) they are grown or produced in areas of third countries in the vicinity of their border with Member States (hereinafter: 'third country frontier zones');
  - (b) they are introduced into areas of Member States immediately across that border (hereinafter: 'Member State frontier zones');
  - (c) they are to be processed in the respective Member State frontier zones in such a manner that any phytosanitary risk is eliminated;
  - (d) they do not pose any risk of spreading quarantine pests caused by movements within the frontier zone.

Those plants, plant products and other objects shall only move into and within the Member State frontier zones, and only under the official control of the competent authority.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the following:

- (a) the maximum width of third country frontier zones and Member State frontier zones, as appropriate for the specific plants, plant products and other objects individually;
- (b) the maximum distance of the movement of the plants, plant products and other objects concerned within the third country frontier zones and Member State frontier zones; and
- (c) the procedures concerning the authorisation of the introduction into, and movement within, the Member State frontier zones of plants, plant products and other objects referred to in paragraph 1.

The width of those zones shall be such to ensure that the introduction and movement of those plants, plant products and other objects in the Union territory does not pose any phytosanitary risks to the Union territory or parts of it.

3. The Commission may lay down, by means of implementing acts, specific conditions or measures concerning the introduction into Member State frontier zones of particular plants, plant products and other objects, and specific third countries, which are subject to this Article.

Those acts shall be adopted in accordance with Section 1 of Annex IV on measures to manage the risks of quarantine pests and Section 2 of that Annex on principles for the management of the risks of pests, taking into account the scientific and technical developments.

Those implementing acts shall be adopted, and as appropriate repealed or replaced, in accordance with the examination procedure referred to in Article 99(3).

4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, the frontier zones as referred to in paragraphs 1 and 2 in violation of those paragraphs.

The third country from which the plants, plant products or other objects were introduced into the frontier zone concerned shall also be notified.

#### *Article 45*

#### **Exception from prohibitions and requirements for phytosanitary transit**

1. By way of derogation from Article 40(3) and Article 41(3), Member States may authorise the introduction of plants, plant products and other objects into, and their passing through, the Union territory to a third country (hereinafter 'phytosanitary transit'), where those plants, plant products and other objects fulfil the following conditions:
  - (a) they are accompanied by a signed declaration of the professional operator in control of those plants, plant products and other objects stating that those plants, plant products or other objects are in phytosanitary transit;

- (b) they are packed and moved in such a way that there is no risk of spreading of Union quarantine pests during their introduction into, and passing through, the Union territory;
- (c) they are introduced into, passed through and, without delay, moved out of the Union territory under official control by the competent authorities concerned.

The competent authority of the Member State where those plants, plant products or other objects are introduced into, or for the first time moved within, the Union territory shall inform the competent authorities of all other Member States through which those plants, plant products or other objects are to be moved prior to being moved out of the Union territory.

2. Where so stipulated by the acts adopted pursuant to Article 27(1) and (2) and Article 29(1) and (2), this Article shall apply accordingly.
3. The Commission shall be empowered, in accordance with Article 98, to adopt delegated acts setting out the contents of the declaration referred to in point (a) of paragraph 1.
4. The Commission may, by means of implementing acts, adopt format specifications for the declaration referred to in point (a) of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).
5. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, the Union territory as referred to in paragraph 1 in violation of the provisions of that paragraph.

The third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

#### *Article 46*

### **Plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions**

1. By way of derogation from Articles 40(3) and 41(3), Member States may, on application, authorise the introduction into, and the movement within, their territory of plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions, if all of the following requirements are fulfilled:
  - (a) the presence of the plants, plant products or other objects concerned does not cause an unacceptable risk of the spread of a Union quarantine pest if adequate restrictions are imposed;
  - (b) the storage facilities in which those plants, plant products or other objects are to be kept and the quarantine stations, as referred to in Article 56, in which they are to be used are appropriate;

- (c) the scientific and technical qualifications of the personnel by whom the activity involving those plants, plant products or other objects is to be carried out are appropriate.
2. The competent authority shall assess the risk of the spread of Union quarantine pests by the plants, plant products or other objects concerned, as referred to in paragraph 1(a), taking into account the identity, biology and means of dispersal of the Union quarantine pests concerned, the activity envisaged, the interaction with the environment and other relevant factors relating to the risk posed by those plants, plant products or other objects.

It shall assess the storage facilities in which those plants, plant products or other objects are to be kept, as referred to in paragraph 1(b), and the scientific and technical qualifications of the personnel by whom the activity involving those plants, plant products or other objects is to be carried out, as referred to in paragraph 1(c).

On the basis of those assessments the competent authority shall authorise the introduction of those plants, plant products or other objects into, or their movement within, the Union territory if the requirements set out in paragraph 1 are fulfilled.

3. Where an authorisation is granted, it shall include all of the following conditions:
- (a) the plants, plant products or other objects concerned are to be kept in storage facilities found to be appropriate by the competent authorities and referred to in the authorisation;
  - (b) the activity involving those plants, plant products or other objects is to be carried out in a quarantine station designated in accordance with Article 56 by the competent authority and referred to in the authorisation;
  - (c) the activity involving those plants, plant products or other objects is to be carried out by personnel whose scientific and technical qualifications are found to be appropriate by the competent authority and referred to in the authorisation;
  - (d) those plants, plant products or other objects are to be accompanied by the authorisation when introduced into or moved within the Union territory.

4. The authorisation shall be limited to the amount that is adequate for the activity concerned and shall not exceed the capacity of the designated quarantine station.

It shall include the restrictions necessary to adequately mitigate the risk of the spread of the Union quarantine pests concerned.

5. The competent authority shall monitor compliance with the conditions referred to in paragraph 3 and the limitation and the restrictions referred to in paragraph 4 and take the necessary action in case those conditions, that limitation or those restrictions are not complied with.
6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules concerning:

- (a) the exchange of information between Member States and the Commission concerning the introduction into, and movement within, the Union territory of the plants, plant products and other objects concerned;
  - (b) the assessments and authorisation referred to in paragraph 2; and
  - (c) the monitoring of compliance, the action in case of non-compliance and notification thereof, as referred to in paragraph 5.
7. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of the provisions of paragraphs 1 to 4.

Where applicable, those notifications shall also include the measures taken by the Member States on the plants, plant products and other objects concerned, and the whether the introduction into, or movement within, the Union territory of those plant, plant products or other objects has been allowed after the implementation of those measures.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

Member States shall annually submit to the Commission a report summarising the relevant information on the authorisations granted pursuant to paragraph 1 and the results of the monitoring referred to in paragraph 5.

#### *Article 47*

#### **Temporary measures concerning plants for planting**

1. The Commission may adopt, by means of implementing acts, temporary measures as regards the introduction into, and movement within, the Union territory of plants for planting from third countries, where the following conditions are fulfilled:
- (a) there is no or little phytosanitary experience as regards trade in the plants for planting concerned originating in or dispatched from the third country concerned;
  - (b) no assessment has been carried out as regards the phytosanitary risks for the Union territory in respect of those plants for planting from the third country concerned;
  - (c) those plants for planting are likely to pose phytosanitary risks which are not linked, or cannot yet be linked, to Union quarantine pests listed pursuant to Article 5(2) and (3) or pests for which measures have been adopted pursuant to Article 29.

Those implementing acts shall be adopted, and as appropriate repealed or replaced, in accordance with the examination procedure referred to in Article 99(3).

2. The temporary measures referred to in paragraph 1 shall be adopted in accordance with Annex III on elements to identify plants for planting which pose phytosanitary risks for the Union territory and Section 2 of Annex IV on principles for the management of the risks of pests.

Those measures shall provide for one of the following, as necessary in the case concerned:

- (a) intensive sampling, at the point of introduction, of each lot of plants for planting introduced into the Union territory and testing of samples;
  - (b) where absence of the phytosanitary risk cannot be ensured by intensive sampling and testing at the introduction of the plants for planting concerned into the Union territory, a quarantine period to verify the absence of that phytosanitary risk in those plants for planting;
  - (c) where absence of the phytosanitary risk cannot be ensured by intensive sampling and testing at the introduction of the plants for planting concerned into the Union territory and a quarantine period, prohibition of the introduction of those plants for planting into the Union territory.
3. The measures referred to in paragraph 1 shall apply for a maximum of two years. This period may be prolonged once for a maximum of two years.
  4. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).
  5. By way of derogation from the measures adopted pursuant to paragraph 1, Article 46 shall apply to the introduction into, and the movement within, the Union territory of plants for planting used for scientific purposes, trials, varietal selection, breeding and exhibitions.
  6. Member States shall notify the Commission and the other Member States where a plant, plant product or other object has been subject to the measures referred to in points (a) or (b) of paragraph 2.

Member States shall notify the Commission and the other Member States where, following the application of the measures referred to in points (a) or (b) of paragraph 2, a pest has been found which is likely to pose new phytosanitary risks.

Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where the introduction of a plant, plant product or other object into the Union territory was refused, or its movement within the Union territory prohibited, because the Member State concerned considered that the prohibition referred to in point (c) of paragraph 2 was violated. Where applicable, those notifications shall include the measures taken by the Member States on the plants, plant products and other objects concerned pursuant to Article 64(3) of Regulation (EU) No .../... [*Office of Publications, please insert number of Regulation on Official Controls*].

Where applicable, the third country from which the plants, plant products or other objects were dispatched for introduction into the Union territory shall also be notified.

*Article 48*

**Amendment of Annex III**

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Annex III on elements to identify plants for planting which pose phytosanitary risks for the Union territory, as regards the characteristics and origin of those plants for planting, to adapt to the developments of technical and scientific knowledge.

**SECTION 2**

**MEASURES RELATING TO PROTECTED ZONES**

*Article 49*

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

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, and the prohibitions and the protected zones concerned, as set out in Part B of Annex III to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, the plants, plant products and other objects shall be identified by their respective CN code.

2. In case a plant, plant product or other object, coming from outside the protected zone concerned, poses a phytosanitary risk of an unacceptable level by its likelihood to host a protected zone quarantine pest, and that risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend, as appropriate, the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the protected zones concerned.

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level, or it poses such a risk but that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend that implementing act.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

The acceptability of the level of that phytosanitary risk shall be assessed in accordance with the principles set out in Section 2 of Annex II on principles for the management of the risks of pests.

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 shall not be introduced into the respective protected zone from the third country, or area of the Union territory, concerned.
4. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 99(4).
5. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States of any cases where plants, plant products or other objects have been introduced into, or moved within the protected zone concerned, in violation of the prohibitions adopted pursuant to this Article.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the protected zone concerned shall also be notified.

#### *Article 50*

#### **Plants, plant products and other objects subject to special requirements for protected zones**

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, the respective protected zones and the requirements, as set out in Part B of Annex IV to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, the plants, plant products and other objects shall be identified by their respective CN code.

2. In case a plant, plant product or other object, coming from outside the protected zone concerned poses a phytosanitary risk of an unacceptable level for that protected zone by its likelihood to host a protected zone quarantine pest, and that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the measures to be applied to it. Those measures, and the requirements referred to in paragraph 1, are hereinafter referred to as 'special requirements for protected zones'.

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level for the protected zone concerned, or it poses such a risk but that risk cannot be reduced to an acceptable level by the special requirements for protected zones, the Commission shall amend that implementing act.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

The acceptability of the level of that phytosanitary risk shall be assessed, and the measures to reduce that risk to an acceptable level shall be adopted, in accordance with the principles set out in Section 2 of Annex II on principles for the management of the risks of pests.

On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 99(4).

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 may only be introduced into, or moved within, the respective protected zone if the special requirements for protected zones are fulfilled.
4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where plants, plant products or other objects have been introduced into, or moved within, the protected zone concerned, in violation of the measures adopted pursuant to this Article.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

#### *Article 51*

### **Information to be provided to travellers, clients of postal services and internet clients as regards protected zones**

Article 43 concerning information to be provided to travellers, clients of postal services and internet clients shall apply accordingly as regards the introduction of plants, plant products and other objects from third countries into protected zones.

#### *Article 52*

### **Exception from prohibitions and requirements for frontier zones as regards protected zones**

Article 44 concerning the exceptions from prohibitions and requirements for frontier zones shall apply as regards the plants, plant products and other objects listed pursuant to Article 49(1) and (2) and Article 50(1) and (2) with regard to protected zones bordering third country frontier zones.

#### *Article 53*

### **Exception from prohibitions and requirements for phytosanitary transit as regards protected zones**

Article 45 concerning the exceptions from prohibitions and requirements for phytosanitary transit shall apply accordingly as regards the plants, plant products and other objects listed pursuant to Article 49(1) and (2) and Article 50(1) and (2) with regard to phytosanitary transit through protected zones.

*Article 54*

**Plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions as regards protected zones**

By way of derogation from the prohibitions and requirements provided for in Articles 49(3) and 50(3), Article 46 shall apply as regards the plants, plant products and other objects listed pursuant to Article 49(1) and (2) and Article 50(1) and (2) with regard to the introduction into and the movement within protected zones of plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions.

**SECTION 3**

**OTHER MEASURES CONCERNING PLANTS, PLANT PRODUCTS AND OTHER OBJECTS**

*Article 55*

**General requirements for packaging and vehicles**

1. Packaging material used for plants, plant products or other objects, referred to in the implementing acts adopted pursuant to Articles 27(1) and (2), 29(1) and (2), 40(1), 41(1) and (2), 47(1), 49(1) and 50(1) and moving into or within the Union territory, shall be free from Union quarantine pests.

The same shall apply to vehicles transporting such plants, plant products and other objects.

2. The packaging material referred to in paragraph 1, other than wood packaging material, shall cover the plants, plant products and other objects concerned in such a way that, during their movement into or within the Union territory, there is no risk of spreading of Union quarantine pests.

The vehicles referred to in paragraph 1 shall, as appropriate, be covered or closed in such a way that, during their movement into or within the Union territory, there is no risk of spreading of Union quarantine pests.

3. Paragraphs 1 and 2 shall apply to protected zones also as regards the respective protected zone quarantine pests.

*Article 56*

**Designation of quarantine stations**

1. Member States shall designate in their territory quarantine stations for plants, plant products, other objects and pests, or authorise the use of designated quarantine stations in other Member States, provided that those stations fulfil the requirements set out in paragraph 2.

The competent authority may, in addition, on request, designate a facility as a quarantine station provided that it fulfils the requirements set out in paragraph 2.

2. Quarantine stations shall meet the following conditions:

- (a) they provide physical isolation of the plants, plant products and other objects to be kept in quarantine and ensure they cannot be accessed or removed from those stations without consent of the competent authority;
  - (b) where the activities carried out in the quarantine stations concern plants, plant products or other objects, they provide suitable growing or incubation conditions conducive for the development on those plants, plant products and other objects of signs and symptoms of quarantine pests;
  - (c) they have surfaces of smooth and impervious material allowing effective cleaning and decontamination;
  - (d) they have surfaces resistant to deterioration and to attack by insects and other arthropods;
  - (e) they have irrigation, sewage and ventilation systems which exclude the transmission or escaping of quarantine pests;
  - (f) they have systems for sterilisation, decontamination or destruction of infested plants, plant products and other objects, waste and equipment before removal from the stations;
  - (g) they provide for protective clothing and shoe covering;
  - (h) they have, if appropriate, systems for de-contamination of personnel and visitors upon exit of the station;
  - (i) a definition of the tasks of those stations, and the conditions under which they shall carry out those tasks, is available;
  - (j) a sufficient number of suitably qualified, trained and experienced personnel is available.
3. Member States shall communicate a list of the designated quarantine stations in their territory to the Commission and the other Member States upon request.

#### *Article 57*

#### **Operation of quarantine stations**

1. The person responsible for the quarantine station shall monitor that station and the immediate vicinity of that station for the presence of quarantine pests.  
  
Where such a pest is found to be present, the person responsible for the quarantine station concerned shall take the appropriate action. It shall notify the competent authority of that presence and of that action.
2. The person responsible for the quarantine station shall ensure that personnel and visitors wear protective clothing and shoe covering and, where appropriate, are subject to decontamination upon leaving that station.
3. The person responsible for the quarantine station shall keep records on the following points:

- (a) the personnel employed;
- (b) the visitors accessing the station;
- (c) the plants, plant products and other objects entering and leaving the station;
- (d) the place of origin of such plants, plant products and other objects;
- (e) observations concerning the presence of pests on such plants, plant products and other objects.

Those records shall be kept for three years.

#### *Article 58*

#### **Supervision of quarantine stations and revocation of designation**

1. The competent authority shall organise audits or inspections of the quarantine stations, at least one per year, to verify whether those stations meet the conditions referred to in Article 56(2) and Article 57.
2. The competent authority shall revoke the designation referred to in Article 56(1) without delay where:
  - (a) following an audit or inspection, it appears that that quarantine station fails to fulfil the conditions referred to in Article 56(2) or Article 57;
  - (b) the person responsible for that quarantine station fails to take appropriate and timely remedial action.

#### *Article 59*

#### **Release of plants, plant products and other objects from quarantine stations**

1. Plants, plant products and other objects shall only leave the quarantine stations, upon authorisation by the competent authorities, if it is confirmed that they are free from Union quarantine pests, or, where applicable, protected zone quarantine pests.
2. Competent authorities may authorise the movement of plants, plant products and other objects from the quarantine stations to other quarantine stations or to any other locations only if measures are taken to ensure that no Union quarantine pests, or, where applicable, protected zone quarantine pests, are spread in the area concerned.

#### *Article 60*

#### **Movement out of the Union territory**

1. Where the movement of a plant, plant product or other object out of the Union is governed by a phytosanitary agreement with a third country, that movement shall comply with that agreement.
2. Where the movement of a plant, plant product or other object out of the Union is not governed by a phytosanitary agreement with a third country, that movement shall

take place in accordance with the phytosanitary rules of the third country into which that plant, plant product or other object is to be moved.

3. Where the movement of a plant, plant product or other object out of the Union is neither governed by a phytosanitary agreement with a third country nor by the phytosanitary rules of the third country into which that plant, plant product or other object is to be moved, the requirements for movement of plants, plant products and other objects within the Union territory, as set out in the list referred to in Article 41(1) and (2), shall apply.

Those requirements shall, however, not apply where they concern a pest that fulfils either of the following conditions:

- (a) it is recognised by that third country as being present in its territory and not under official control;
- (b) it can be reasonably assumed that it does not qualify as a quarantine pest with respect to the territory of that third country.

## **Chapter V**

### **Registration of professional operators and traceability**

#### *Article 61*

#### **Official register of professional operators**

1. The competent authority shall keep and update a register containing the professional operators who carry out the activities, listed in the second subparagraph, in the territory of the Member State concerned, and are covered by one of the following points:
  - (a) they are professional operators whose activities concern plants, plant products or other objects covered by an implementing act provided for in Articles 27(1), (2) or (3), 29(1), (2) or (3), 40(1), 41(1) or (2), 47(1), 49(1) or 50(1), or subject to the provisions of Articles 43(1) or (2), 44(1), 45(1), 51, 52 or 53;
  - (b) they are professional operators within the meaning of Article 3(6) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material law*].

This paragraph shall apply as regards the following activities:

- (a) planting;
- (b) growing;
- (c) production;
- (d) introduction into the Union territory;
- (e) movement within the Union territory;

- (f) movement out of the Union territory;
- (g) producing and/or making available on the market in the meaning of Article 3(5) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material law*];
- (h) sales through distance contracts.

That register shall be referred to as 'the register'. Professional operators registered pursuant to points (a) and (b) of the first subparagraph shall be referred to as 'registered operators'.

2. A professional operator may be registered in the register of a competent authority more than once, provided that each registration is linked to different premises, collective warehouses and dispatching centres as referred to in Article 62(2)(d). For each of those registrations, the procedure of Article 62 shall apply.
3. Paragraph 1 shall not apply to a professional operator covered by one or more of the following points:
  - (a) it supplies exclusively small, as appropriate to the plants, plant products and other objects concerned, quantities of plants, plant products and other objects to final users, by other means than sales through distance contracts;
  - (b) its professional activity concerning plants, plant products and other objects is limited to transporting such plants, plant products or other objects for another professional operator;
  - (c) its professional activity exclusively concerns the transport of objects of all kinds using wood packaging material.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out one or more of the following:

- (a) further categories of professional operators to be exempted from the application of paragraph 1, where that registration would constitute a disproportionate administrative burden for them compared to the phytosanitary risk of their professional activities;
- (b) particular requirements for the registration of certain categories of professional operators;
- (c) the maximum figure for small quantities of particular plants, plant products or other objects as referred to in point (a) of the first subparagraph.

#### *Article 62*

#### **Procedure of registration**

1. Professional operators falling within the scope of points (a) or (b) of the first subparagraph of Article 61(1) shall submit an application to the competent authorities for inclusion in the register.

2. That application shall include the following elements:
  - (a) name, address and contact details of the professional operator;
  - (b) a statement concerning the intention of the professional operator to exercise each of the activities referred to in Article 61(1) concerning plants, plant products and other objects;
  - (c) a statement concerning the intention of the professional operator to carry out each of the following activities:
    - (i) issuing of plant passports for plants, plant products and other objects, pursuant to Article 79(1);
    - (ii) placing of the mark on wood packaging material, referred to in Article 91(1);
    - (iii) issuing of any other attestation, as referred to in Article 93(1);
    - (iv) issuing of official labels for plant reproductive material, pursuant to Article 19 of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material*];
  - (d) address of the premises, collective warehouses and dispatching centres used by the professional operator in the Member State concerned to carry out the activities referred to in Article 61(1) for the purpose of the registration;
  - (e) the genera and species of the plants and plant products, and, where appropriate, nature of other objects, concerned by the activities of the professional operator.
3. The competent authorities shall register a professional operator where the application for registration contains the elements of paragraph 2.
4. Registered professional operators shall, where appropriate, submit an application for updating the data referred to in points (a), (d) and (e) of paragraph 2, and the statements referred to in points (b) and (c) of paragraph 2.
5. Where the competent authority becomes aware that the registered operator does not carry out any more the activities of Article 61(1), or that the registered operator has submitted an application no longer complying with the requirements of paragraph 2, it shall request that operator to comply with those requirements immediately or within a specified period of time.

In case the registered operator does not comply with those requirements within the period of time set by the competent authority, the competent authority shall revoke the registration of that operator.

### *Article 63* **Content of the register**

The register shall contain the elements set out in points (a), (b), (d) and (e) of Article 62(2) and the following elements:

- (a) the official registration number;
- (b) the two-letter code indicated in norm ISO 3166-1-alpha-2<sup>31</sup> for the Member State in which the professional operator is registered;
- (c) an indication whether the professional operator is authorised for each of the activities referred to in point (c) of Article 62(2).

#### *Article 64*

#### **Availability of information of official registers**

1. The Member State keeping the register shall, on request, make the information it contains available to the other Member States or the Commission.
2. The Member State keeping the register shall make available, on request, the information referred to in Article 63, with the exception of points (d) and (e) of Article 62(2), to any professional operator.

#### *Article 65*

#### **Traceability**

1. A professional operator to which plants, plant products or other objects are supplied that are subject to prohibitions, requirements or conditions pursuant to Articles 40(1), 41(1) and (2), 44(1) and (3), 45(1), 46(1) and (3), 47(1), 49(1) and (2), 50(1) and (2), 52, 53 and 54 shall keep a record for each plant, plant product or other object supplied, allowing that operator to identify the professional operators supplying it.
2. A professional operator supplying plants, plant products or other objects that are subject to prohibitions, requirements or conditions pursuant to Articles 40(1), 41(1) and (2), 44(1) and (3), 45(1), 46(1) and (3), 47(1), 49(1) and (2), 50(1) and (2), 52, 53 and 54 shall keep a record allowing that professional operator to identify, for each plant, plant product or other object it supplied, the professional operators whom it was supplied.
3. Professional operators shall keep the records referred to in paragraphs 1 and 2 for three years from the date on which the plant, plant product or other object concerned was supplied to or by them.
4. On request, they shall communicate the information in the records referred to in paragraphs 1 and 2 to the competent authorities.
5. Paragraphs 1 to 4 shall not apply to the professional operators referred to in point (b) of Article 61(3).

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<sup>31</sup> ISO 3166-1:2006, Codes for the representation of names of countries and their subdivisions – Part 1: Country codes. International Organisation for Standardization, Geneva.

*Article 66*

**Movements of plants, plant products and other objects within the premises of the professional operator**

1. Professional operators shall have in place traceability systems and procedures to allow identification of the movements of their plants, plant products and other objects within their own premises.

The first subparagraph shall not apply to the professional operators referred to in point (b) of Article 61(3).

2. The information, as identified by the systems and procedures referred to in paragraph 1, on the movement of the plants, plant products and other objects within those premises shall be made available to the competent authority on request.

## **Chapter VI**

### **Certification of plants, plant products and other objects**

#### **SECTION 1**

##### **PHYTOSANITARY CERTIFICATES REQUIRED FOR THE INTRODUCTION OF PLANTS, PLANT PRODUCTS AND OTHER OBJECTS INTO THE UNION TERRITORY**

*Article 67*

**Phytosanitary certificate for introduction into the Union territory**

1. A phytosanitary certificate for introduction of plants, plant products and other objects into the Union territory shall be a document, issued by a third country, which fulfils the conditions of Article 71, has the contents set out in Part A of Annex V, or, where applicable, Part B of Annex V, and certifies that the plant, plant product or other object concerned complies with all of the following requirements:
  - (a) it is free from Union quarantine pests;
  - (b) it complies with the provisions of Article 37(1) concerning the presence of Union quality pests on plants for planting;
  - (c) it complies with the requirements referred to in Article 41(1) and (2);
  - (d) where applicable, it complies with rules adopted in accordance with the provisions adopted pursuant to Article 27(1) and (2) and Article 29(1).
2. Where applicable, the phytosanitary certificate shall specify under the heading 'Additional Declaration', and in accordance with the implementing acts adopted pursuant to Articles 41(1) and (2) and 50(1) and (2), which specific requirement is fulfilled, where there is a choice between several options. This specification shall include a reference to the relevant option provided in those acts.
3. Where applicable, the phytosanitary certificate shall state that the plants, plant products or other objects concerned comply with phytosanitary measures recognised

as equivalent, pursuant to Article 42, to the requirements of the implementing act adopted pursuant to Article 41(2).

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Parts A and B of Annex V to adapt them to the scientific and technical developments and the development of international standards.

#### *Article 68*

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

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required for introduction into the Union territory.

That list shall include:

- (a) the plants, plant products and other objects listed in Point I of Part B of Annex V to Directive 2000/29/EC;
- (b) plants, plant products and other objects for which requirements have been adopted pursuant to Articles 27(1) and 29(1) concerning their introduction into the Union territory;
- (c) seeds listed pursuant to Article 37(2);
- (d) plants, plant products and other objects listed pursuant to Articles 41(1) and (2).

Points (a) to (d) shall not apply, however, where the act adopted pursuant to Articles 27(1), 29(1) or 41(1) and (2) requires proof of compliance in the form of an official mark, as referred to in Article 91(1), or another official attestation, as referred to in Article 93(1).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

2. The Commission shall, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:
  - (a) where a plant, plant product or other object, listed in that implementing act, does not fulfil paragraph 1(b), (c) or (d);
  - (b) where a plant, plant product or other object, not listed in that act, fulfils paragraph 1(b), (c) or (d).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in accordance with the principles set out in Section 2

of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts a Union quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

4. By way of derogation from paragraphs 1, 2 and 3, no phytosanitary certificate shall be required for the plants, plant products or other objects, which are subject to Articles 44, 45, 46 and 70.

#### *Article 69*

### **Plants, plant products and other objects for which phytosanitary certificates are required for introduction into a protected zone**

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required, in addition to the cases referred to in Article 68 (1), (2) and (3), for their introduction into certain protected zones from those third countries.

That list shall include:

- (a) the plants, plant products and other objects listed in Point II of Part B of Annex V to Directive 2000/29/EC;
- (b) plants, plant products and other objects listed pursuant to Article 50(1) or (2).

Points (a) and (b) shall not apply, however, where the act adopted pursuant to Article 50(1) or (2) requires proof of compliance in the form of an official mark, as referred to in Article 91(1), or another official attestation, as referred to in Article 93(1).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

2. The Commission shall, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:
  - (a) where a plant, plant product or other object, listed in that implementing act, does not fulfil paragraph 1(b);
  - (b) where a plant, plant product or other object, not listed in that act, fulfils paragraph 1(b).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in accordance with the principles set out in Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not

listed in that act, hosts the respective protected zone quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

4. By way of derogation from paragraphs 1, 2 and 3, no phytosanitary certificate shall be required for the plants, plant products or other objects, which are subject to Articles 52, 53, 54 and 70.

#### *Article 70*

#### **Exceptions for travellers' luggage, clients of postal services and internet clients**

1. Small quantities of particular plants, plant products and other objects from a third country may be exempted from the requirement for a phytosanitary certificate set out in Article 68(1) and Article 69(1), if they comply with all of the following conditions:
  - (a) they are introduced into the Union territory as part of travellers' personal luggage, as consignments shipped following sales through distance contracts to final users (hereinafter: 'internet clients'), or as shipments delivered by postal services to final users;
  - (b) they are not to be used for professional or commercial purposes;
  - (c) they are listed pursuant to paragraph 2.

That exemption shall not apply to plants for planting, other than seeds.

2. The Commission shall, by means of implementing acts, list the plants, plant products and other objects referred to in paragraph 1 and the third countries concerned, and set out the maximum quantity, as appropriate, of the plants, plant products and other objects concerned that shall be subject to the exemption of that paragraph and, where appropriate, one or more of the risk management measures set out in Section 1 of Annex IV.

That listing and the setting out of the maximum quantity concerned and, where appropriate, the risk management measures shall be decided on the basis of the phytosanitary risk posed by small quantities of those plants, plant products and other objects, in accordance with the criteria set out in Section 2 of Annex IV.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

#### *Article 71*

#### **Conditions to be fulfilled by a phytosanitary certificate**

1. The competent authority shall only accept a phytosanitary certificate accompanying plants, plant products or other objects to be introduced from a third country, if the content of that certificate complies with Part A of Annex V. Where the plants, plant

products or other objects are to be introduced from a third country from which they do not originate, the competent authority shall only accept a phytosanitary certificate complying with Part B of Annex V.

It shall not accept that phytosanitary certificate where the additional declaration referred to in Article 67(2), where applicable, is not present or not correct, and where the statement referred to in Article 67(3), where applicable, is not present.

2. The competent authority shall only accept a phytosanitary certificate if it fulfils the following requirements:
  - (a) it is issued in at least one of the official languages of the Union;
  - (b) it is addressed to the Union or one of its Member States;
  - (c) it has been issued no more than 14 days before the date on which the plants, plant products or other objects covered by it have left the third country, in which it was issued.
3. In the case of a third country which is party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the official national plant protection organisation of that third country or, under its responsibility, by a public officer who is technically qualified and duly authorised by that official national plant protection organisation.
4. In the case of a third country which is not party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the authorities competent in accordance with the national rules of that third country and notified to the Commission. The Commission shall inform the Member States and the operators, through the electronic notification system referred to in Article 97, pursuant to point (a) of Article 131 of the Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*], of the notifications received.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, supplementing the conditions for acceptance referred to in the first subparagraph, to ensure the reliability of those certificates.

5. Electronic phytosanitary certificates shall only be accepted when provided through, or in electronic exchange with, the computerised information management system referred to in Article 130 of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*].

#### *Article 72*

#### **Invalidation of phytosanitary certificate**

1. Where a phytosanitary certificate has been issued in accordance with Article 67(1), (2) and (3), and the competent authority concerned concludes that the conditions referred to in Article 71 are not fulfilled, it shall invalidate that phytosanitary certificate and ensure that it does not accompany any longer those plants, plant products or other objects concerned. In that case, and in respect of the plants, plant products or other objects concerned, the competent authority shall take one of the

measures as set out in Article 64(3) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*].

2. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where a phytosanitary certificate was invalidated pursuant to paragraph 1.

The third country which had issued that phytosanitary certificate shall also be notified.

## **SECTION 2**

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

#### *Article 73*

#### **Plant passports**

A plant passport shall be an official label for movement of plants, plant products and other objects within the Union territory and, where applicable, into and within protected zones, which certifies compliance with all requirements set out in Article 80 and, for movement into protected zones, Article 81, and has the content and format set out in Article 78.

#### *Article 74*

#### **Plants, plant products and other objects for which a plant passport is required for movement within the Union territory**

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, for which a plant passport is required for their movement within the Union territory.

That list shall include:

- (a) all plants for planting, other than seeds;
- (b) the plants, plant products and other objects listed in point (I) of Part (A) of Annex V to Directive 2000/29/EC;
- (c) plants, plant products and other objects for which requirements have been adopted pursuant to Article 27(1), (2) or (3) or 29(1), (2) or (3) concerning their movement within the Union territory;
- (d) seeds listed pursuant to Article 37(2);
- (e) plants, plant products and other objects listed pursuant to Article 41(1) and (2).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

2. The Commission shall, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:

- (a) where a plant, plant product or other object, not listed in that act, fulfils paragraphs 1(c), (d) or (e);
- (b) where a plant, plant product or other object , listed in that implementing act, does not fulfil paragraph 1(c), (d) or (e);

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(3).

- 3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in accordance with the principles of Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts a Union quarantine pest or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

- 4. By way of derogation from paragraphs 1, 2 and 3, no plant passport shall be required for the plants, plant products or other objects, which are subject to Articles 44, 45, 46 and 70.

#### *Article 75*

#### **Plants, plant products and other objects for which a plant passport is required for introduction into, and movement within, protected zones**

- 1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, for which a plant passport is required for their introduction into certain protected zones.

That list shall include:

- (a) the plants, plant products and other objects listed in point (II) of Part A of Annex V to Directive 2000/29/EC;
- (b) other plants, plant products and other objects listed pursuant to Article 50(2).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

- 2. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:

- (a) where a plant, plant product or other object, not listed in that act, fulfils paragraph 1(b);
- (b) where a plant, plant product or other object , listed in that implementing act, does not fulfil paragraph 1(a) or (b).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, and in accordance with the principles of Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts the respective protected zone quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

4. By way of derogation from paragraphs 1, 2 and 3, no plant passport shall be required for the plants, plant products or other objects, which are subject to Articles 52, 53, 54 and 70.

#### *Article 76*

### **Exception for final users**

No plant passport shall be required for the movement of small, as appropriate to the plants, plant products and other objects concerned, quantities of plants, plant products or other objects to a final user.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the maximum figure for small quantities of particular plants, plant products or other objects.

#### *Article 77*

### **Exceptions for movements within and between the premises of a professional operator**

No plant passport shall be required for the movements of plants, plant products and other objects within and between the premises of the same professional operator.

#### *Article 78*

### **Content and format of the plant passport**

1. The plant passport shall take the form of a distinct label, which shall be printed on any suitable substrate, provided that the plant passport is kept separate from any other information or label which may also be indicated on that substrate.

The plant passport shall be clearly legible and indelible.

2. The plant passport for movement within the Union territory shall contain the elements set out in Part A of Annex VI.

The plant passport for introduction into, and movement within, a protected zone shall contain the elements set out in Part B of Annex VI.

3. In the case of plants for planting produced, or made available on the market, in the meaning of Article 3(5) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material law*], as pre-basic, basic or certified material in the meaning of Article 10 of that Regulation, the plant passport shall be included, in a distinct form, in the official label produced in

accordance with Article 22 of that Regulation, or, where applicable, in the master certificate issued in accordance with Article 122(1) of that Regulation.

Where this paragraph applies, the plant passport for movement within the Union territory shall contain the elements set out in Part C of Annex VI.

Where this paragraph applies, the plant passport for introduction into, and movement within, a protected zone shall contain the elements set out in Part D of Annex VI.

4. The Commission shall be empowered to adopt, pursuant to Article 98, delegated acts amending Parts A, B, C and D of Annex VI, to adapt those elements, where applicable, to scientific and technical developments.
5. Within one year from the entry into force of this Regulation, the Commission shall adopt, by means of implementing acts, the format specifications of the plant passport for movement within the Union territory and the plant passport for introduction into, and movement within, a protected zone, as regards the plant passports referred to in the first and second subparagraphs of paragraph 2 and in the second and third subparagraphs of paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Where the nature of particular plants, plant products or other objects so requires, specific size specifications may be set out for them.

#### *Article 79*

#### **Issuance by authorised professional operators and competent authorities**

1. Plant passports shall be issued by registered operators, authorised, in accordance with Article 84, by the competent authorities to issue plant passports, hereinafter 'authorised operators', under the supervision of the competent authorities.

Authorised operators shall issue plant passports only for the plants, plant products or other objects for which they are responsible.

2. Plant passports may, however, be issued by the competent authorities where a registered operator requests so.
3. Authorised operators shall only issue plant passports in the premises, collective warehouses and dispatching centres referred to in Article 62(2)(d).

#### *Article 80*

#### **Substantive requirements for a plant passport for movement within the Union territory**

A plant passport shall be issued for movement within the Union territory for a plant, plant product or other object only where it fulfils the following requirements:

- (a) it is free from Union quarantine pests;
- (b) it complies with the provisions of Article 37(1) concerning the presence of Union quality pests on plants for planting;

- (c) it complies with the requirements referred to in Article 41(1) and (2);
- (d) where applicable, it complies with rules adopted in accordance with the provisions adopted pursuant to Article 27(1) and (2) and Article 29(1) and (2); and
- (e) where applicable, it complies with measures adopted by the competent authorities for the eradication of Union quarantine pests pursuant to Article 16(1) and the eradication of pests provisionally qualifying as Union quarantine pests pursuant to Article 28(1).

#### *Article 81*

### **Substantive requirements for a plant passport for movement into and within a protected zone**

1. A plant passport shall be issued for introduction into, and movement within, a protected zone for a plant, plant product and other object only where it fulfils all of the requirements of Article 80, and in addition the following requirements:
  - (a) it is free from the respective protected zone quarantine pest; and
  - (b) it complies with the requirements referred to in Article 50(1) and (2).
2. Where Article 33(2) applies, the plant passport referred to in paragraph 1 shall not be issued.

#### *Article 82*

### **Examinations for plant passports**

1. A plant passport may only be issued for plants, plant products and other objects for which a meticulous examination in accordance with paragraphs 2, 3, and 4 has shown that they fulfil the requirements of Article 80, and, where applicable, Article 81.

Plants, plant products and other objects may either be examined individually or by representative samples. The examination shall also cover the packaging material of the plants, plant products or other objects concerned.
2. The examination shall be carried out by the authorised operator, or, where applicable under Article 79(2), by the competent authorities.
3. The examination shall fulfil the following conditions:
  - (a) it shall be carried out frequently, at appropriate times and taking into account the risks involved;
  - (b) it shall be carried out at the premises, collective warehouses and dispatching centres referred to in Article 62(2)(d); and
  - (c) it shall be made by visual examination and, in the case of suspicion of the presence of a Union quarantine pest or, in case of a protected zone, the protected zone quarantine pest concerned, by sampling and testing.

That examination shall take place without prejudice to any specific examination requirements or measures adopted in accordance with Article 27(1), (2) or (3), 29(1), (2) or (3), 41(1) and (2), and 50(1) and (2).

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out detailed measures concerning visual examination, sampling and testing, and the frequency and timing of the examinations, referred to in paragraphs 1, 2 and 3, with regard to specific plants, plant products and other objects, on the basis of the particular phytosanitary risks they may present. Those examinations shall, where appropriate, concern certain plants for planting belonging to the categories referred to in Article 12(1) of Regulation (EU) No .../... (*Office of Publications, please insert number of Regulation on the production and making available on the market of plant reproductive material*), and, where appropriate, shall be carried out for any of the elements, as appropriate, set out in Part D of Annex II to that Regulation.

Where the Commission adopts such a delegated act for specific plants for planting, and those plants for planting are subject to certification schemes pursuant to Article 20(1) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on the production and making available on the market of plant reproductive material*], the respective examinations shall be combined in a single certification scheme.

When adopting those delegated acts, the Commission shall take into account the technical and scientific knowledge and developments.

#### *Article 83*

### **Attaching of the plants passports**

Plant passports shall be attached by the authorised operators, or, where so applicable under Article 79(2), by the competent authorities, to each lot of the plants, plant products and other objects concerned before they are moved within the Union territory pursuant to Article 74 or into or within a protected zone pursuant to Article 75. Where such plants, plant products or other objects are moved in a package, bundle or container, the plant passport shall be attached to that package, bundle or container.

#### *Article 84*

### **Authorisation of professional operators to issue plant passports**

1. The competent authority shall grant an authorisation to a professional operator to issue plant passports (hereinafter 'the authorisation to issue plant passports') where that professional operator complies with the following conditions:
  - (a) it possesses the necessary knowledge to carry out the examinations referred to in Article 82 concerning the Union quarantine pests, protected zone quarantine pests and Union quality pests that could affect the plants, plant products and other objects concerned, and concerning the signs of the presence of those pests and the symptoms caused by them, the means to prevent the presence and spread of those pests, and the means to eradicate them;

- (b) it has in place systems and procedures enabling it to fulfil its obligations concerning traceability pursuant to Article 65 and 66.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out qualification requirements to be fulfilled by the professional operators in order for them to comply with the conditions of paragraph 1(a).

#### *Article 85*

#### **Obligations of authorised operators**

1. Where an authorised operator intends to issue a plant passport, it shall identify and monitor the points of its production process, and the points concerning the movement of plants, plant products and other objects by that operator, which are critical as regards compliance with the rules adopted pursuant to Article 27(1), (2) and (3), Article 29(1), (2) and (3), Article 37(1), Article 41(3), Article 80 and Article 82, and, where applicable, Article 33(2), Article 50(3) and Article 81.

It shall keep records concerning the identification and monitoring of those points.

2. The authorised operator referred to in paragraph 1 shall provide appropriate training to its personnel involved in the examinations referred to in Article 82, to ensure that that personnel possesses the necessary knowledge to carry out those examinations.

#### *Article 86*

#### **Phytosanitary risk management plans**

1. The competent authority may approve, as appropriate, phytosanitary risk management plans of authorised operators, setting out the measures implemented by those operators to fulfil the obligations set out in Article 85(1).
2. The phytosanitary risk management plan shall cover, where appropriate in the form of instruction manuals, at least the following:
- (a) the information required under Article 62(2) concerning the registration of the authorised operator;
  - (b) the information required under Article 65(3) and 66(1) concerning the traceability of plants, plant products and other objects;
  - (c) a description of the production processes of the authorised operator and its activities as regards movement and sales of plants, plant products and other objects;
  - (d) an analysis of the critical points referred to in Article 85(1) and the measures taken by the authorised operator to mitigate the phytosanitary risks associated with those critical points;
  - (e) the procedures in place and actions foreseen in the case of suspicion or findings of quarantine pests, the recording of those suspicion or findings and the recording of the actions taken;

- (f) the roles and responsibilities of the personnel involved in the notifications referred to in Article 9(1), the examinations referred to in Article 82(1), and the issuance of plant passports pursuant to Article 79(1), Article 88(1) and (2) and Article 89;
  - (g) the training provided to the personnel referred to in point (f).
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending the elements referred to in paragraph 2.

#### *Article 87*

#### **Withdrawal of authorisation**

1. Where the competent authority becomes aware that an authorised operator does not comply with Article 82(1), (2), (3) or (4) or Article 84(1), or that a plant, plant product or other object, for which that professional operator has issued a plant passport, does not comply with Article 80 or, where applicable, Article 81, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue.
2. Where the competent authority has taken measures in accordance with paragraph 1, other than the withdrawal of the authorisation to issue plant passports, and non-compliance continues, that authority shall without delay withdraw that authorisation.

#### *Article 88*

#### **Replacing a plant passport**

1. An authorised operator which has received a lot of plants, plant products or other objects, for which a plant passport has been issued, or the competent authority acting on request of a professional operator, may issue a new plant passport for that lot, replacing the plant passport initially issued for that lot, provided that the conditions of paragraph 3 are fulfilled.
2. Where a lot of plants, plant products or other objects, for which a plant passport has been issued, is divided into two or more lots, the authorised operator responsible for those new lots, or the competent authority acting on request of a professional operator, shall issue a plant passport for each new lot resulting from the division, provided that the conditions set out in paragraph 3 are fulfilled. Those plant passports shall replace the plant passport issued for the initial lot.

Where two lots, for each of which a plant passport has been issued, are combined into a single lot, the authorised operator responsible for that new lot, or the competent authority acting on request of a professional operator, shall issue a plant passport for that lot. That plant passport shall replace the plant passport issued for the initial lots, provided that the conditions in paragraph 3 are fulfilled.

3. A plant passport, as provided for in paragraphs 1 and 2, may only be issued if the following conditions are fulfilled:

- (a) the identity of the plants, plant products or other objects concerned is guaranteed; and
  - (b) the plants, plant products or other objects concerned continue to comply with the requirements referred to in Articles 80 and 81.
4. Where a plant passport is issued pursuant to paragraphs 1 or 2, the examination referred to in Article 82(1) shall not be required.
  5. Following the replacement of a plant passport referred to in paragraphs 1 and 2, the authorised operator concerned shall retain the replaced plant passport for three years.

In case a plant passport is issued by the competent authority to replace a plant passport, the professional operator, on whose request it is issued, shall retain the replaced plant passport for three years.

#### *Article 89*

#### **Plant passports replacing phytosanitary certificates**

1. By way of derogation from Article 82, where a plant, plant product or other object, introduced into the Union territory from a third country, which for movement within the Union territory requires a plant passport pursuant to the implementing acts referred to in Article 74(1) and 75(1), such a passport shall be issued where the checks pursuant to Article 47(1) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*] concerning the introduction of the respective plant, plant product or other object have been completed satisfactorily.
2. Following the issuance of a plant passport referred to in paragraph 1, the authorised operator issuing that plant passport shall, where applicable, retain the phytosanitary certificate for three years.

Where point (c) of Article 95(2) applies, that phytosanitary certificate shall be replaced by a certified copy of it.

#### *Article 90*

#### **Obligation to remove the plant passport**

1. The professional operator which has under its control a lot of plants, plant products or other objects, shall remove the plant passport from that lot, in case it becomes aware that any of the requirements of Articles 78 to 82, 84 or 85 are not fulfilled.

The professional operator shall invalidate that plant passport by drawing a clearly visible and indelible diagonal red line over it.

2. In case the professional operator fails to comply with paragraph 1, the competent authorities shall remove the plant passport from the lot concerned and shall invalidate that plant passport by drawing a clearly visible and indelible diagonal red line over it.

3. Where paragraphs 1 and 2 apply, the professional operator concerned shall retain the invalidated plant passport for three years.
4. Where paragraphs 1 and 2 apply, the professional operator concerned shall inform accordingly the authorised operator, or competent authority, who issued the invalidated plant passport.
5. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where a plant passport was removed and invalidated pursuant to paragraph 2.

### **SECTION 3**

#### **OTHER ATTESTATIONS**

#### *Article 91*

#### **Marking of wood packaging material**

1. The mark attesting that wood packaging material has been treated against Union quarantine pests and protected zone quarantine pests, in accordance with a method established pursuant to Article 27(1) or (2), Article 29(1) or (2), Article 41(1) or (2) or Article 50(1) or (2), shall contain the elements set out in Annex VII.
2. The Commission shall be empowered, in accordance with Article 98, to adopt delegated acts amending Annex VII to adapt that mark to the development of international standards.
3. The mark shall only be applied by a professional operator authorised in accordance with Article 92.
4. The Commission shall adopt, by means of implementing acts, the format specifications of the mark referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

#### *Article 92*

#### **Authorisation and supervision of professional operators applying the mark of wood packaging material in the Union territory**

1. An authorisation to apply the mark referred to in Article 91(3) shall be granted to a registered operator provided that it fulfils the following conditions:
  - (a) it possesses the necessary knowledge to carry out the treatment of the wood packaging material required pursuant to the acts referred to in Article 91(1);
  - (b) it operates appropriate facilities to carry out that treatment (hereinafter: 'treatment facilities').

The Commission shall be empowered, in accordance with Article 98, to adopt delegated acts amending the requirements for authorisation, where appropriate in view of the development of scientific and technical knowledge.

The authorisation shall be granted by the competent authority on application.

2. By way of derogation from paragraph 1, the authorisation referred to in that paragraph may be granted, concerning the marking of wood packaging material entirely composed of treated wood, where the registered operator fulfils all of the following conditions:
  - (a) it exclusively uses wood from treatment facilities operated by a registered operator authorised pursuant to paragraph 1;
  - (b) it ensures that the wood used for that purpose can be traced back to those treatment facilities;
  - (c) where applicable pursuant to Articles 27(1) and (2), 29(1) and (2), 41(1) and (2) and 50(1) and (2), it exclusively uses wood referred to in point (a) which is accompanied by a plant passport.
3. The competent authority shall supervise the professional operators authorised pursuant to paragraph 1, to verify and ensure that they treat and mark wood packaging material in accordance with Article 91(1) and fulfil the conditions set out in paragraphs 1 and 2.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, supplementing the requirements set out in this paragraph concerning the supervision of professional operators by the competent authority.

4. Where the competent authority becomes aware that a professional operator does not comply with the requirements referred to in paragraphs 1, 2 or 3, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue.

Where the competent authority has taken those measures, other than the withdrawal of the authorisation referred to in paragraph 1, and non-compliance continues, that authority shall without delay withdraw the authorisation referred to in paragraph 1.

#### *Article 93*

#### **Attestations other than the mark of wood packaging material**

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the elements to be contained in official attestations, specific for plants, plant products or other objects, other than wood packaging material, which are required by the applicable international standards as form of proof of the implementation of measures adopted pursuant to Article 27(1) or (2), Article 29(1) or (2), Article 41(1) or (2) or Article 50(1) or (2).
2. Those delegated acts may also set out requirements concerning one or more of the following:
  - (a) the authorisation of professional operators as regards the issuance of the official attestations referred to in paragraph 1;

- (b) the supervision by the competent authority of the professional operators authorised pursuant to point (a);
  - (c) the withdrawal of that authorisation referred to in point (a).
3. The Commission shall adopt, by means of implementing acts, the format specifications of the attestations referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

## **SECTION 4**

### **EXPORT OF PLANTS, PLANT PRODUCTS AND OTHER OBJECTS FROM THE UNION TERRITORY**

#### *Article 94*

#### **Phytosanitary certificate for export**

1. Where for the export of a plant, plant product or other object from the Union territory to a third country, a phytosanitary certificate is required by the rules of that third country (hereinafter: 'phytosanitary certificate for export'), that certificate shall be issued by the competent authority, at the request of the professional operator which has under its control the plant, plant product or other object to be exported.
2. The phytosanitary certificate for export shall be issued provided that the information available is sufficient to certify compliance with the requirements of the third country concerned. That information may originate, where applicable, from one or more of the following elements:
  - (a) a plant passport, as referred to in Article 73, accompanying the plant, plant product or other object concerned;
  - (b) the mark of wood packaging material as referred to in Article 91(1), or the attestation referred to in Article 93(1);
  - (c) the information included in the pre-export certificate referred to in Article 96;
  - (d) official information included in the phytosanitary certificate as referred to in Article 67, where the plant, plant products or other object concerned has been introduced into the Union territory from a third country;
  - (e) official inspections, sampling and testing of the plant, plant product or other object concerned.
3. The phytosanitary certificate for export shall contain the elements set out in Part A of Annex VIII.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Part A of Annex VIII to adapt it to scientific and technical developments and the development of international standards.
5. The Commission shall adopt, by means of implementing acts, the format specifications of the phytosanitary certificate as referred to in paragraph 1. Those

implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

6. Electronic phytosanitary certificates for export shall only be valid when provided through, or in electronic exchange with, the computerised information management system referred to in Article 130 of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*].

#### *Article 95*

#### **Phytosanitary certificate for re-export**

1. Where a plant, plant product or other object originates in a third country and has been introduced into the Union territory from that, or another, third country, a phytosanitary certificate for re-export may be issued instead of the phytosanitary certificate for export.

The phytosanitary certificate for re-export shall be issued by the competent authority at the request of the professional operator which has under its control the plant, plant product or other object to be exported.

2. The phytosanitary certificate for re-export shall be issued provided that all of the following conditions are complied with:
  - (a) the plant, plant product or other object concerned has not been grown, produced or processed in the Member State from which it is exported to the third country concerned;
  - (b) the plant, plant product or other object concerned has not been exposed to any risk of infestation with quarantine pests, listed as such by the third country of destination, during storage in the Member State from which it is to be exported to that third country;
  - (c) where available, the phytosanitary certificate accompanying the plant, plant product or other object concerned from the third country of origin, or a certified copy of it, is attached to the phytosanitary certificate for re-export.
3. The provisions of Article 94(2), concerning the information sufficient to certify compliance with the requirements of the third country concerned, shall apply accordingly.
4. The phytosanitary certificate for re-export shall contain the elements set out in Part B of Annex VIII.
5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Part B of Annex VIII to adapt it to scientific and technical developments and the development of international standards.
6. The Commission shall adopt, by means of implementing acts, the format specifications of the phytosanitary certificate as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

7. Electronic phytosanitary certificates for re-export shall only be valid when provided through, or in electronic exchange with, the computerised information management system referred to in Article 130 of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*].

#### *Article 96*

#### **Pre-export certificates**

1. The Member State from which the plants, plant products and other objects referred to in Article 94(1) are exported and the Member State in which the plants, plant products and other objects were grown, produced or processed, shall exchange information as necessary for issuing, without delay, the phytosanitary certificate for export.
2. The exchange of information referred to in paragraph 1 shall take the form of a harmonised document (hereinafter 'pre-export certificate'), in which the Member State, in which the plants, plant products and other objects were grown, produced or processed, attests compliance of those plants, plant products or other objects with specific phytosanitary requirements concerning one or more of the following:
  - (a) the absence of particular pests in the plants, plants products or other objects concerned;
  - (b) the origin of the plants, plant products or other objects concerned;
  - (c) the phytosanitary procedures applied to the production or processing of the plants, plant products or other objects concerned.
3. The pre-export certificate shall be issued, on request of the professional operator, by the Member State in which the plants, plant products or other objects were grown, produced or processed, while those plants, plant products or other objects are on the premises of the professional operator concerned.
4. The pre-export certificate shall accompany the plants, plant products and other objects concerned during their movement within the Union territory, unless the information contained in it is exchanged between the Member States concerned by electronic means.
5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the contents of the pre-export certificate.
6. The Commission shall adopt, by means of implementing acts, the format specifications of the pre-export certificate. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

## **Chapter VII**

### **Supporting measures by the Commission**

#### *Article 97*

##### **Establishment of electronic notification system**

1. The Commission shall establish an electronic system for the submission of notifications by the Member States.

That system shall be connected to and compatible with the computerised information management system referred to in Article 130(1) of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on Official Controls*].

2. Where the notification concerns the presence of a pest in plants, plant products or other objects introduced into, officially presented for introduction into, or moved within, the Union territory, the notification referred to in paragraph 1 shall contain a reference to the plants, plant products and other objects concerned, the nature of the non-compliance and the measures taken.

Where the notification concerns the presence of a pest in the territory of a Member State, other than in a plant, plant product or other object introduced into, officially presented for introduction into, or moved within, the Union territory, the notification referred to in paragraph 1 shall contain a reference to the plants, plant products and other objects concerned, the name of the pest, the location and GPS coordinates of that presence, and the measures taken.

## **Chapter VIII**

### **Final provisions**

#### *Article 98*

##### **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), 7(1) and (2), 8(6), 11(3), 20, 22(3), 25(4), 30, 32(4), 34(1), 38, 44(2), 45(3), 46(6), 48, 61(3), 67(4), 71(4), 76, 78(4), 82(4), 84(2), 86(3), 91(2), 92(1) and (3), 93(1), 94(4), 95(5) and 96(5) 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 Articles 1(2), 7(1) and (2), 8(6), 11(3), 20, 22(3), 25(4), 30, 32(4), 34(1), 38, 44(2), 45(3), 46(6), 48, 61(3), 67(4), 71(4), 76, 78(4), 82(4), 84(2), 86(3), 91(2), 92(1) and (3), 93(1), 94(4), 95(5) and 96(5) 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 Articles 1(2), 7(1) and (2), 8(6), 11(3), 20, 22(3), 25(4), 30, 32(4), 34(1), 38, 44(2), 45(3), 46(6), 48, 61(3), 67(4), 71(4), 76, 78(4), 82(4), 84(2), 86(3), 91(2), 92(1) and (3), 93(1), 94(4), 95(5) and 96(5) 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 99*

#### **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.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.

#### *Article 100*

#### **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 those provisions to the Commission by ..... [*Office of Publications, please insert date of application of this Regulation*] at the latest and shall notify them without delay of any subsequent amendments affecting them.

#### *Article 101* **Repeals**

1. Directive 2000/29/EC is repealed.

The following acts are also repealed:

- (a) Directive 69/464/EEC;
- (b) Directive 69/466/EEC;
- (c) Directive 74/647/EEC ;
- (d) Directive 93/85/EEC;
- (e) Directive 98/57/EC;
- (f) Directive 2007/33/EC.

2. References to those repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IX hereto.

#### *Article 102* **Amendment of Regulation (EU) [...]/2013**

*[Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material]*

Regulation (EU) No [...] /2013 [*Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*] is amended as follows:

(1) In Article 1, point (e) is replaced by the following:

'(e) on protective measures against pests of plants;'

(2) In Article 17(1), points (a), (b) and (c) are replaced by the following:

'(a) measures to eradicate a pest from an infested area, taken by the competent authorities pursuant to Article 16(1), 27(1) or 29(1) of Regulation (EU) No [...] / [...] of the European Parliament and of the Council [on protective measures against pests of plants]\*;

(b) measures to contain a priority pest, listed pursuant to Article 6(2) of Regulation (EU) No [...] / [...]\*, against which Union containment measures have been adopted pursuant to Article 27(2) or Article 29(2) of that Regulation, in an

infested area from which that priority pest cannot be eradicated, where those measures are essential to protect the Union territory against further spread of that priority pest. Those measures shall concern the eradication of that pest from the buffer zone surrounding that infested area in case its presence is detected in that buffer zone;

- (c) prevention measures taken against the spread of a priority pest, listed pursuant to Article 6(2) of Regulation (EU) No [...]/\*, against which Union measures have been adopted pursuant to Article 27(3) or Article 29(3) of that Regulation, where those measures are essential to protect the Union territory against further spread of that priority pest.

\* OJ L ..., ....., p. ...' [*Office of Publications, please insert this footnote, referring to the present Regulation, in Regulation (EU) No [...]\*/2013 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*]

(3) Article 18 is amended as follows:

- (a) In the first paragraph, points (a) and (b) are replaced by the following:

- '(a) they concern Union quarantine pests not known to occur in the Union territory, listed pursuant to Article 5(2) of Regulation (EU) No [...]/\*;

- (b) they concern priority pests listed pursuant to Article 6(2) of Regulation (EU) No [...]/\*;

- (c) they concern pests, not listed as Union quarantine pests, which are covered by a measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/\*.

\* OJ L ..., ....., p. ...' [*Office of Publications, please insert this footnote, referring to the present Regulation, in Regulation (EU) No [...]\*/2013 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*]

- (b) The second paragraph is replaced by the following:

'For measures fulfilling the condition laid down in point (c) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/\*.

\* OJ L ..., ....., p. ...' [*Office of Publications, please insert this footnote, referring to the present Regulation, in Regulation (EU) No [...]\*/2013 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*]

(4) Paragraph 1 of Article 19 is amended as follows:

- (a) The following point (ca) is inserted after point (c):

'(ca) costs incurred by Member States for compensation to the operators referred to in Article 2(7)(a), (b) and (c) of Regulation (EU) [...]/\* for the value of the destroyed plants, plant products or other objects subject to the measures referred to in Article 16 of that Regulation, as regards priority pests, listed pursuant to Article 6(2) of that Regulation;

\* OJ L ..., ....., p. ...' [*Office of Publications, please insert this footnote, referring to the present Regulation, in Regulation (EU) No [...]\*/2013 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*]

(b) Point (d) is replaced by the following:

'(d) in exceptional and duly justified cases, taking into account the Union added value of the measures, the costs incurred in carrying out other necessary measures than those referred to in points (a) to (ca), provided that such measures are set out in the grant decision referred to in Article 35(3).'

(c) The following second subparagraph is added:

'For the purposes of point (ca) of the first subparagraph, the compensation shall not exceed the market value of the plants, plant products or other objects immediately before they were destroyed and the salvage value, if any, shall be deducted from the compensation.'

(5) Article 20 is amended as follows:

(a) In the first paragraph, points (a) and (b) are replaced by the following:

'(a) they concern Union quarantine pests not known to occur in the Union territory, listed pursuant to Article 5(2) of Regulation (EU) No [...]/\*;

(b) they concern priority pests listed pursuant to Article 6(2) of Regulation (EU) [...]/\*;

(c) they concern pests not listed as Union quarantine pests which are covered by a measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/\*.

\* OJ L ..., ....., p. ...' [*Office of Publications, please insert this footnote, referring to the present Regulation, in Regulation (EU) No [...]\*/2013 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*]

(b) The third paragraph is replaced by the following:

'For measures fulfilling the condition laid down in point (c) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/\*.

- \* OJ L ..., ....., p. ...' [*Office of Publications, please insert this footnote, referring to the present Regulation, in Regulation (EU) No [...]/2013 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*]

### *Article 103*

#### **Entry into force and application**

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

It shall apply [*Office of Publications, please insert date counting 36 months from the entry into force*].

2. Article 97(2) shall apply from the date when the systems referred to in Article 97(1) are established.
3. The acts referred to in points (a), (d), (e) and (f) of Article 101(1) shall be repealed on 31 December 2021. In case of conflict between the provisions of those acts and the provisions of this Regulation, the provisions of this Regulation shall prevail.

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## ANNEX I

**Territories for which, for the purpose of this Regulation, references to third countries shall be read as references to third countries and to those territories, and for which references to the Union territory shall be read as references to the Union territory without those territories, as referred to in Article 1(2)**

The territories of:

1. Guadeloupe
2. French Guiana
3. Martinique
4. Réunion
5. Saint-Martin
6. Mayotte
7. Ceuta
8. Melilla
9. The Canary Islands

## ANNEX II

### **Criteria for the qualification of pests according to their risk to the Union territory**

#### **SECTION 1**

##### **CRITERIA TO IDENTIFY PESTS WHICH QUALIFY AS A QUARANTINE PEST, AS REFERRED TO IN ARTICLES 3, 7(1) AND 28(2)**

(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, where that taxonomic level is scientifically appropriate based on its virulence, host range or vector relationships.

(2) Presence of the pest in the territory in question

One or more of the following conditions shall apply:

- (a) the pest is not known to be present in the territory in question;
- (b) the pest is not known to be present in the territory in question, except in a limited part of it;
- (c) the pest is not known to be present in the territory in question, except for scarce, irregular, isolated and infrequent presences in it.

Where points (b) or (c) apply, the pest shall be considered to be distributed to a limited extent.

(3) Capability of entry, establishment and spread of the pest in the territory in question

(a) *Capability of entry*

The pest shall be considered capable of entry into the territory in question, or, if present, into the part of that territory where it is distributed to a limited extent (hereinafter: 'endangered area'), either by natural spread, or if all of the following conditions are fulfilled:

- (i) it is associated, as regards plants, plant products or other objects which are moved into the territory in question, with those plants, plant products and other objects in the territory where they originate or from where they are moved into the territory in question;
- (ii) it survives during transport or storage;
- (iii) it may be transferred to a suitable host plant, plant product or other object in the territory in question.

(b) *Capability of establishment*

The pest shall be considered capable of perpetuating its presence for the foreseeable future (hereinafter: 'establishment') in the territory in question, or, if present, the part of that territory where it is distributed to a limited extent, if all of the following conditions are fulfilled:

- (i) hosts of the pest and, where relevant, vectors for transmission of the pest are available;
- (ii) the decisive environmental factors are favourable for the pest concerned and, where applicable, its vector, enabling it to survive periods of climatic stress and complete its life cycle;
- (iii) cultivation practices and control measures applied in that territory are favourable;
- (iv) the survival methods, reproductive strategy, genetic adaptability of the pest and its minimum viable population size support its establishment.

(c) *Capability of spread*

The pest shall be considered capable of territorial spread in the territory in question, or, if present, the part of that territory where it is distributed to a limited extent, if one or more of the following conditions is fulfilled:

- (i) the environment is suitable for natural spread of the pest;
- (ii) barriers to natural spread of the pest are insufficient;
- (iii) commodities or conveyances allow for movement of the pest;
- (iv) hosts and, where relevant, vectors of the pest are present;
- (v) natural enemies and antagonists of the pest are not present or not sufficiently capable to suppress the pest.

(4) Potential economic, social and environmental impact

The entry, establishment and spread of the pest in the territory in question, or, if present, the part of that territory where it is distributed to a limited extent, shall have unacceptable economic, social and/or environmental impacts for that territory, or the part of that territory where it is distributed to a limited extent, as regards one or more of the following points:

- (a) crop losses in terms of yield and quality;
- (b) costs of control measures;
- (c) costs of replanting and losses due to the necessity of growing substitute crops;
- (d) effects on existing production practices;

- (e) effects on street trees, parks and public and private green;
- (f) effects on native plants, biodiversity and ecosystem services;
- (g) effects on the establishment, spread and impact of other pests, due to the capacity of the pest concerned to act as a vector for other pests;
- (h) changes to producer costs or input demands, including control costs and costs of eradication and containment;
- (i) effects on producer profits that result from changes in production costs, yields or price levels;
- (j) changes to domestic or foreign consumer demand for a product resulting from quality changes;
- (k) effects on domestic and export markets and prices paid, including effects on export market access and likelihood of phytosanitary restrictions imposed by trading partners;
- (l) resources needed for additional research and advice;
- (m) environmental and other undesired effects of control measures;
- (n) effects on Natura 2000 or other protected areas;
- (o) 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;
- (p) costs of environmental restoration;
- (q) effects on food security;
- (r) effects on employment;
- (s) effects on water quality, recreation, tourism, animal grazing, hunting, fishing.

As regards points (a) to (g), direct effects on hosts in the endangered area shall be taken into account. Those effects shall be assessed taking account of the range of the host species, and on the basis of the types, amount and frequency of the damage suffered by those host species.

As regards points (h) to (s), indirect effects within and outside the endangered area shall be taken into account.

## SECTION 2

### CRITERIA TO IDENTIFY UNION QUARANTINE PESTS WHICH QUALIFY AS A PRIORITY PEST AS REFERRED TO IN ARTICLES 6(1) AND 7(2)

A Union quarantine pest shall be considered to have most severe economic, social or environmental impact for the Union territory, if its entry, establishment and spread fulfils one or more of the following points:

- (a) Economic impacts: the pest has the potential to cause major losses in terms of the direct and indirect effects referred to in point (4) of Section I for crops with a total annual production value for the Union territory of at least EUR 1 billion.
- (b) Social impacts: the pest has the potential to cause one or more of the following effects:
  - (i) a significant employment decrease in the agriculture, horticulture or forestry sector concerned;
  - (ii) risks to food security or food safety;
  - (iii) the disappearance of, or permanent large-scale damage to, main tree species growing or cultivated in the Union territory.
- (c) Environmental impacts: the pest has the potential to cause one or more of the following effects:
  - (i) effects on species and habitats listed under the provisions of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora<sup>32</sup> and Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds<sup>33</sup>;
  - (ii) major and permanent increases of the use of plant protection products on the crops concerned.

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<sup>32</sup> OJ L 206, 22.7.1992, p. 7.

<sup>33</sup> OJ L 20, 26.1.2010, p. 7.

### SECTION 3

#### CRITERIA FOR A PRELIMINARY ASSESSMENT TO IDENTIFY PESTS WHICH PROVISIONALLY QUALIFY AS A UNION QUARANTINE PEST REQUIRING TEMPORARY MEASURES AS REFERRED TO IN ARTICLES 21(1), 28(1), 29(1) AND 30

#### SUBSECTION 1

##### CRITERIA FOR A PRELIMINARY ASSESSMENT TO IDENTIFY PESTS WHICH PROVISIONALLY QUALIFY AS A UNION QUARANTINE PEST REQUIRING TEMPORARY MEASURES AS REFERRED TO IN ARTICLE 28(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 Member State's territory

The pest is not previously known to be present in the territory of a Member State. Based on the information available to that Member State, the pest is also not previously known to be present in Union territory, or is considered to fulfil the conditions set out in points (b) or (c) of point (2) of Section 1 as regards the Union territory.

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

Based on the information available to the Member State, the pest meets the criteria defined in points (3)(b) and (c) of Section 1 as regards its territory and, to the extent possible for the Member State to assess this, the Union territory.

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

Based on the information available to the Member State, the pest has unacceptable economic, social and/or environmental impacts as regards its territory and, to the extent possible for the Member State to assess this, the Union territory, if it would establish and spread in that territory, as concerns one or several of the areas defined in point (4) of Section 1.

Those impacts shall include at least one or more of the direct effects listed under point (4)(a) to (g) of Section 1.

#### SUBSECTION 2

##### CRITERIA FOR A PRELIMINARY ASSESSMENT TO IDENTIFY PESTS WHICH PROVISIONALLY QUALIFY AS A UNION QUARANTINE PEST REQUIRING TEMPORARY MEASURES AS REFERRED TO IN ARTICLE 29(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 territory

The pest is not previously known to be present in Union territory or is considered to fulfil the conditions set out in points (b) or (c) of point (2) of Section 1 as regards the Union territory.

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

Based on the information available to the Union, the pest meets the criteria defined in points (3)(b) and (c) of Section 1 as regards the Union territory.

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

Based on the information available to the Union, the pest has unacceptable economic, social and/or environmental impacts as regards the Union territory, if it would establish and spread in that territory, as concerns one or several of the areas defined in point (4) of Section 1.

Those impacts shall include at least one or more of the direct effects listed under point (4)(a) to (g) of Section 1.

#### **SECTION 4**

##### **CRITERIA TO IDENTIFY PESTS WHICH QUALIFY AS A UNION QUALITY PEST AS REFERRED TO IN ARTICLE 36 AND 38**

(1) Identity of the pest

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

(2) Probability of spread in the Union territory of the pest

The spread of the pest shall be assessed to take place mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects.

That assessment shall include, as appropriate, the following aspects:

- (a) the number of life cycles of the pest on the concerned hosts;
- (b) the biology, epidemiology and survival of the pest;
- (c) 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;
- (d) secondary infestation and transmission of the pest from the concerned host to other plants and vice versa;
- (e) climatological factors;
- (f) cultural practices before and after harvest;

- (g) soil types;
- (h) susceptibility of the concerned host and relevant stages of host plants;
- (i) presence of vectors for the pest;
- (j) presence of natural enemies and antagonists of the pest;
- (k) presence of other hosts susceptible to the pest;
- (l) prevalence of the pest in the Union territory;
- (m) intended use of the plants.

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

Infestations of the plants for planting referred to in point (2) with the pest shall have an unacceptable economic impact on the intended use of those plants as regards one or more of the following points:

- (a) crop losses in terms of yield and quality;
- (b) extra costs of control measures;
- (c) extra costs of harvesting and grading;
- (d) costs of replanting;
- (e) losses due to the necessity of growing substitute crops;
- (f) effects on existing production practices;
- (g) effects on other host plants at the place of production;
- (h) effects on the establishment, spread and impact of other pests, due to the capacity of the pest concerned to act as a vector for those other pests;
- (i) effects on producer costs or input demands, including control costs and costs of eradication and containment;
- (j) effects on producer profits that result from changes in production costs, yields or price levels;
- (k) changes to domestic or foreign consumer demand for a product resulting from quality changes;
- (l) effects on domestic and export markets and prices paid;
- (m) effects on employment.

As regards points (a) to (h), direct effects on hosts in the endangered area shall be taken into account. Those effects shall be assessed on the basis of the types, amount and frequency of the respective damage.

As regards points (i) to (m), indirect effects within and outside the endangered area shall be taken into account.

## ANNEX III

### Elements to identify plants for planting which pose phytosanitary risks for the Union territory, as referred to in Articles 47(2) and 48

Plants for planting from third countries shall be considered likely to pose phytosanitary risks for the Union territory, as referred to in Article 47(1), where those plants for planting fulfil at least three of the following conditions, including at least one of the conditions provided in points (1)(a), (b) and (c):

- (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 territory 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 territory.
  - (c) They belong to a plant genus or family known to commonly harbour pests without signs and symptoms of those pests, or with a latent period for the expression of those signs or symptoms of at least three months, implying that the presence of pests on those plants for planting is likely to be missed during official controls at introduction into the Union territory, without recourse to sampling and testing or submission to quarantine procedures.
  - (d) They are grown outdoors in the third countries of origin.
  - (e) They are not treated with generic plant protection products prior to or during shipment.
  - (f) They are not subject to official export controls and certification in the third country of origin.
  - (g) 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 purposes of official controls at introduction into the Union territory.
- (2) Origin of the plants for planting
  - (a) They originate from, or are moved from, a third country which is the source of frequent notifications of interceptions of quarantine pests not listed pursuant to Article 5(2).
  - (b) They originate from, or are moved from, a third country which is not a member of the IPPC.

## ANNEX IV

### **Measures and principles for the management of the risks of pests**

#### **SECTION 1**

##### **MEASURES TO MANAGE THE RISKS OF QUARANTINE PESTS AS REFERRED TO IN ARTICLES 16(1), 20, 24(2), 27(4), 28(1), 29(4), 40(2), 41(2), 44(3), 49(2) AND 50(2)**

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 as regards 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, visual examination, 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 purposes 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 purposes of point (f), those measures may include requirements with regard to:

- (a) the registration, authorisation and official supervision of professional 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 91(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 method, 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, visual examination, 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 purposes 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 91(1) to attest compliance with the provisions referred to in point (a) to (d);
- (b) the registration, authorisation and official supervision of professional operators applying the treatment referred to in point (d).

(3) Measures targeting pathways for quarantine pests, other than consignments of plants, plant products or other objects

- (a) Restrictions on the introduction and movement of quarantine pests as a commodity.
- (b) Surveillance, visual examination, 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, visual examination, 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, visual examination, 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 16(1), 17(2), 27(4), 28(1), 29(4), 31(1), 37(5), 44(3), 47(2), 68(3), 69(3), 70(2), 74(3) AND 75(3)**

The management of the risks of Union quarantine pests, protected zone quarantine pests and Union quality pests shall respect the following principles:

(1) Necessity

Measures to manage the risk of a pest shall be applied only where such measures are necessary to prevent the introduction, establishment and spread of that pest.

(2) Proportionality

Measures taken to manage the risk of a pest shall be consistent with the risk posed by the pest concerned and the level of protection that is required.

(3) Minimal impact

Measures taken to manage the risk of a pest 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

Measures taken to manage the risk of a pest 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 that same pest 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

Measures taken to manage the risk of a pest 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. Those measures should reflect, and, where appropriate, be modified or removed to reflect new or updated risk analysis or relevant scientific information.

(6) Feasibility

Measures taken to manage the risk of a pest should be such as to allow that the objective of those measures is likely achieved.

**ANNEX V**

**Contents of phytosanitary certificates for introduction into the Union territory**

**PART A**

**PHYTOSANITARY CERTIFICATES FOR EXPORT AS REFERRED TO IN ARTICLE 71(1)**

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**Model Phytosanitary Certificate**

No. \_\_\_\_\_

Plant Protection Organization of \_\_\_\_\_

TO: Plant Protection Organization(s) of \_\_\_\_\_

**I. Description of Consignment**

Name and address of exporter: \_\_\_\_\_

Declared name and address of consignee: \_\_\_\_\_

Number and description of packages: \_\_\_\_\_

Distinguishing marks: \_\_\_\_\_

Place of origin: \_\_\_\_\_

Declared means of conveyance: \_\_\_\_\_

Declared point of entry: \_\_\_\_\_

Name of produce and quantity declared: \_\_\_\_\_

Botanical name of plants: \_\_\_\_\_

This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

They are deemed to be practically free from other pests.\*

## II. Additional Declaration

[Enter text here]

## III. Disinfestation and/or Disinfection Treatment

Date \_\_\_\_\_ Treatment \_\_\_\_\_ Chemical (active ingredient) \_\_\_\_\_

Duration and temperature \_\_\_\_\_

Concentration \_\_\_\_\_

Additional information \_\_\_\_\_

\_\_\_\_\_

Place of issue \_\_\_\_\_

(Stamp of Organization) \_\_\_\_\_ Name of authorized officer \_\_\_\_\_

Date \_\_\_\_\_

(Signature)

\_\_\_\_\_

No financial liability with respect to this certificate shall attach to \_\_\_\_\_ (name of Plant Protection Organization) or to any of its officers or representatives.\*

\* Optional clause

**PART B**  
**PHYTOSANITARY CERTIFICATES FOR RE-EXPORT AS REFERRED TO IN ARTICLE 71(1)**

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**Model Phytosanitary Certificate for Re-Export**

No. \_\_\_\_\_

Plant Protection Organization of \_\_\_\_\_ (contracting party of re-export)

TO: Plant Protection Organization(s) of \_\_\_\_\_ (contracting party(ies) of import)

**I. Description of Consignment**

Name and address of exporter: \_\_\_\_\_

Declared name and address of consignee: \_\_\_\_\_

Number and description of packages: \_\_\_\_\_

Distinguishing marks: \_\_\_\_\_

Place of origin: \_\_\_\_\_

Declared means of conveyance: \_\_\_\_\_

Declared point of entry: \_\_\_\_\_

Name of produce and quantity declared: \_\_\_\_\_

Botanical name of plants: \_\_\_\_\_

This is to certify that the plants, plant products or other regulated articles described above \_\_\_\_\_ were imported into (contracting party of re-export) \_\_\_\_\_ from \_\_\_\_\_ (contracting party of origin) covered by Phytosanitary Certificate No. \_\_\_\_\_,

\*original  \*certified true copy

of which is attached to this certificate; that they are

\*packed  \*repacked

in

\*original  \*new

containers, that based on the

\*original phytosanitary certificate

and

\*additional inspection

they are considered to conform with the current phytosanitary requirements of the importing contracting party, and that during storage in \_\_\_\_\_ (contracting party of re-export), the consignment has not been subjected to the risk of infestation or infection.

\*Insert tick in appropriate  boxes

## II. Additional Declaration

[Enter text here]

## III. Disinfestation and/or Disinfection Treatment

Date \_\_\_\_\_ Treatment \_\_\_\_\_ Chemical (active ingredient) \_\_\_\_\_

Duration and temperature \_\_\_\_\_

Concentration \_\_\_\_\_

Additional information \_\_\_\_\_

\_\_\_\_\_

Place of issue \_\_\_\_\_

(Stamp of Organization) \_\_\_\_\_ Name of authorized officer \_\_\_\_\_

Date \_\_\_\_\_

(Signature)

\_\_\_\_\_

No financial liability with respect to this certificate shall attach to \_\_\_\_\_ (name of Plant Protection Organization) or to any of its officers or representatives.\*

\* Optional clause

## **ANNEX VI**

### **Plant passports**

#### **PART A**

##### **PLANT PASSPORTS FOR MOVEMENT WITHIN THE UNION TERRITORY AS REFERRED TO IN THE FIRST SUBPARAGRAPH OF ARTICLE 78(2)**

- (1) The plant passport for movement within the Union territory shall contain the following elements:
  - (a) in its upper left hand corner, the words 'Plant Passport';
  - (b) in its upper right hand corner, the flag of the European Union;
  - (c) the letter 'A.', followed by the botanical name of the plant species or taxon concerned, in case of plants and plant products, or, where appropriate, the name of the object concerned;
  - (d) the letter 'B.', followed by subsequently the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator issuing the plant passport is registered, a hyphen and the registration number of the professional operator concerned;
  - (e) the letter 'C.', followed by the lot number of the plant, plant product or the other object concerned;
  - (f) the letter 'D.', optionally followed by the name of the third country of origin or two-letter code, referred to in point (b) of Article 63, for the Member State of origin.
- (2) The lot number referred to in point 1(e) may be replaced by a reference to a unique traceability barcode, hologram, chip or other data carrier, present on the lot.

#### **PART B**

##### **PLANT PASSPORTS FOR MOVEMENT INTO AND WITHIN PROTECTED ZONES AS REFERRED TO IN THE SECOND SUBPARAGRAPH OF ARTICLE 78(2)**

- (1) The plant passport for movement into and within protected zones shall contain the following elements:
  - (a) in its upper left hand corner, the words 'Plant Passport — ZP';
  - (b) immediately underneath those words, the scientific name(s) of the protected zone quarantine pest(s) concerned;
  - (c) in the upper right hand corner, the flag of the European Union;
  - (d) the letter 'A.', followed by the botanical name of the plant species or taxon concerned, in case of plants and plant products, or, where appropriate, the name of the object concerned;

- (e) the letter 'B.', followed by subsequently the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator issuing the plant passport is registered, a hyphen and the registration number of the professional operator concerned;
  - (f) the letter 'C.', followed by the lot number of the plant, plant product or the other object concerned;
  - (g) the letter 'D.', optionally followed by the name of the third country of origin or two-letter code, referred to in point (b) of Article 63, for the Member State of origin.
- (2) The lot number referred to in point 1(f) may be replaced by a reference to a unique traceability barcode, hologram, chip or other data carrier, present on the lot.

### **PART C**

#### **PLANT PASSPORTS FOR MOVEMENT WITHIN THE UNION TERRITORY, COMBINED WITH A CERTIFICATION LABEL, AS REFERRED TO IN THE SECOND SUBPARAGRAPH OF ARTICLE 78(3)**

- (1) The plant passport for movement within the Union territory, combined in a joint label with the official label referred to in Article 19 of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material law*], or the master certificate referred to in Article 122 of that Regulation, shall contain the following elements:
- (a) in the upper left hand corner of the joint label, the words 'Plant Passport';
  - (b) in the upper right hand corner of the joint label, the flag of the European Union.

The plant passport shall be positioned in the joint label immediately above, and have the same width as, that official label or, where applicable, that master certificate.

Where point (c), (d), (e) or (f) as referred to in point (1) of Part A is not contained in that official label or, where applicable, that master certificate, that point shall be provided in the plant passport referred to in the first subparagraph.

- (2) Point (2) of Part A shall apply accordingly.

### **PART D**

#### **PLANT PASSPORTS FOR MOVEMENT INTO AND WITHIN PROTECTED ZONES, COMBINED WITH A CERTIFICATION LABEL, AS REFERRED TO IN THE THIRD SUBPARAGRAPH OF ARTICLE 78(3)**

- (1) The plant passport for movement into and within protected zones, combined in a joint label with the official label referred to in Article 19 of Regulation (EU) No .../.... [*Office of Publications, please insert number of Regulation on plant reproductive material law*], or the master certificate referred to in Article 122 of that Regulation, shall contain the following elements:
- (a) in the upper left hand corner of the joint label, the words 'Plant Passport — ZP';
  - (b) immediately underneath those words, the scientific name(s) of the protected zone quarantine pest(s) concerned;

(c) in the upper right hand corner of the joint label, the flag of the European Union.

The plant passport shall be positioned in the joint label immediately above, and have the same width as, that official label or, where applicable, that master certificate.

Where point (d), (e), (f) or (g) as referred to in point (1) of Part B is not contained in that official label or, where applicable, that master certificate, that point shall be provided in the plant passport referred to in the first subparagraph.

(2) Point (2) of Part B shall apply accordingly.

## **ANNEX VII**

### **Mark for wood packaging material referred to in Article 91(1)**

The mark applied to wood packaging material pursuant to Article 91(1) shall contain the following elements:

- (a) on its left hand, the logo of the IPPC;
- (b) on its right hand, subsequently the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator applying that mark is registered, a hyphen, the registration number of the professional operator concerned, and the letters 'HT'.

No other information shall be contained within the border of the mark.

The mark shall not be hand drawn.

## ANNEX VIII

### **Contents of phytosanitary certificates for export and re-export as referred to in Articles 94(3) and 95(4)**

#### **PART A**

##### **PHYTOSANITARY CERTIFICATES FOR EXPORT AS REFERRED TO IN ARTICLE 94(3)**

- (1) The phytosanitary certificate for movement out of the Union territory, for the purpose of export to a third country, shall contain the following elements:
  - (a) the words 'Phytosanitary certificate', followed by subsequently:
    - (i) the letters 'EU';
    - (ii) the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator requesting the issuance of the phytosanitary certificate for export is registered;
    - (iii) a slash;
    - (iv) a unique identification code for the certificate, consisting of numbers or a combination of letters and numbers, the letters representing, as applicable, the province and district of the Member State where the certificate is issued;
  - (b) the words 'Name and address of exporter', followed by the name and address of the registered operator requesting the issuance of the phytosanitary certificate for export;
  - (c) the words 'Declared name and address of consignee', followed by the declared name and address of the consignee;
  - (d) the words "Plant protection organisation of", followed by the name of the Member State of which the plant protection organisation issues the certificate, and subsequently the words 'to the plant protection organisation(s) of', followed by the name or, as applicable, names, of the country or, as applicable, countries of destination;
  - (e) the words 'Place of origin', followed by the place of origin of the plants, plant products or other objects included in the consignment for which the certificate is issued;
  - (f) the words "Declared means of conveyance", followed by the declared means of conveyance of that consignment;
  - (g) the words "Declared point of entry", followed by the declared point of entry into the country of destination of that consignment;
  - (h) the words "Distinguishing marks: number and description of packages; name of produce; botanical name of plants", followed by the number and type of packages included in the consignment;

- (i) the words "Quantity declared", followed by the quantity of the plants, plant products or other objects included in that consignment, expressed by number or weight;
  - (j) the words 'This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests. They are deemed to be practically free from other pests.';
  - (k) the words "Additional declaration", followed by the additional declaration referred to in Article 67(2) and the statement referred to in Article 67(3) and, optionally, any further phytosanitary information relevant to the consignment. If there is insufficient space for the whole of the additional declaration, the text is to be continued on the back of the form;
  - (l) the words 'Disinfestation and/or disinfection treatment';
  - (m) the word "Treatment", followed by the treatment that has been applied to that consignment;
  - (n) the words "Chemical (active ingredient)", followed by the active ingredient of the chemical used for the treatment referred to in point (m);
  - (o) the words "Duration and temperature", followed by the duration and, where applicable, temperature of that treatment;
  - (p) the word "Concentration", followed by the concentration of that chemical reached during that treatment;
  - (q) the word "Date", followed by the date on which that treatment was applied;
  - (r) the word "Additional information", followed by any additional information that the competent authority wishes to include in the certificate;
  - (s) the words 'Place of issue', followed by the place of issuance of the phytosanitary certificate;
  - (t) the word 'Date', followed by the date of issuance of the phytosanitary certificate;
  - (u) the words 'Name and signature of authorised officer', followed by the name and signature of the officer issuing and signing the phytosanitary certificate;
  - (v) the words 'Stamp of organisation', followed by the official stamp of the competent authority issuing the phytosanitary certificate.
- (2) The paper used shall contain the embossed seal of the competent authority that signs the certificate.

## **PART B**

### **PHYTOSANITARY CERTIFICATES FOR RE-EXPORT AS REFERRED TO IN ARTICLE 95(4)**

- (1) The phytosanitary certificate for movement out of the Union territory, for the purpose of re-export to a third country, shall contain the following elements:
  - (a) the words 'Phytosanitary certificate for re-export', followed by subsequently:
    - (i) the letters 'EU';
    - (ii) the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator requesting the issuance of the phytosanitary certificate for re-export is registered;
    - (iii) a slash;
    - (iv) a unique identification code for the certificate, consisting of numbers or a combination of letters and numbers, the letters representing, as applicable, the province and district of the Member State where the certificate is issued;
  - (b) the words 'Name and address of exporter', followed by the name and address of the registered operator requesting the issuance of the phytosanitary certificate for re-export;
  - (c) the words 'Declared name and address of consignee', followed by the declared name and address of the consignee;
  - (d) the words "Plant protection organisation of", followed by the name of the Member State of which the plant protection organisation issues the certificate, and subsequently the words 'to the plant protection organisation(s) of', followed by the name or, as applicable, names, of the country or, as applicable, countries of destination;
  - (e) the words 'Place of origin', followed by the place of origin of the plants, plant products or other objects included in the consignment for which the certificate is issued;
  - (f) the words "Declared means of conveyance", followed by the declared means of conveyance of that consignment;
  - (g) the words "Declared point of entry", followed by the declared point of entry into the country of destination of that consignment;
  - (h) the words "Distinguishing marks: number and description of packages; name of produce; botanical name of plants", followed by the number and type of packages included in the consignment;
  - (i) the words "Quantity declared", followed by the quantity of the plants, plant products or other objects included in that consignment, expressed by number or weight;
  - (j) the following text:

'This is to certify

- that the plants or plant products described above were imported into ..... (country of re-export) from ..... (country of origin) covered by phytosanitary certificate No .....
- \*original     \*certified true copy of which is attached to this certificate,
- that they are
- \*packed     \*repacked
- in
- \*original     \*new containers,
- that based on the
- \*original phytosanitary certificate
- and
- \*additional inspection,
- they are considered to conform with the current phytosanitary regulation of the importing country, and
- that during storage in ..... (country of re-export) the consignment has not been subjected to the risk of infestation or infection.

\* Insert tick in appropriate boxes',

in which text the required information shall be filled and the applicable boxes ticked;

- (k) the words "Additional declaration", followed by the additional declaration referred to in Article 67(2) and the statement referred to in Article 67(3) and, optionally, any further phytosanitary information relevant to the consignment. If there is insufficient space for the whole of the additional declaration, the text is to be continued on the back of the form;
- (l) the words 'Disinfestation and/or disinfection treatment';
- (m) the word "Treatment", followed by the treatment that has been applied to that consignment;
- (n) the words "Chemical (active ingredient)", followed by the active ingredient of the chemical used for the treatment referred to in point (m);
- (o) the words "Duration and temperature", followed by the duration and, where applicable, temperature of that treatment;
- (p) the word "Concentration", followed by the concentration of that chemical reached during that treatment;
- (q) the word "Date", followed by the date on which that treatment was applied;

- (r) the word "Additional information", followed by any additional information that the competent authority wishes to include in the certificate;
  - (s) the words 'Place of issue', followed by the place of issuance of the phytosanitary certificate;
  - (t) the word 'Date', followed by the date of issuance of the phytosanitary certificate;
  - (u) the words 'Name and signature of authorised officer', followed by the name and signature of the officer issuing and signing the phytosanitary certificate;
  - (v) the words 'Stamp of organisation', followed by the official stamp of the competent authority issuing the phytosanitary certificate.
- (2) The paper used shall contain the embossed seal of the competent authority that signs the certificate.

## ANNEX IX

### Correlation table

Council Directive 69/464/EEC	This Regulation	Regulation (EU) No .../.... [ <i>Office of Publications, please insert number of Regulation on Official Controls</i> ]
Article 1	Article 27(1)	—
Article 2	Article 27(1)(d)	—
Articles 3, 4 and 5	Article 27(1)(c)	—
Article 6	Article 27(1)(e)	—
Article 7	—	—
Article 8	Article 8	—
Article 9	Article 31(1)	—
Articles 10 and 11	Article 27(1)(c)	—
Articles 12 and 13	—	—
Council Directive 93/85/EEC	This Regulation	Regulation (EU) No .../.... [ <i>Office of Publications, please insert number of Regulation on Official Controls</i> ]
Article 1	Article 27(1)	—
Article 2	Article 27(1)(f)	—
Article 3	Article 9	—
Articles 4 to 8	Article 27(1)(a), (b) and (c)	—
Article 9	—	—
Article 10	Article 8	—
Article 11	Article 31(1)	—
Article 12	Article 27(1)	—
Articles 13 to 15	—	—
Annexes I to V	Article 27(1)	—
Council Directive 98/57/EC	This Regulation	Regulation (EU) No .../.... [ <i>Office of Publications, please insert number of Regulation on Official Controls</i> ]
Article 1	Article 27(1)	—

Article 2	Article 27(1)(f)	—
Article 3	Article 9	—
Article 4 to 7	Article 27(1)(a), (b) and (c)	—
Article 8	—	—
Article 9	Article 8	—
Article 10	Article 31(1)	—
Article 11	Article 27(1)	—
Articles 12 to 14	—	—
Annexes I to VII	Article 27(1)	—
Council Directive 2007/33/EC	This Regulation	Regulation (EU) No .../.... [ <i>Office of Publications, please insert number of Regulation on Official Controls</i> ]
Article 1	Article 27(1)	—
Articles 2 and 3	Article 27(1) and (2)	—
Articles 4 to 8	Article 27(1)(f)	—
Articles 9 to 13	Article 27(1) and (2)	—
Article 14	Article 8	—
Article 15	Article 31(1)	—
Article 16	Article 27(1)	—
Article 17	Article 99	—
Articles 18 to 20	—	—
Annexes I to IV	Article 27(1)	—
Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../.... [ <i>Office of Publications, please insert number of Regulation on Official Controls</i> ]
Article 1(1), (2) and (3)	Article 1	—
Article 1(4)	—	Article 3
Article 1(5) and (6)	—	—
Article 2(1)(a)	Article 2(1)	—
Article 2(1)(b)	Article 2(2)	—

Article 2(1)(c)	—	—
Article 2(1)(d)	Article 2(3)	—
Article 2(1)(e)	Article 1(1)	—
Article 2(1)(f)	Article 73	—
Article 2(1)(g)	—	Articles 3, 25 and 36
Article 2(1)(h)	Articles 32 to 35	—
Article 2(1)(i), first subparagraph	Article 71	Article 4
Article 2(1)(i), second subparagraph	—	Articles 4 and 19
Article 2(1)(i), third subparagraph	—	Article 129
Article 2(1)(j)	—	Article 2(28)
Article 2(1)(k)	—	Article 3
Article 2(1)(l)	—	Article 3
Article 2(1)(m)	—	Article 3
Article 2(1)(n)	—	Article 3
Article 2(1)(o)	Article 2(6)	—
Article 2(1)(p)	—	Article 2(26)
Article 2(1)(q)	—	—
Article 2(1)(r)	—	Article 2(48)
Article 2(2)	Article 2(2), second subparagraph	—
Article 3(1)	Article 5(1)	—
Article 3(2) and (3)	Articles 5(1), 37(1) and 41(3)	—
Article 3(4)	—	—
Article 3(5)	Article 32(2) and 50(3)	—
Article 3(6)	Articles 5(2) and 32(3)	—
Article 3(7)	Articles 5(3), 27(1) and 37(1)	—
Articles 3(8) and (9)	Articles 8, 46 and 54	—
Article 4(1)	Article 40(1)	—
Article 4(2)	Article 49(1)	—
Article 4(3)	—	—

Article 4(4)	—	—
Article 4(5)	Articles 8, 46 and 54	—
Article 4(6)	Article 44	—
Article 5(1)	Article 40(3)	—
Article 5(2)	Article 49(3)	—
Article 5(3)	Articles 40(2) and 49(2)	—
Article 5(4)	Articles 51 and 70	—
Article 5(5)	Articles 8, 46 and 54	—
Article 5(6)	Article 44	—
Article 6(1) to (4)	Article 82(1), (2) and (3)	—
Article 6(5), first and second subparagraphs	Article 82(1), (2) and (3)	—
Article 6(5), third subparagraph	Articles 61 and 64	—
Article 6(5), fourth subparagraph	Article 10	—
Article 6(5), fifth subparagraph	Article 76	—
Article 6(6)	Articles 61 and 65	—
Article 6(7)	Article 76	—
Article 6(8), first indent	—	—
Article 6(8), second indent	Article 53	—
Article 6(8), third indent	Article 82(4)	—
Article 6(8), fourth indent	Articles 62, 65 and 85	—
Article 6(8), fifth indent	—	—
Article 6(8), sixth indent	Article 76	—
Article 6(9)	Article 62	—
Article 10(1)	Articles 78(3), 80, 81 and 82	—
Article 10(2)	Articles 74, 75 and 76	—
Article 10(3)	Article 88	—
Article 10(4)	Article 82(4)	—
Article 11(1)	Article 82(1)	—
Article 11(2)	—	—

Article 11(3)	—	Article 19(d)
Article 11(4)	Article 87	—
Article 11(5)	Article 87	—
Article 12(1)	—	Articles 43, 134, 135 and 136
Article 12(2)	Articles 65(3), 88(5) and 90(2)	Article 4(1)(g) and (h)
Article 12(3)	—	Article 115
Article 12(4)	Articles 41(4) and 90(1) and (5)	Articles 19(d), 103, 130, 134, 135 and 136
Article 13(1) and (2)	Article 71(5)	Articles 45 and 89(1)(f)
Article 13(3) and (4)	—	—
Article 13a(1)	—	Article 47
Article 13a(2)	—	Article 52
Article 13a(3)	Article 71	—
Article 13a(4)	Article 71	—
Article 13a(5)	—	Articles 50 and 52
Article 13b(1)	—	Article 63
Article 13b(2)	—	Article 49
Article 13b(3)	—	Article 46
Article 13b(4)	—	Article 46
Article 13b(5)	—	Article 46
Article 13b(6)	—	—
Article 13c(1)(a)	—	Article 55
Article 13c(1)(b)	Article 61	—
Article 13c(1)(c)	—	Article 54, 55 and 56
Article 13c(2)(a)	—	Article 47
Article 13c(2)(b)	—	Article 51
Article 13c(2)(c)	—	Article 51
Article 13c(2)(d)	—	Article 51
Article 13c(2)(e)	—	Article 49, 50 and 51
Article 13c(2)(f)	—	Article 47

Article 13c(3)	—	Articles 55 and 130
Article 13c(4)	—	Articles 55, 58 and 62
Article 13c(5)	—	—
Article 13c(6)	Article 89	—
Article 13c(7)	Article 72	Articles 134, 135 and 136
Article 13c(8)	Articles 40(4), 41(4), 49(5), 50(4) and 97	Article 130
Article 13d(1)	—	Articles 77 and 78
Article 13d(2)	—	Article 79
Article 13d(3)	—	Articles 79 and 83
Article 13d(4)	—	Article 80
Article 13d(5)	—	Articles 78 and 79
Article 13d(6)	—	—
Article 13d(7)	—	—
Article 13e	Articles 94 and 95	—
Article 14	Articles 5(3) and (4), 32(3), 37(2) and (3), 40(2), 41(2), 49(2), 50(2), 68(2) and (3), 69(2) and (3), 74(2) and (3) and 75(2) and (3)	—
Article 15(1)	Article 41(2), first subparagraph	—
Article 15(2)	Article 41(2), second subparagraph	—
Article 15(3)	Article 67(3)	—
Article 15(4)	—	—
Article 16(1)	Article 10(1) and (2) and Article 16	—
Article 16(2), first subparagraph	Article 28	—
Article 16(2), second subparagraph	Article 14(1)	—
Article 16(2), third subparagraph	Article 14(1)	—
Article 16(2), fourth subparagraph	—	—
Article 16(3)	Article 29	—
Article 16(4)	Articles 27(1), 29(1) and 47(1)	—
Article 16(5)	Articles 27(6), 29(6) and 47(4)	—

Article 18	Article 99	—
Article 20	—	—
Article 21(1)	—	Article 115(1) and (2)
Article 21(2)	—	Article 115(4)
Article 21(3)	—	Article 115(1) and (3)
Article 21(4)	—	Article 115(1) and (3)
Article 21(5)	—	Articles 117 and 118
Article 21(6)	Article 97	Article 130
Article 21(7)	—	—
Article 21(8)	—	—
Article 22	—	—
Article 23(1)	—	—
Article 23(2)	—	—
Article 23(3)	Article 102	—
Article 23(4)	—	—
Article 23(5), first subparagraph	—	—
Article 23(5), second subparagraph	—	—
Article 23(5), third subparagraph	—	—
Article 23(5), fourth subparagraph	—	—
Article 23(5), fifth subparagraph	—	—
Article 23(6), first subparagraph	—	—
Article 23(6), second subparagraph	—	—
Article 23(6), third subparagraph	—	—
Article 23(6), fourth subparagraph	—	—
Article 23(7)	—	—
Article 23(8)	—	—
Article 23(9)	—	—
Article 23(10)	—	—
Article 24(1)	—	—

Article 24(2)	—	—
Article 24(3)	—	—
Article 25	—	—
Article 26	—	—
Article 27	—	Article 87(2)
Article 27a	—	Articles 107 to 110
Article 28	—	—
Article 29	—	—
Annex I, Part A, Section I	Article 5(2)	—
Annex I, Part A, Section II	Article 5(2)	—
Annex I, Part B	Article 32(3)	—
Annex II, Part A, section I	Article 5(2)	—
Annex II, Part A, Section II	Article 37(2)	—
Annex II, Part B	Article 32(3)	—
Annex III, Part A	Article 40(1)	—
Annex III, Part B	Article 49(1)	—
Annex IV, Part A	Article 41(1)	—
Annex IV, Part B	Article 50(1)	—
Annex V, Part A, Point I	Article 74(1)	—
Annex V, Part A, Point II	Article 75(1)	—
Annex V, Part B, Point I	Article 68(1)	—
Annex V, Part B, Point II	Article 69(1)	—
Annex VI	—	—
Annex VII	Annex VIII	—
Annex VIII	—	—
Annex VIIIa	—	—
Annex IX	—	—