

+



EUROPEAN COMMISSION

Brussels, **XXX**  
SANCO/2012/11811  
[...] (2012) **XXX** draft

Proposal for a

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

**on protective measures against organisms harmful to plants (OJ L ...)**

(Text with EEA relevance)

## 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.

Pests and diseases from other continents are especially dangerous. European plants and trees usually lack adequate genetic resistance against foreign pests and micro-organisms ('harmful organisms') and they do not have natural enemies here. When introduced into Europe, foreign harmful organisms 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 and diseases may elicit trade bans from third countries, damaging EU exports. Not all pests can be controlled with pesticides and, where available, pesticide use may be undesirable.

#### Regulatory framework

The current EU regulatory framework for plant health aims to protect European agriculture and forestry by preventing the entry and spread of non-native harmful organisms. The main tool hereby is Council Directive 2000/29/EC<sup>1</sup>, which also reflects international trade agreements in this area. The EU plant health regime is unique in that it is an open regime: movements of plants and plant products into and within the Union are allowed on condition that specific restrictions and requirements are respected (e.g. provenance from a pest free area or appropriate treatment). The high volumes of imports from other continents nevertheless imply a high probability of future outbreaks of foreign harmful organisms.

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 harmful organisms caused by globalisation of trade. Moreover climate change enables those harmful organisms to survive in Europe, while they could not in the past, and renders crops and ecosystems more vulnerable to new pests and diseases. Major outbreaks in the past decade of dangerous import-related harmful organisms affecting forestry have raised societal and political awareness of the costs and impacts of inadequate protection.

#### 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 harmful organisms at EU level across all 27 Member States, the need for better instruments for controlling the presence and natural spread of harmful organisms in case they eventually reach the Union territory, a need for modernising and upgrading the

---

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

<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)

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 harmful organisms 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 organisms into quality organisms, as requested by operators and Member States, so as to use the resources available to the plant health quarantine authorities for true Union priorities. In the meanwhile, the proposal ensures that the existing practical arrangements in the Member States concerning the certification of plant reproductive material for quality organisms can remain. Altogether, the rearrangements between the EU plant health regime and plant reproductive material regime should result in increased legislative flexibility and in reduced burden for operators. The proposed new arrangements will, however, require improved coordination between the competent authorities in the Member States for plant health and plant reproductive material.

The proposal does not contain provisions concerning official controls by the competent authorities of compliance by operators with the Union plant health legislation, as are currently present in Directive 2000/29/EC. Those controls are now being positioned exclusively in the proposal for a Regulation on Official Controls (replacing Regulation (EC) 882/2004<sup>3</sup>). This will also allow improved coherence with the new Customs Code and allow simplified procedures at import.

---

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

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

The proposal will be complementary to the proposal concerning Invasive Alien Species foreseen for 2012 under the EU Biodiversity Strategy in the Commission Work Programme<sup>4</sup>.

## **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>5</sup>. The Commission initiated a comprehensive evaluation of the regime from the introduction of the internal market (1993)<sup>6</sup> and contracted the necessary study out to an external consultant<sup>7</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>8</sup> was presented in a second conference on 28 September 2010 including stakeholders, the 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>9</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

---

<sup>4</sup> [http://ec.europa.eu/atwork/programmes/docs/cwp2012\\_annex\\_en.pdf](http://ec.europa.eu/atwork/programmes/docs/cwp2012_annex_en.pdf)

<sup>5</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>6</sup> Taking account of a previous evaluation of the financial aspects of the regime, completed in 2008.

<sup>7</sup> Food Chain Evaluation Consortium (FCEC), consisting of Civic Consulting, Agra CEAS Consulting (project leader), Van Dijk Management Consultants and Arcadia International.

<sup>8</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)

<sup>9</sup> Advisory Groups on Seeds, Advisory Group on Cotton, Advisory Group on Floriculture and Ornamentals, Advisory Group on Citrus, Advisory Group on Potato.

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>10</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 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 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 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

---

<sup>10</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)

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 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, 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 Regulation on Union expenditures for food and feed, animal health and welfare, 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 for Official Controls.

#### Fundamental rights

Not only operators but also citizens will be subject to the provisions of the Regulation. The competent authorities of the Member States will need to have access to private gardens, in addition to the premises of operators, to ensure the implementation of the Regulation, where necessary including statutory destruction of plants infested or potentially infested by quarantine organisms. 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 plant health measures are respected equally by all (refraining from destruction of infested plants in private gardens would annihilate the benefits of eradication measures imposed on 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 organism will be obliged to notify the presence of that quarantine organisms 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 harmful organisms 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 organisms 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**

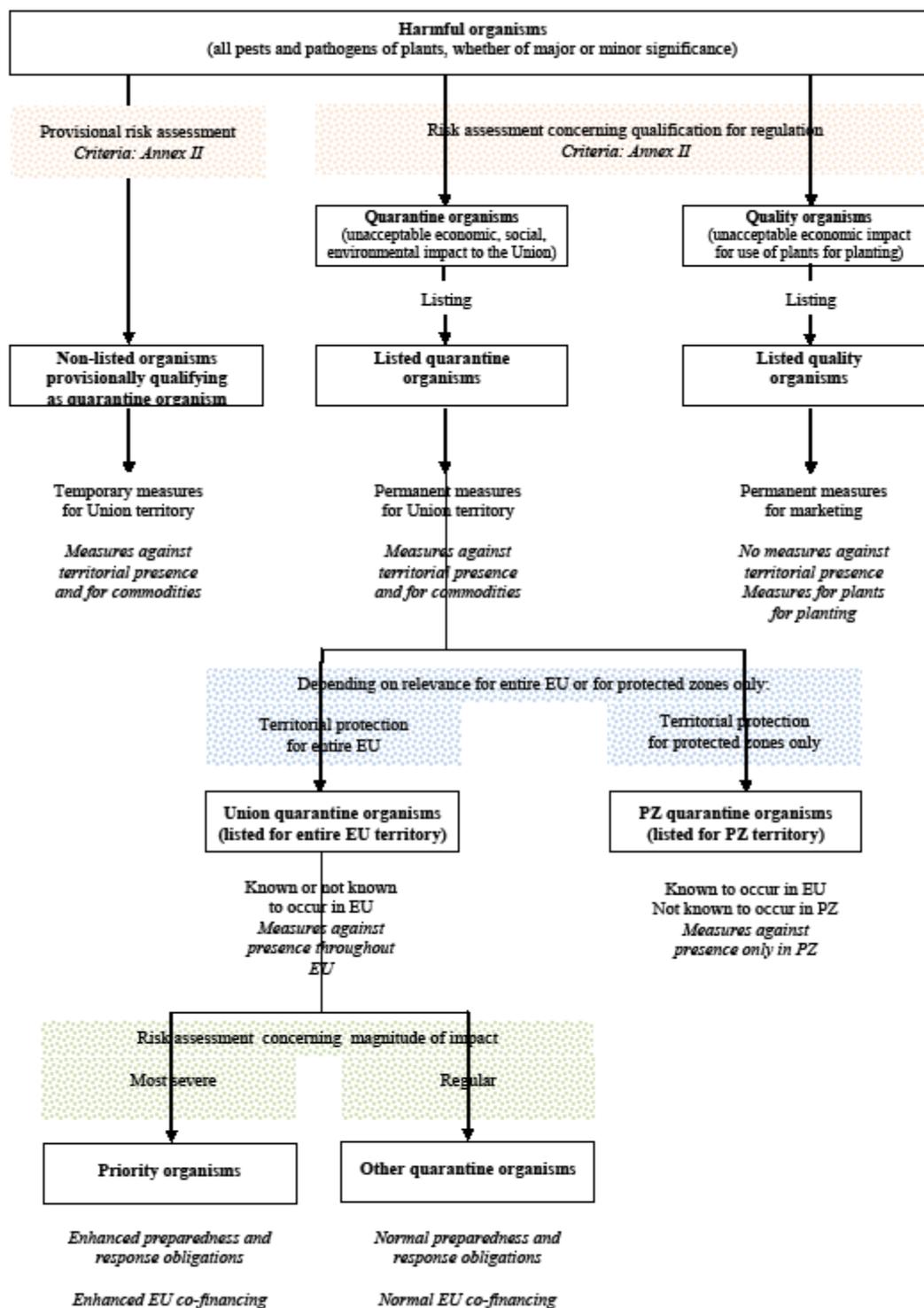
The territorial scope of the regime does not include any overseas departments of Member States, as those departments belong to other biogeographic regions of the world, where exactly those harmful organisms occur against which the European territories of the Member States require protection. The territorial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

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

Definitions are provided as necessary.

#### **Chapter II: Quarantine organisms**

In Directive 2000/29/EC, harmful organisms are listed in specific Annexes. The proposal, instead, sets out the conceptual nature of quarantine organisms and subsequently lists them in implementing acts, either as Union quarantine organisms or Protected Zone quarantine organisms. Union quarantine organisms require eradication measures in the entire Union territory, while for Protected Zone quarantine organisms that is only the case within specified protected zones where certain harmful organisms are absent, while they are known to occur in other parts of the Union territory. The proposal empowers the Commission to list certain quarantine organisms as priority organisms for the Union, up to a maximum of 10% of the listed Union quarantine organisms. Those organisms 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 harmful organism qualifies as a quarantine organism, Union or Protected Zone quarantine organism, or priority organism are provided in Annex II of the Regulation. A transfer is foreseen of the harmful organisms 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 harmful organisms currently listed in Annex I and Annex II of Directive 2000/29/EC.



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

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

The provisions in this chapter empower the Commission to adopt implementing acts on permanent measures to manage quarantine organisms that have become established in the Union territory. Those acts can also be adopted on a temporary basis for non-listed quarantine organisms requiring emergency measures, if necessary using the urgency procedure established under the Lisbon Treaty. The tools developed in this chapter exist today under Directive 2000/29/EC, however the proposal develops those tools explicitly. A provision is included allowing Member States to take stricter measures against harmful organisms 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 organisms 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 organisms

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

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

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

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

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

The introduction into the Union of regulated plants, plant products and other objects by passengers in their luggage will no longer be exempted from the respective requirements and prohibitions. This is necessary because such luggage has been found an increasing risk for the plant health status of the Union.

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

#### Chapter V: Registration of operators and traceability

The proposal requires the relevant operators to be registered, in a register which will also contain the operators required to be registered under the plant reproductive material Regulation. This should reduce burden for operators. Registered operators shall fulfil certain requirements for the traceability of the plant material under their control.

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

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

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

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

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

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

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

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

#### Chapter VII: Measures supporting the implementation of this Regulation

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

#### Chapter VIII: Final provisions

The proposal foresees that the Commission will be assisted by a new Standing Committee, which will include the existing Committees dealing with the Food Chain, Animal and Plant Health (instead of the existing Standing Committee on Plant Health).

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

#### **4. BUDGETARY IMPLICATION**

The financial provisions and appropriations for implementing the Regulation up to 31 December 2020 are being presented in the Regulation on Union expenditures for food and feed, animal health and welfare, plant health and plant reproductive material.

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,

(1) Council Directive 2000/29/EC lays down protective measures against the introduction into the Union of organisms harmful to plants or plant products and against their spread within the Union.

(2) On 21 November 2008, the Council invited the Commission to proceed to an evaluation of the plant health regime, to consider possible modifications to the existing legal framework and the impact of such modifications and to present a proposal for a plant health strategy, putting prevention at the core of the plant health system.

(3) In the light of the outcome of that evaluation and the experience gained from the application of Directive 2000/29/EC, the increase of plant health risks due to globalisation of trade and climate change, and the expansion of the EU since that Directive entered into force, that Directive should be replaced.

(4) To simplify application of the new act and to ensure consistent implementation throughout the Member States, this act should take the form of a Regulation.

(5) Plant production, agriculture, forests, landscape, public and private green and natural ecosystems and biodiversity are very important for Union's economy, society and environment. Therefore it is imperative to adopt measures to protect plants, and their products, from organisms harmful to their health.

(6) 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 29<sup>th</sup> session.

(7) Action against harmful organisms must be comprehensive and taken at different levels in order to be effective. In this respect measures should be adopted against the entry of harmful organisms into the Union, their spread within the Union and their eradication. If eradication is not possible, in certain cases containment measures should be applied through measures applicable at Union level.

(8) Different pests and diseases have co-evolved with the native plant species in different continents. Including non-European territories in the territorial scope of the new plant health law would likely allow the free movement of plant material with non-European pests from other continents into Europe. For the purpose of this Regulation, certain territories of the Union which are not in Europe and which are biogeographically not linked to Europe should therefore be considered as third countries.

(9) Harmful organisms which are not present in the Union territory, or, if present, only distributed to a limited extent within the Union territory, which are capable to enter into, establish and spread within the Union territory, or in those parts of it where they are not present, and there would have an unacceptable economic, environmental or social impact, should be specifically identified as quarantine organisms. Where feasible and effective measures are available, the entry, establishment and spread of those organisms into the Union, or parts of it, should be prohibited.

(10) Quarantine organisms, which are not present in the Union territory or, if present, distributed only to a limited extent within that territory and whose presence would have

unacceptable economic, social or environmental impacts for the entire Union, should be specifically identified and listed as 'Union quarantine organisms'. Their identification should take place on the basis of a clear framework of risk assessment principles to ensure a transparent and scientifically sound decision making.

(11) Quarantine organisms with the most severe economic, environmental and social effects for the entire Union, should be identified and listed as 'priority organisms'. Those organisms should be identified on the basis of a clear framework of risk assessment principles to ensure a transparent and scientifically sound decision making.

(12) Quarantine organisms 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 organisms'. The introduction into and the movement within the respective protected zones of 'protected zone quarantine organisms' should be prohibited. Their identification should take place on the basis of a clear framework of risk assessment principles to ensure a transparent and scientifically sound decision making.

(13) The harmful organisms currently listed in Annexes I and II of Directive 2000/29/EC are presumed to meet those risk assessment criteria for their current categorisation, other than the harmful organisms currently listed in Section II of Part A of Annex II.

(14) The role of operators in the early prevention of phytosanitary risks and ensuring early action in case of outbreaks is of crucial importance. Therefore they should also share the responsibility for the effective implementation of this Regulation. In this respect they should communicate and co-operate with the competent authorities on actual or suspected risks and swiftly inform the consumers and recall their products from the market, where so required due to phytosanitary reasons. The obligation of notification to the competent authorities should also apply for all those involved in investigations or studies concerning harmful organisms, as well as on any other natural or legal person who might be aware of the presence of those organisms. Where that notification implies that personal data of the 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.

(15) Harmonised rules should be adopted concerning the early provision from the competent authorities to other competent authorities, the Commission, the operators and the public of information concerning the presence of harmful organisms and the applicable phytosanitary risks and measures. This is important to ensure the most proactive and effective policy towards harmful organisms at a Union level.

(16) Operators should be obliged to take immediate measures to eliminate quarantine organisms found present in plants, plant products and other objects which are under their controls. Therefore harmonised rules should be adopted concerning that obligation, as well as their actions in case those plants, plant products or other objects have left their immediate control.

(17) It is important for the Union that Member States identify at the earliest possible stage any imminent dangers for plant health. These risks may arise from any evidence which should be notified immediately to the Commission and the other Member States. The same obligation should be established for the operators, who should respectively inform the competent authorities.

(18) As a further step to ensure a proactive approach, Member States should take all necessary measures to eradicate, when found present in their territories, Union quarantine organisms. Harmonised rules should be adopted setting out the specific obligations of the Member States, which should include restriction of the area at risk, with the establishment of an infested and a buffer zone. In the case of the presence of priority harmful organisms in their territories, Member States should moreover establish official programmes for their eradication.

(19) In certain cases, Member States should impose measures for the eradication of quarantine organisms on plants in private premises of citizens. For this purpose, they should also 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.

(20) Proactive action by Member States is very important to prevent the presence and spread of harmful organisms. The first step of that action should be the conduct of surveys to determine the absence, detect the presence or determine the distribution in their territories over a defined period of time of quarantine organisms in the surveyed areas.

(21) In view of the significance of priority organisms, rules should be established ensuring that the surveys of the Member States concerning those organisms should be enhanced compared to the surveys on other quarantine organisms.

(22) In addition to the conducted surveys, Member States should have in place generic contingency plans to address the potential presence, establishment and/or spread of harmful organisms in general and, additionally, specific contingency plans for each priority harmful organism. These plans should be set up in accordance with applicable international standards.

(23) Where a priority organism is found present in the Union territory, a specific eradication programme should be set up.

(24) In certain cases there is a need to address the presence of particular quarantine organisms in a harmonised manner if phytosanitary protection at Union level requires so. There should be therefore a possibility to adopt Union measures harmonising measures concerning notifications, eradication, official plans, surveys and contingency plans regarding particular quarantine organisms. Those measures should also allow Member States, in certain cases, to adopt measures for the containment of a quarantine organism, if eradication measures have proven unsuccessful.

(25) In order to ensure swift and effective policies against organisms which are not listed as Union quarantine organisms, but may qualify as such, Member States should be allowed to take any temporary eradication measures to protect the territory of the Union for a limited period of time, in accordance with the precautionary principle. Those measures should be based on a preliminary risk assessment. A full risk assessment should be completed within no longer than 24 months to ensure scientific certainty concerning the nature of those organisms.

(26) For the same reasons as for the previous paragraph, and in order to ensure a proactive protection of the Union territory, the Commission should have the possibility to adopt temporary measures against organisms which are not listed as Union quarantine organisms, but are likely to qualify as such. Those measures should be based on the notifications of temporary measures of the Member States or on any other evidence. They should be based on a provisional risk assessment. After the termination of those measures, the Commission

should be in a position to decide on whether those organisms should be listed as Union quarantine organisms or not.

(27) The framework for the risk assessments principles to determine the quarantine organisms, including priority organisms and the organisms on which temporary measures should be taken, should be based on the standards adopted by the International Plant Protection Convention (IPPC). Those principles should be also in line with the principles of (SPS) to ensure a proportionate, necessary, effective and non-discriminatory approach while identifying and listing the organisms concerned.

(28) There is a need to harmonise the EU legislation on plant health to ensure that measures against harmful organisms are sufficiently effective. This is also important to avoid distortions of trade. Therefore plants, plant products and other objects which have entered into and are moved within the Union in accordance with the provisions of this Regulation, should not be subject to any movement restrictions as regards their plant health and examination requirements other than those laid down in Union legislation.

(29) In principle, all parts of the Union should benefit from the same degree of protection against harmful organisms. However, differences in ecological conditions and in the distribution of certain harmful organisms must be taken into account. In consequence, 'protected zones' exposed to particular plant health risks should be defined and should be accorded special protection under conditions compatible with the internal market. Rules should be adopted concerning the recognition, modification or revocation of recognition of the protected zones, surveys, and actions to be taken in case quarantine harmful organisms are found present in their territories.

(30) Certain harmful organisms, which do not qualify as quarantine organisms, should qualify as 'quality organisms' in case their presence on certain plants for planting has unacceptable economic impacts on the intended use of those plants and they are transmitted mainly through those plants for planting. Those organisms should be listed on the basis of specific criteria of risk assessment. Their presence on the specific plants for planting should be prohibited. Criteria should be set for the establishment of thresholds below which the presence of those organisms would nevertheless be acceptable on the respective plants for planting.

(31) Several plants, plant products and other objects originating from third countries, are likely to host harmful organisms with unacceptable economic, environmental and social impacts for the Union. For those commodities, certain acceptable risk mitigation measures are available, while not for others. Those plants, plant products and other objects should be specifically identified and listed, together with the respective countries of origin. Depending on whether acceptable mitigation measures are available or not, their entry into and movement within the Union should be either subject to those measures or prohibited.

(32) The international movement of new species of plants for planting with which there is limited experience with trade brings along high risks of the entry of new quarantine organisms. In order to ensure swift and effective policies 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 based on a provisional risk assessment, in accordance with the precautionary principle. Those measures should consist either of intensified physical controls or quarantine at introduction into the Union, or of a temporary import prohibition. They should be in place for a limited period of time, allowing to in the meanwhile carry out a risk assessment for the Union territory on the basis of which permanent measures, if any, can be decided.

(33) Harmonised rules should be adopted determining conditions for derogations from the requirements or prohibitions of introduction of plants, plant products and other objects into the Union. A possibility should be granted to the Commission to recognise certain measures of third countries as equivalent to the requirements for the entry into and movement within the Union of certain plants, plant products and other objects, and criteria for the recognition of that equivalence should be set.

(34) The application of the Union plant health regime to the Union as an area without internal frontiers, and the introduction of protected zones make it necessary to distinguish between requirements applicable to Union products on the one hand and those applicable to imports from third countries on the other, and to identify harmful organisms relevant for protected zones. Therefore prohibitions or specific conditions for certain harmful organisms, plants, plant products or other organisms should apply only in respect of their entry and movement in the specific protected zones of the Union, as their presence in the rest of the Union territory would pose no unacceptable risk for plant health.

(35) 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 organisms.

(36) Member States should designate quarantine facilities in their territories to ensure the implementation of certain conditions of this Regulation against the entry into and movement within the Union of certain harmful organisms. In this view, harmonised standards should be adopted concerning those quarantine facilities.

(37) It would be appropriate to ensure that plants, plant products and other objects intended for export or re-export from the Union to a third country comply with the respective rules for their movement within the Union. If requested so by the authorities of the importing country, or established by the legislation, standards, codes of practice and other procedures in force in the importing country, or if a bilateral agreement has been concluded between the Union and a third country, those plant, plant products and other objects should comply with the respective provisions of the third country.

(38) In order to ensure transparency and more effective controls with regards to plant health, operators involved in the marketing, production and treatment of plants, plant products and other objects regulated by this Regulation should be registered in public registers set up by the Member States. In order to reduce administrative burden, those registers should also include all operators concerned by the [PRM Regulation].

(39) Experience has shown that plant health can be jeopardised where it is impossible to trace plants, plant products and other objects which have contributed to the spread of harmful organisms. It is therefore necessary to establish a comprehensive system of traceability within plant and plant products businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or competent authorities. Thereby the potential for unnecessary wider disruption in the event of health plant problems could be avoided. In this context it is also necessary to ensure that an operator can identify, for a reasonable period of time, at least the business from which the plants, plant products or other object has been supplied, and businesses and professionals to whom that material has been supplied. This is necessary to ensure that, on investigation, traceability can be assured at all stages.

(40) The introduction from third countries into the Union, or into the respective protected zones, of plants for planting, other than seeds, and of certain plants, plant products and other objects for which particular phytosanitary requirements are established pursuant to this Regulation, should only be permitted if accompanied by a phytosanitary certificate. Those

plants, plant products and other objects should be listed to ensure clarity with respect to markets and controlling authorities.

(41) Those phytosanitary certificates should comply with the requirements of the International Plant Protection Convention (IPPC) and attest compliance with the requirements and measures established pursuant to the provisions of this Regulation. In order to ensure the credibility of the phytosanitary certificates, harmonised rules should be established concerning the conditions of their validity and cancellation.

(42) The movement within the Union, or within the respective protected zones, of plants for planting, other than seeds, and of certain plants, plant products and other objects for which particular phytosanitary requirements are established pursuant to this Regulation, should only be permitted if accompanied by a plant passport. Those plants, plant products and other objects should be listed to ensure clarity with respect to markets and controlling authorities.

(43) Plant passports should not accompany products intended for final users, as this would entail disproportionate costs and administrative burdens for operators.

(44) Plant passports should be official labels attesting that the plants, plant products and other objects concerned originate from an officially registered and supervised operator who fulfils the necessary phytosanitary requirements. Therefore, and in order to increase flexibility and to reduce financial and administrative burdens, plant passports should be issued by the operators authorised for this purpose by the competent authorities. In order to ensure a reliable framework for those authorisations, harmonised requirements and procedures should be established for the granting and withdrawal of those authorisations, as well as for the supervision of authorised operators by the competent authorities.

(45) However, and since several operators may not have the resources to issue plant passports, the possibility should exist that, upon their request, plant passports are issued by the competent authorities.

(46) Operators issuing plant passports bear enhanced responsibilities concerning the health of the respective goods. Therefore they should ensure advanced knowledge on the concerned harmful organisms and the manners to identify these, eradicate their outbreaks and/or prevent their spread.

(47) Plants, plant products and other objects for which plant passports are required, should be certified through a plant passport after they have been examined concerning their compliance with certain provisions of this Regulation before moving within the Union. Specific rules should be adopted to ensure a level of effective examinations at Union level. For the purpose of reducing the burden of operators and the administration, those rules should also ensure an efficient certification scheme which should be combined, where applicable, with the certification of those plants pursuant to [PRM Regulation].

(48) Harmonised rules should be adopted concerning the logo, information items, form, format, replacement and prohibition of use of the plant passport to ensure the smooth functioning of the internal market in this area.

(49) Plant passports should replace the phytosanitary certificates, once the concerned plants, plant products and other objects enter and are moved within the Union. Moreover, and in order to simplify the respective procedure and reduce the burden of operators, the plant passport should be combined with the official label for plants for planting issued under [PRM Regulation], in case a plant passport and a certification label are required for those plants for planting pursuant to that Regulation and the current one. For reasons of consistency and

transparency, this label should contain the logo and the information required for plant passports.

(50) Harmonised rules should be set out concerning the certification of wood packaging material which is subject to specific provisions of this Regulation. The operators applying treatments of wood packaging material and the specific mark on this material should be authorised, registered and supervised by the Member States to ensure the application of the respective standards.

(51) It is desirable to ensure a harmonised framework for the movement within the Union of certain plants, plant products and other objects intended for export to third countries. In this view harmonised rules should be adopted concerning issuance and the format of the phytosanitary certificates for export and re-export pursuant to the provisions of IPPC. Harmonised rules should also be adopted concerning pre-export documents in which the Member States, where the goods concerned originate, officially attest that those goods comply with certain phytosanitary requirements relevant to export. Moreover, certain conditions should be adopted concerning the documents for transit of plants, plant products and other objects through the Union.

(52) It would be disproportionate to apply the requirements of this Regulation on plants used for trials or scientific purposes, where they are carried out under well controlled conditions and under official supervision.

(53) It would be disproportionate to apply the requirements of this Regulation on plants and plant products sold exclusively on the local market or sold to final users. Therefore the prohibitions and conditions for the above listed harmful organisms, plants, plant products and other objects should not apply where they are subject to those activities.

(54) Council Directives 74/647/EEC and 69/466/EEC set out measures on the control of carnation leaf-rollers and San Jose scale respectively. Since the entry into force of those Directives, the concerned harmful organisms have been widely spread throughout the Union, thus their containment is not feasible any more. Those Directives should therefore be repealed.

(55) In order to assist with implementation of this Regulation, the Commission should establish a team of Union phytosanitary experts to provide assistance to the competent authorities in this respect.

(56) It is desirable to facilitate a more efficient system for the submission of notifications and reports concerning certain measures of this Regulation. The Commission should therefore establish an electronic application system for the notification and reporting on those measures.

(57) *[Recital on four control Directives for potato diseases and repealed secondary acts – SANCO reservation: the decision concerning the exact acts to be repealed, should be taken at a later stage in consultation with the Legal Service]*

Proposal for a

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

**on protective measures against organisms harmful to plants (OJ L ...)**

(Text with EEA relevance)

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 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>11</sup>,

Having regard to the opinion of the Committee of the Regions<sup>12</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

[Initial capital...].

HAVE ADOPTED THIS REGULATION:

## **Chapter I** **General provisions**

### *Article 1*

#### **Subject matter and scope**

1. This Regulation lays down rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products (hereinafter “harmful organisms”) and measures to reduce those risks to an acceptable level.

2. For the purpose of this Regulation, the territories listed in Annex I shall be considered not to belong to the territory of the Union. Any reference in this Regulation to third countries shall be construed as also including those territories.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, supplementing Annex I with further territories which are referred to in Article 355(1) of the Treaty on the Functioning of the European Union and are not situated in Europe.

### *Article 2*

#### **Definitions**

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

1. 'plants' means living plants and the following specified 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;

---

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

<sup>12</sup> OJ C , , p. .

- (h) cut trees retaining foliage;
  - (i) leaves, foliage;
  - (j) plant tissue cultures, including cell cultures, germplasm, meristem tips, chimaeric clones, micro-propagated material;
  - (k) live pollen;
  - (l) buds, bud-wood, cuttings, scions, grafts.
2. 'plant products' means products of plant origin, unprocessed or having undergone simple preparation, in so far as these are not plants and they may present a plant health risk.

Except where it is expressly provided otherwise, wood shall only be considered 'plant product' in one or more of the following cases:

- (a) in so far as it retains all or part of its natural round surface, with or without bark, excluding processed wood produced by glue, heat or pressure or a combination thereof;
- (b) in the form of sawn wood, chips, particles, sawdust, wood waste, shavings or scrap;
- (c) in the form of wood used in supporting, protecting or carrying a commodity, in the form of packing cases, boxes, crates, drums and packings, pallets, box pallets and load boards, pallet collars and dunnage, whether or not actually in use in the transport of objects (hereinafter 'wood packaging material').

Except where it is expressly provided otherwise, bark shall be considered a 'plant product'.

- 3. 'plants for planting' means plants, capable of and intended for producing or reproducing entire plants, which are 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 harmful organisms, including soil or growing medium;
- 5. 'competent authority' means a competent authority as defined in Article 2(2)(b) of [revised Reg. 882/2004];
- 6. 'lot' means a number of units of a single commodity, identifiable for phytosanitary purposes by its homogeneity of composition and origin, forming part of a consignment;
- 7. 'operator' means any person, governed by public or private law, involved professionally in one or more of the following activities concerning plants, plant products and other objects:
  - (a) planting;
  - (b) growing;
  - (c) production;
  - (d) movement into, within and out of the Union;
  - (e) marketing;

8. 'final user' means any person acting for purposes which are outside its trade, business or profession, who receives for his own use small quantities of plants or plant products;
9. 'test' means an official examination, other than visual, to determine if harmful organisms are present or to identify harmful organisms;
10. 'treatment' means a procedure for the killing, inactivation or removal of harmful organisms, or for rendering those organisms infertile or for their devitalisation;
11. 'protected zone' means an area where a specific harmful organism is not present, and which requires protection due to specific phytosanitary risks that that organism poses to that area;
12. 'occurrence' means the presence in an area of a harmful organism officially recognised to be indigenous or introduced and not officially reported to have been eradicated.

## **Chapter II Quarantine organisms**

### **SECTION 1 PROHIBITION AND LISTING OF QUARANTINE ORGANISMS**

#### *Article 3*

#### **Prohibition of introduction and movement of quarantine organisms**

1. A harmful organism is referred to as 'quarantine organism' insofar as it fulfils the following criteria:
  - (a) its identity is sufficiently characterised, in accordance with point (1) of Section 1 of Annex II;
  - (b) it is not present in the Union territory, or, if present, only distributed to a limited extent within the Union territory, in accordance with point (2) of Section 1 of Annex II;
  - (c) it is capable to enter into, establish and spread within the Union territory, or in those parts of it where it is not present, in accordance with point (3) of Section 1 of Annex II;
  - (d) its entry, establishment and spread would have an unacceptable economic, environmental or social impact in accordance with point (4) of Section 1 of Annex II; and
  - (e) feasible and effective measures are available to prevent the entry, establishment and spread of that organism and mitigate its phytosanitary risks and impacts.
2. The introduction into, the movement within, and actions contributing to the establishment and spread in the Union of quarantine organisms shall be prohibited, with the exception of certain quarantine organisms which are present in parts of the Union territory, and for which this Regulation provides that that prohibition shall only apply to certain protected zones.

#### *Article 4*

##### **Listing of Union quarantine organisms**

1. A quarantine organism, as referred to in Article 3, is referred to as 'Union quarantine organism' insofar as its presence would have unacceptable economic, social or environmental impacts for the entire Union.

The introduction of Union quarantine organisms into and their movement within the Union shall be prohibited. That prohibition shall also concern actions contributing to the establishment and spread of those organisms in the Union.

2. The Commission shall establish, by means of an implementing act, a list of Union quarantine organisms.

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

Organisms known to occur in the Union and organisms not known to occur in the Union shall be indicated as such in that list.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2) and amended in accordance with the examination procedure referred to in Article 82(3).

The amendments of that act shall take place in accordance with the criteria set out in paragraph 1 concerning the identification of Union quarantine organisms, in agreement with the criteria set out in Section 1 of Annex II concerning the identification of quarantine organisms, while taking into account the scientific and technical developments.

#### *Article 5*

##### **Priority organisms**

1. A Union quarantine organism is referred to as 'priority organism' insofar as its potential economic, environmental or social impacts are most severe for the Union.
2. The Commission shall list, by means of implementing acts, the priority organisms in accordance with the criteria set out in Section 2 of Annex II. The number of the organisms of that list shall not exceed 10% of the number of the Union quarantine organisms listed pursuant to Article 4(2).

Those implementing acts shall be adopted and, where applicable amended, in accordance with the examination procedure referred to in Article 82(3).

On duly justified imperative grounds of urgency to address a serious risk to plant health, the Commission shall immediately list Union quarantine organisms as priority organisms, by means of implementing acts, in accordance with the procedure referred to in Article 82(4).

#### *Article 6*

##### **Listing of protected zone quarantine organisms**

1. A quarantine organism, as referred to in Article 3, is referred to as 'protected zone quarantine organism' insofar as it is present in the Union territory but absent from specific parts of that territory, and its presence has unacceptable economic, social or environmental impacts only for specific protected zones.

The introduction of protected zone quarantine organisms into and their movement within certain protected zones shall be prohibited. That prohibition shall also concern actions contributing to the establishment and spread of those organisms in those protected zones.

2. The Commission shall establish, by means of an implementing act, a list of protected zone quarantine organisms.

That list shall include the harmful organisms 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 82(2) and amended in accordance with the examination procedure referred to in Article 82(3).

The amendments of that act shall take place in accordance with the criteria set out in paragraph 1 concerning the identification of protected zone quarantine organisms, in agreement with the criteria set out in Section 1 of Annex II concerning the identification of quarantine organisms, while taking into account the scientific and technical developments.

#### *Article 7*

### **Amendment of Annex II**

The Commission shall be empowered to adopt delegated acts in accordance with Article 81 amending Annex II, taking into account the developments of technical and scientific knowledge, and development in international standards.

#### *Article 8*

### **Organisms used for scientific purposes, trials or varietal selections**

The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, setting out conditions under which the prohibition referred to in Article 3 shall not apply to quarantine organisms when used for scientific purposes, trials or varietal selections, while ensuring that the spread of those organisms is obviated.

Those delegated acts may empower the Commission to define, by means of implementing acts, those conditions for specific quarantine organisms. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

## **SECTION 2**

### **MEASURES RELATING TO THE ENTIRE UNION TERRITORY**

#### *Article 9*

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

1. Where anyone, including persons involved in investigations and studies, becomes aware of, or suspects, the presence of a Union quarantine organism, that person shall immediately notify the competent authority.
2. If so requested by the competent authority, the person referred to paragraph 1 shall provide the competent authority with the information concerning the origin and the nature of the material concerned.

#### *Article 10*

### **Confirmation of presence of Union quarantine organisms**

Where a Member State suspects the presence of a Union quarantine organism, in a part of its territory where it was previously not known to be present, it shall immediately take the measures necessary to confirm whether that organism is present or not.

#### *Article 11*

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

1. A Member State shall notify the Commission and the other Member States in any of the following situations:
  - (a) it becomes aware of the presence in its territory of a Union quarantine organism not known to be present in the Union;
  - (b) it becomes aware of the presence in its territory of a Union quarantine organism known to be present in the Union, if that presence is encountered for the first time in a part of its territory where it was previously unknown;
  - (c) it becomes aware of the presence of a Union quarantine organism in a consignment of plants, plant products or other objects introduced into or moved within the Union.
2. The notifications referred to in paragraph 1 shall be submitted within 3 working days following the confirmation by the Member State of the presence of the respective Union quarantine organism pursuant to Article 10.
3. The Commission may, by means of implementing acts, lay down that the obligations referred to in paragraph 1 shall also apply to the suspected presence of specific Union quarantine organisms, which has not been confirmed yet pursuant to Article 10. Those implementing acts shall also determine the time limit within which those notifications shall be submitted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

#### *Article 12*

#### **Information provided to operators by the competent authorities**

Where any of the situations provided for in Article 11(1) arises, the competent authorities shall ensure that operators, whose plants, plant products or other objects may be affected, are immediately informed of the presence of the Union quarantine organism concerned.

#### *Article 13*

#### **Information provided to the public by the competent authorities**

Competent authorities shall inform the public in case priority organisms are found for the first time in the respective Member State, or in parts of that Member State where they were not known to be present. That information shall include the measures imposed by the competent authorities on any person concerned.

#### *Article 14*

#### **Notification of imminent dangers**

1. In case a quarantine organism is not yet present in the Union territory or in particular areas of it, and a Member State has evidence that there is an imminent danger of the introduction of that quarantine organism into, or its establishment or spread within, the Union territory or those areas, that Member State shall immediately notify in writing the Commission and the other Member States of that evidence, and of the

measures which it would like to see taken to protect the Union territory from that organism.

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

#### *Article 15*

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

1. Where an operator becomes aware that a Union quarantine organism is present in plants, plant products and other objects which are under its control, it shall immediately take, in co-ordination with the competent authorities, the measures necessary to eliminate that organism and avoid its spread.
2. Where the plants, plant products or other objects referred to in paragraph 1 have left the control of the operator concerned, that operator shall immediately, in co-ordination with the competent authorities, take measures to effectively and accurately inform the persons under whose control those plants, plant products and other objects would likely be. Where so requested by the competent authorities, it shall immediately initiate procedures to withdraw the plants, plant products and other objects concerned from the market and, where the plants, plant products or other objects may have reached the consumer, to recall them from those consumers.
3. That operator shall provide all necessary information to the competent authority, in order for the latter to inform the public in case actions need to be taken with regards to the plants, plant products and other objects referred to in paragraph 1.

#### *Article 16*

##### **Eradication of Union quarantine organisms**

1. If the presence of a Union quarantine organism is confirmed, the competent authority shall immediately take all necessary measures to eliminate that organism from the area concerned, including measures to prevent its spread out of that area (hereinafter: 'to eradicate').

The measures referred to in this paragraph shall be one or more of the measures listed in Section 1 of Annex III, and shall be taken in accordance with the risk management principles set out in Section 2 of that Annex

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

#### *Article 17*

##### **Establishment of restricted areas**

1. For the implementation of, and in addition to, the measures taken to eradicate the organism concerned pursuant to Article 16(1), the competent authority shall immediately establish a restricted area. That area shall consist of an infested zone and a buffer zone.

The infested zone shall contain at least:

- (a) all plants known to be infested by the organism concerned;
- (b) all plants showing signs or symptoms indicating possible infestation by that organism;
- (c) all other plants liable to be infested by that organism due to close proximity to or common origin with infested plants, or plants grown from them.

The buffer zone shall be an area adjacent to the infested zone and shall surround it. Its size shall be appropriate in view of the risks caused by the capability of the organism concerned to spread naturally.

The buffer zone may not need to be established, if it is assessed that the organism concerned may be eradicated within the infested zone without any probability to spread outside that zone.

2. The establishment of the restricted area shall take place on the basis of a delimiting survey for the presence of the organism concerned in the surrounding area of the location where that organism was found present.
3. By way of derogation to paragraph 1, in cases where it is provisionally assessed that there is no risk of spreading of that organism out of the location where it has been found, the respective competent authority shall first carry out an investigation on the risk of infestation of any plants or plant products. On the basis of that survey, the competent authority shall determine whether there is a need to establish a restricted area. The competent authority shall notify to the Commission and the other Member States the conclusions of that investigation.
4. In the case where a restricted area is required to extend beyond the border with another Member State, the competent authority shall immediately contact the competent authority of that Member State to take all appropriate actions referred to in paragraph 1.

#### *Article 18*

#### **Surveys in the restricted areas and following actions**

1. Member States shall carry out annual surveys on the development of the presence of the organism concerned in the restricted areas referred to in Article 17. Those surveys shall be based on sound scientific and technical principles and shall be carried out at appropriate times with regard to the possibility to detect the potential presence of the concerned organism. In accordance with the results of those surveys, they shall modify the restricted areas, as appropriate.
2. Any further presence of the organism concerned in the buffer zones of restricted areas, detected during those surveys, shall be immediately notified by the Member State concerned to the Commission and the other Member States. Where appropriate, the infested and buffer zones shall be duly modified.
3. Member States may decide to remove a restricted area, provided that the surveys referred to in paragraph 1 confirmed the absence of the organism concerned in that restricted area during a sufficiently long period to allow the confirmation of the absence of that organism. That decision shall take into account the biology of the organism concerned, the presence of host plants, the eco-climatic conditions and the likely success of the eradication measures taken.

### *Article 19*

#### **Progress reports on eradication measures**

Member States shall submit to the Commission and the other Member States, at their request, an annual report on the progress of the eradication measures referred to in Articles 16, 17 and 18.

### *Article 20*

#### **Amendment of Annex III**

The Commission shall be empowered to adopt delegated acts in accordance with Article 81, amending Annex III, taking into account the developments of technical and scientific knowledge, and development in international standards.

### *Article 21*

#### **Surveys for quarantine organisms**

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

This Article shall not apply to protected zone quarantine organisms.

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

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

3. Member States shall notify the programmes referred to in paragraph 2 to the Commission and the other Member States at their initiation. Annual reports of the results of those surveys shall be notified to the Commission and the other Member States by 30 April of the following year.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, amending the elements to be included in the programmes referred to in the second subparagraph of paragraph 2.

### *Article 22*

#### **Surveys on priority organisms**

1. In addition to the surveys provided for in Article 21(1), Member States shall carry out specific surveys for each priority organism on their territories, on an annual basis.

Those surveys shall, compared to the surveys referred to in Article 21(1), include an increased number of inspections, samples and tests, as appropriate for the relevant organisms.

The Commission shall, by means of implementing acts, set out requirements for the number of inspections, samples and tests for particular priority organisms. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

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

#### *Article 23*

#### **Contingency plans for priority organisms**

1. Each Member State shall prepare, for each priority organism which may enter into and establish in its territory, a separate plan setting out the actions to be taken in case of a confirmed or suspected presence of such an organism, hereinafter ‘the contingency plan’.
2. The contingency plan shall set out the following:
  - (a) the roles and responsibilities of the bodies involved in those actions;
  - (b) provisions for communication of any presence of priority organisms and respective measures to the Commission, the other Member States, the operators concerned and the public;
  - (c) provisions for recording of findings of the presence of the priority organisms concerned;
  - (d) measures to be taken for the eradication of the priority organisms concerned;
  - (e) provisions for laboratory testing; and
  - (f) provisions for training of personnel of the competent authorities.
3. Member States shall provide for the evaluation and review of their contingency plans.
4. Member States shall communicate their contingency plans to the Commission and to the other Member States upon request.

#### *Article 24*

#### **Eradication programmes for priority organisms**

1. In the case of confirmation of the presence of a priority organism in the territory of a Member State pursuant to Article 10, the concerned competent authority shall immediately determine and specify, through an eradication programme, the precise measures it intends to take pursuant to Articles 16 and 17 to eradicate the organism concerned. That programme shall include a description of the design and organisation of surveys and figures for the planned number of inspections, samples to be taken and laboratory tests to be carried out.
2. Member States shall notify to the Commission and the other Member States the eradication programmes referred to in paragraph 1 at their request.

## *Article 25*

### **Permanent Union measures for specific Union quarantine organisms**

1. The Commission shall adopt, by means of implementing acts, measures ensuring the harmonised application of Articles 15, 16 and 17 concerning the eradication of specific Union quarantine organisms and restriction measures to be taken, Article 18 concerning the surveys in restricted areas and following actions, Article 21 concerning the surveys to be carried out, and Articles 23 and 24 concerning contingency plans and eradication programmes for those organisms and, where applicable, plants, plant products and other objects which may host them. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).
2. In the case the Commission concludes, on the basis of the surveys referred to in Article 18 or any other evidence, that the eradication of the concerned organism is not possible in certain restricted areas, the implementing acts referred to in paragraph 1 may set out measures with the single purpose to prevent the spread of those organisms out of those areas (hereinafter: 'to contain'). In the case of a priority organism, the concerned competent authority shall adopt a programme for the purpose of containment of that organism. The provisions of Article 24 shall apply accordingly concerning that programme.
3. The implementing acts referred to in paragraph 1 may set out that specific additional protective measures are taken and intensified surveys are carried out in certain areas, outside the restricted areas established pursuant to Article 17, to ensure the protection of the Union territory from the organisms concerned.
4. The measures referred to in paragraphs 1 to 3 shall be taken in accordance with the provisions of Annex III, taking into account the specific risks of the respective organisms and the need to implement the necessary risk mitigation measures in a harmonised manner at Union level.
5. The Commission shall follow the development of the situation and, where appropriate, shall amend or repeal the measures referred to in paragraphs 1 to 3, in accordance with the procedure referred to in paragraph 1.
6. On duly justified imperative grounds of urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable emergency measures, by means of implementing acts, in accordance with the procedure referred to in Article 82(4).

## *Article 26*

### **Temporary measures by Member States**

1. Where a Member State becomes aware of the presence in its territory of an organism which may qualify as a Union quarantine organism, but which is not listed as such pursuant to Article 4(2), it shall immediately carry out a preliminary assessment of the phytosanitary risk posed by that organism. That assessment shall take place in accordance with the criteria set out in Section 3 of Annex II.
2. In the case the Member State concludes, on the basis of the assessment referred to in paragraph 1, that the organism concerned is likely to qualify as a Union quarantine organism, it shall immediately take temporary eradication measures. Articles 16 and 17 shall apply accordingly for those eradication measures. Those measures shall be

taken in accordance with the risk management principles set out in Section 2 of Annex III.

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

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

#### *Article 27*

#### **Temporary Union measures**

1. Following the notification referred to in Article 26(3) and (4), or any other relevant evidence concerning the presence in, or imminent danger for entry into, the Union territory of an organism which is likely to qualify as a Union quarantine organism, but which is not listed as such pursuant to Article 4(2), the Commission shall preliminarily assess the phytosanitary risk posed by that organism for the Union territory. That assessment shall take place in accordance with the criteria set out in Section 3 of Annex II.
2. In the case the Commission concludes, on the basis of the assessment referred to in paragraph 1, that the organism concerned is likely to qualify as a Union quarantine organism, it shall adopt as appropriate, by means of implementing acts, temporary measures to mitigate the respective phytosanitary risks. Those measures shall concern, as appropriate, the notification of the presence of the quarantine organism concerned, eradication and establishment of restricted areas, the surveys to be carried out, the contingency and eradication programmes for that organism and, where applicable, plants, plant products and other objects which may host it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).
3. In the case the Commission concludes, on the basis of surveys or any other evidence, that the eradication of the concerned organism is not possible in certain restricted areas, the implementing acts referred to in paragraph 2 may set out measures with the single purpose to contain those organisms.
4. The implementing acts referred to in paragraph 2 may set out that specific additional protective measures are taken and intensified surveys are carried out in certain areas, outside the restricted areas established pursuant to paragraph 2, to ensure the protection of the Union territory from the organisms concerned.
5. The measures referred to in paragraphs 2 to 4 shall be taken in accordance with the provisions of Annex III, taking into account the specific risks of the respective organisms and the need to implement the necessary risk mitigation measures in a harmonised manner at Union level.
6. The implementing acts referred to in paragraph 2 may provide that the measures taken by the Member States pursuant to Article 26 are to be repealed or amended. Until a measure has been adopted under the aforesaid procedure, the Member State may maintain the measures that it has employed.

7. The Commission shall follow the development of the situation and, where appropriate, shall amend or repeal the measures referred to in paragraphs 2 to 4, in accordance with the procedure referred to in paragraph 2.
8. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable emergency measures, by means of implementing acts, in accordance with the procedure referred to in Article 82(4).

#### *Article 28*

#### **More stringent requirements adopted by Member States**

1. Member States may apply within their territories more stringent measures than the measures adopted pursuant to Articles 25(1) to (3) and Articles 27(2) to (4), if so justified by the objective of phytosanitary protection and in accordance with the provisions of Annex III.

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

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

### **SECTION 3**

#### **MEASURES CONCERNING PROTECTED ZONES**

#### *Article 29*

#### **Requirements for qualification as protected zone**

A geographic area in the Union territory shall qualify as a protected zone for a particular protected zone quarantine organism, as referred to in Article 6(1), if it complies with the criteria set out by the FAO International Standard for Phytosanitary Measures (ISPM) No 4<sup>13</sup> concerning a pest free area, and further fulfils the following criteria:

- (a) the concerned organism is present in the Union but is not present in that area;
- (b) the concerned organism is capable to enter into, establish and spread within that area, as identified in accordance with the criteria set out in Section 1 of Annex II;
- (c) the entry, establishment and spread of the concerned organism has unacceptable economic, environmental or social impacts in that area, as identified in accordance with the criteria set out in Section 3 of Annex II; and
- (d) feasible and effective measures are available to prevent the entry, establishment and spread of the concerned organism and to mitigate its phytosanitary risks and impacts in that area.

---

<sup>13</sup> Food and Agriculture Organisation of the United Nations, Rome, 2011. International Standards for Phytosanitary Measures No 4: Requirements for the establishment of pest-free areas (1995).

### *Article 30*

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

1. The Commission shall recognise, by means of an implementing act, the protected zones recognised by Regulation (EC) No 690/2008. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
2. The Commission may recognise, by means of an implementing act, further protected zones with respect to specified quarantine organisms. That recognition may only take place if it is concluded, on the basis of the assessment by the Commission of the available evidence, that the requirements of Article 29 are fulfilled. That evidence shall include reports from surveys during the three previous years concerning the presence or absence of the relevant quarantine organism from the proposed protected zone. Those surveys shall have been carried out at appropriate times with regards to the possibility to detect the potential presence of the concerned organism and have been based on sound scientific and technical principles.

The implementing act referred to in subparagraph 1 shall be adopted and amended in accordance with the examination procedure referred to in Article 82(3).

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones.

### *Article 31*

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

1. The obligations laid down in Articles 9 to 12 concerning the confirmation, notification and information of the presence of Union quarantine organisms, in Article 15 concerning measures to be taken by the operators in relation to Union quarantine organisms and in Articles 16, 17 and 18 concerning the eradication of Union quarantine organisms and the establishment of restricted areas shall apply accordingly for the protected zone quarantine organisms with regard to the respective protected zones.
2. The restricted areas established within a protected zone and the eradication measures taken in those areas pursuant to paragraph 1 shall be immediately notified to the Commission and the other Member States.

### *Article 32*

#### **Surveys on protected zone quarantine organisms**

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

The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, laying down detailed rules for surveys to be carried out for purposes of this paragraph.

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

*Article 33*

**Revocation or amendment of the protected zones**

1. The Commission shall revoke, upon the request of the Member State concerned, the recognition of a protected zone.
2. The Commission shall revoke the recognition of a protected zone in case the surveys referred to in Article 32 have not been carried out in accordance with Article 32(1).
3. The Commission shall revoke the recognition of a protected zone in case the respective protected zone quarantine organism has been found present in that zone and one of the following conditions is fulfilled:
  - (a) no restricted area has been designated, in accordance with Article 17, within three months after the presence of that organism was confirmed;
  - (b) the eradication measures taken in a restricted area pursuant to Article 31(1) have not been successful within 24 months after the presence of that organism was confirmed;
  - (c) reports of official investigations by the Commission demonstrate major negligent reaction to the presence of that organism in the concerned protected zone.
4. By derogation to point 3(b), the boundaries of the protected zone may be modified, on the request of the Member State concerned, to exclude that restricted area.

In that case, the Member State concerned shall notify the Commission, the other Member States and, via the internet, the operators of the amended boundaries of that protected zone, including maps.
5. In case paragraphs 1, 2, 3 or 4 apply, the Commission shall revoke, or where applicable modify the boundaries of, the protected zone concerned, by means of an implementing act. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 82(3).

## **Chapter III**

### **Quality organisms**

#### *Article 34*

#### **Prohibition of presence of quality organisms**

1. A harmful organism is referred to as a 'quality organism' insofar as it fulfils the following criteria:
  - (a) its identity is sufficiently characterised, in accordance with point (1) of Section 4 of Annex II;
  - (b) it is present in the Union and it does not qualify as a Union quarantine organism, in accordance with point (2) of Section 4 of Annex II;
  - (c) it is transmitted mainly through specific plants for planting, in accordance with point (3) of Section 4 of Annex II;
  - (d) its presence on those plants for planting has unacceptable economic impacts on the intended use of those plants for planting, in accordance with point (4) of Section 4 of Annex II;
  - (e) feasible and effective measures are available to prevent the presence of that organism on the plants for planting concerned and to mitigate its impacts.
2. The presence of quality organisms on the plants for planting concerned shall be prohibited.

By way of derogation from the first subparagraph, the presence of quality organisms on certain plants for planting shall be prohibited when they exceed certain thresholds, established in accordance with the risk management principles set out in Section 2 of Annex III, and only if the following conditions are fulfilled:

- (a) the presence of those organisms on the specified plants for planting is economically acceptable only below those thresholds;
- (b) it is possible to ensure that the presence of those organisms on the specified plants for planting does not exceed those thresholds by measures concerning the area or place of production of those plants for planting, their parent stock or the lots of those plants for planting; and
- (c) it is possible to verify that the threshold set is not exceeded in lots of those plants for planting.

Subparagraph 1 shall apply without prejudice to the prohibitions concerning the introduction into and the movement within protected zones of the protected zone quarantine organisms referred to in Article 6(1).

#### *Article 35*

#### **Listing of quality organisms**

1. The Commission shall establish, by means of an implementing act, a list of quality organisms. Where applicable, that list may also include specific prohibitions or thresholds concerning the presence of quality organisms on one or more of the following categories in the meaning of Article 11 of [PRM Regulation]:
  - (a) pre-basic material;

- (b) basic material;
- (c) certified material;
- (d) standard material.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

2. The list referred to in paragraph 1 shall include the harmful organisms, and where applicable the thresholds, listed in the following acts:
  - (a) Section II of Part A of Annex II of Directive 2000/29/EC;
  - (b) Annex I, points (3) and (6), and Annex II, point (3), to Council Directive 66/402/EEC on the marketing of cereal seed;
  - (c) the Annex of Directive 93/48/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by fruit plant propagating material and fruit plants intended for fruit production, pursuant to Council Directive 92/34/EEC;
  - (d) the Annex of Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC;
  - (e) Annex II, point (b) of Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed;
  - (f) Annex I, point 6 and Annex II, point B of 2002/56/EC of 13 June 2002 on the marketing of seed potatoes;
  - (g) Annex I, point 4 and Annex II, point 5, of Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants.

This paragraph shall not apply in the case where the harmful organisms concerned qualify as Union quarantine organisms pursuant to Article 4.

3. The implementing act referred to in paragraph 1 may be amended in accordance with the examination procedure referred to in Article 82(3). That amendment shall take place in accordance with the criteria set out in Section 4 of Annex II, while taking into account the scientific and technical developments.

#### *Article 36*

#### **Exception for scientific purposes, trials or varietal selections**

The prohibition referred to in Article 34(2) shall not apply to quality organisms when used for scientific purposes, trials or varietal selections.

## **Chapter IV**

### **Measures concerning plants, plant products and other objects**

#### **SECTION 1**

#### **MEASURES RELATING TO THE ENTIRE UNION TERRITORY**

#### **Subsection 1**

#### **Permanent measures**

### *Article 37*

#### **Listing of plants, plant products and other objects subject to specific requirements**

1. Plants, plant products and other objects which are likely to host Union quarantine organisms, shall be subject, when introduced into or moved within the Union territory, to specific requirements, if they pose a phytosanitary risk which may only be reduced to an acceptable level by the application of those requirements.
2. The Commission shall establish, by means of an implementing act, a list of the plants, plant products and other objects, and the respective requirements referred to in Annex IV, Part A to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
3. The implementing act referred to in paragraph 2 may be amended in accordance with the examination procedure referred to in Article 82(3). Those amendments shall include the listing of the plants, plant products and other objects, and the respective requirements for their introduction into and movement within the Union, as referred to in paragraph 1.

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

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

Where appropriate, those requirements may include approvals of:

- (a) areas in third countries or Member States as free from certain quarantine organisms;
  - (b) methods to verify compliance of plants, plant products and other objects with the requirements of Article 61(2);
  - (c) treatment methods or treatment products;
  - (d) seed production methods.
4. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 82(4).

### *Article 38*

#### **Equivalent phytosanitary measures of third countries**

1. The Commission may recognise, by means of implementing acts, phytosanitary measures adopted by a third country for export to the Union as equivalent to certain requirements, laid down pursuant to Article 37(2), concerning the introduction into the Union of those plants, plant products and other objects, where the following conditions are fulfilled:

- (a) the third country concerned objectively demonstrates that its measures achieve the Union's appropriate level of phytosanitary protection for those plants, plant products and other objects concerned; and
- (b) the scientific and technical justification of that demonstration is confirmed by a risk assessment.

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

2. The implementing acts referred to in paragraph 1 shall be adopted, and where applicable amended or repealed, in accordance with the examination procedure referred to in Article 82(3).

#### *Article 39*

#### **Listing of plants, plant products and other objects the introduction of which into the Union shall be prohibited**

1. The introduction into the Union of plants, plant products and other objects which are likely to host Union quarantine organisms shall be prohibited if they pose a phytosanitary risk which cannot be reduced to an acceptable level by any specific requirements.
2. The Commission shall establish, by means of an implementing act, a list of the plants, plant products and other objects, and the respective third countries of origin and prohibitions referred to in Annex III, Part A of Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
3. The implementing act referred to in paragraph 2 may be amended in accordance with the examination procedure referred to in Article 82(3). Those amendments shall include the listing of the plants, plant products and other objects, and the respective third countries of origin to which the prohibitions referred to in the paragraph 1 apply.  
Those amendments shall take place in accordance with the risk management principles set out in Section 2 of Annex III, while taking into account the scientific and technical developments.
4. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 82(4).

#### *Article 40*

#### **Derogations from requirements or prohibitions**

1. The Commission may decide, by means of implementing acts, to provide for derogations from certain requirements, laid down pursuant to Article 37(2), and certain prohibitions, laid down pursuant to Article 39(2), concerning the introduction into the Union of plants, plant products and other objects from certain third countries, where the following conditions are fulfilled:
  - (a) the risk of the introduction into the Union territory of Union quarantine organisms is eliminated by alternative measures adopted, in accordance with

- the provisions of Annex III, concerning the origin of those plants, plant products or other objects, their treatment or special precautions for their use;
- (b) the scientific and technical justification of the elimination of that risk is confirmed by a risk assessment, where appropriate supplemented by investigations by the Commission in accordance with [Article 72 of Regulation 882] in the country of origin of those plants, plant products or other objects; and
  - (c) the compliance with those alternative measures is attested on the phytosanitary certificate accompanying those plants, plant products and other objects.
2. The implementing acts referred to in paragraph 1 shall be adopted, and where applicable amended or repealed, in accordance with the examination procedure referred to in Article 82(3).

#### *Article 41*

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

1. Provided that there is no risk of quarantine organisms spreading, any requirements or prohibitions adopted pursuant to Articles 37(3) and 39(3) concerning introduction into the Union shall not apply to plants, plant products and other objects which are grown, produced or used in the immediate frontier zones of Member States with third countries and are introduced into the Union in order to be worked in nearby locations in the respective frontier zone. Those plants, plant products and other objects shall only move into and within those locations under the official control of the competent authorities. They shall not move outside those locations and within the other parts of the Union.
  2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, setting out the width of frontier zones and distance of locations from the border and setting out the procedures concerning the authorisation of trans-border movements in accordance with paragraph 1.
  3. The Commission may lay down, by means of implementing acts, specific conditions for the introduction into the Union of particular plants, plant products and other objects, and specific third countries, which are subject to this Article.
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

#### **Subsection 2**

##### **Temporary measures**

#### *Article 42*

##### **Plants for planting presenting new risks**

1. Plants for planting from specified third countries which are likely to pose previously unidentified or newly emerging phytosanitary risks, and for which there is limited experience with trade, may be subject to temporary measures concerning their introduction into the Union. The Commission may adopt such temporary measures, by means of implementing acts, those measures in accordance with the examination procedure referred to in Article 82(3).

2. The measures referred to in paragraph 1 shall be adopted on the basis of preliminary evidence that the plants for planting concerned are likely to host Union quarantine organisms, in accordance with the criteria set out in Section 5 of Annex II. Taking account of the risk management principles set out in Section 2 of Annex III, the measures shall be one of the following:
  - (a) physical checks for quarantine organisms of each lot of the introduced plants, plant products or other objects, on the basis of an intensified sampling and testing regime;
  - (b) imposition of a quarantine period to verify the absence in those plants, plant products and other objects of quarantine organisms, in case this absence cannot be reliably confirmed through checks at the introduction of the plant, plant product or other object concerned into the Union territory;
  - (c) prohibition of introduction into the Union.In addition, those measures may set out that specific plants for planting shall be subject to certification requirements, where this would be necessary to prevent the entry into, and establishment and spread within the Union of the organisms concerned.
3. The measures referred to in paragraph 1 shall have a duration of a maximum of two years. This period may be only once prolonged for two further years, if the circumstances referred to in paragraph 1 remain and justify such a prolongation. In this case, the measures referred to in paragraph 1 may be amended as appropriate.
4. On duly justified imperative grounds of extreme urgency to address a serious risk to plant health, the Commission shall adopt immediately applicable emergency measures, by means of implementing acts, in accordance with the procedure referred to in Article 82(4).

## **SECTION 2**

### **MEASURES RELATING TO PROTECTED ZONES**

#### *Article 43*

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

1. Plants, plant products and other objects which are likely to host protected zone quarantine organisms shall be subject, when introduced into or moved within the respective protected zones, to specific requirements, if they pose a phytosanitary risk to those protected zones which may only be reduced to an acceptable level by the application of those requirements.
2. The Commission shall establish, by means of an implementing act, a list of the plants, plant products and other objects, the respective protected zones and the respective requirements referred to in Annex IV, Part B to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
3. The implementing act referred to in paragraph 2 shall be amended in accordance with the examination procedure referred to in Article 82(3). Those amendments may include the listing of plants, plant products and other objects, and the respective requirements for their introduction into and movement within the respective protected zones. Those acts may restrict the application of those requirements to

plants, plant products and other objects originating in specific areas, where the harmful organisms concerned are known to be present.

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

#### *Article 44*

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

1. The introduction into specified protected zones of plants, plant products and other objects which are likely to host protected zone quarantine organisms shall be prohibited, if they pose a phytosanitary risk to those protected zones which cannot be reduced to an acceptable level by any specific requirements.
2. The Commission shall establish, by means of an implementing act, a list the plants, plant products and other objects, and the respective areas of origin, and the respective prohibitions referred to in Annex III, Part B to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
3. The implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 82(3). Those amendments shall take place in accordance with the risk management principles set out in Section 2 of Annex III, while taking into account the scientific and technical developments.

#### *Article 45*

##### **Derogations and equivalence**

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

#### *Article 46*

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

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

### **SECTION 3**

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

#### *Article 47*

##### **Exceptions for scientific purposes, trials and varietal selection**

The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, setting out conditions under which the specific requirements and prohibitions for the Union territory referred to in Articles 37, 39 and 42, and for certain protected zones referred to in Articles 43 and 44, shall not apply to plants, plant products and other objects when used for scientific purposes, trials, varietal selections or exhibitions, while ensuring that the spread of

quarantine organisms from those plants, plant products and other objects is rendered impossible.

Those delegated acts may empower the Commission to define, by means of implementing acts, those conditions for specific plants, plant products and other objects. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

#### *Article 48*

##### **General requirements for vehicles, packaging and documentation**

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

#### *Article 49*

##### **Quarantine facilities**

1. If so required by acts adopted pursuant to Articles 16, 25, 26, 27, 31 concerning eradication measures, or Articles 37, 38, 40 or 42 concerning specific requirements, Member States shall designate quarantine facilities in their territory or authorise the use of designated quarantine facilities in other Member States.
2. Quarantine facilities shall be designated by the competent authorities at the request of any person or on the initiative of the competent authorities, provided that the conditions in paragraphs 3 to 6 are fulfilled.
3. Quarantine facilities shall meet the following technical biosecurity standards:
  - (a) physical isolation of the plants from other areas, including offices used by personnel, and adequate safeguards to ensure plants cannot be accessed or removed from the station without appropriate authorisation;
  - (b) provision of suitable growing conditions conducive for the development on those plants of signs and symptoms of quarantine organisms;
  - (c) surfaces constructed of smooth and impervious material for cleaning and effective decontamination and resistant to deterioration and to attack by insects and other arthropods;
  - (d) irrigation, sewage and ventilation systems prohibiting transmission or escape of quarantine organisms;
  - (e) systems for sterilisation, decontamination or destruction of waste, including infested plants and materials, and equipment before removal from the station;
  - (f) protective clothing and shoe covering to be worn by all personnel and visitors and removed on exit from the stations and if appropriate decontamination of personnel upon exit of the station.

4. Quarantine facilities shall have access to the necessary diagnostic expertise.
5. Quarantine facilities shall keep records of their activities, the staff authorised to enter the facility, visitors having entered the facility, the consignments of plants kept in the facility, their place of origin and reports of the observations and findings made on those plants, and completion of the required quarantine periods.
6. Quarantine facilities shall have systems in place for monitoring for the presence of quarantine organisms in the facilities and their vicinity, the notification of findings of the presence of those organisms to the competent authorities and action in case of those findings.
7. Plants shall be released from the quarantine facilities, by the competent authorities, only if they are found to be free from quarantine organisms after completion of a quarantine period, the duration of which shall be based on technical-scientific evidence.
8. The competent authorities shall supervise the quarantine facilities and carry out audits on a regular basis to ensure that the facilities meet the requirements referred to in paragraphs 3 to 7. In case it is concluded, on the basis of the results of those audits, that those requirements are no longer met, the competent authorities shall ensure immediate action to restore compliance or revoke the designation of the quarantine facility.
9. Member States shall communicate a list of the designated quarantine facilities in their territory to the Commission and the other Member States upon the request of one of them.

#### *Article 50*

#### **Notifications of non-compliance**

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

#### *Article 51*

#### **Export from the Union**

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

## **Chapter V**

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

#### *Article 52*

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

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

The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, listing the categories of operators subject to this Article. Those delegated acts may specify particular requirements for the registration of certain categories of operators.

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

#### *Article 53*

##### **Procedure for inclusion in the register**

1. Operators referred to in Article 52(1 and 2) shall submit an application to the competent authorities for inclusion in the register.
2. The competent authorities shall adopt a decision, on the basis of the application of the operator, concerning its inclusion in the register.
3. The competent authorities shall revoke the registration if the operator so requests, or they conclude that the operator does not fulfil the criteria of Article 2(8) of this Regulation or, where applicable, of Article 3(4) of [PRM Regulation].

#### *Article 54*

##### **Content of the register**

The register shall contain:

- (a) name and address of the operator, including the contact details;
- (b) address of the premises involved in the activities, including, where applicable, collective warehouses or dispatching centres in the respective production areas;
- (c) official registration number and the code indicated in norm ISO 3166-1 for the Member State in which the operator is registered;
- (d) the activities exercised, as referred to in Article 2(8) with a statement whether the operator concerned issues plants passports or applies the mark referred to in accordance with Annex II to the FAO International Standard for Phytosanitary Measures No 15 on *Regulation of wood packaging material in international trade*<sup>14</sup>, or carries out imports, exports and/or sales through distance contracts;

---

<sup>14</sup> Food and Agriculture Organisation of the United Nations, Rome, 2011. International Standard for Phytosanitary Measures 15: Regulation of wood packaging material in International trade (2009).

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

#### *Article 55*

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

1. The information contained in the official registers shall be made available to any competent authority or the Commission at their request.
2. The information contained in Article 54 (a, c and e) shall be made available to any operator at its request.

#### *Article 56*

##### **Traceability**

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

## **Chapter VI**

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

#### **SECTION 1**

##### **PHYTOSANITARY CERTIFICATES REQUIRED FOR PLANTS, PLANT PRODUCTS AND OTHER OBJECTS**

#### *Article 57*

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

1. The introduction into the Union of certain plants, plant products and other objects shall only be allowed if they are accompanied by a phytosanitary certificate or a phytosanitary certificate for re-export (hereinafter 'phytosanitary certificate').
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, listing the plants, plant products and other objects, and the respective

third countries, for which phytosanitary certificates are required for their introduction into the Union.

Those lists shall include at least:

- (a) plants for planting, other than seeds;
- (b) (the plants, plant products and other objects listed in Annex V, Part B (I) of Directive 2000/29/EC, other than the plants for planting referred to in point (a);
- (c) other plants, plant products and other objects listed pursuant to Articles 37(2), or subject to the measures referred to in Articles 38(1) and 40(1);
- (d) seeds listed pursuant to Article 35(1);
- (e) plants, plant products and other objects for which measures have been adopted pursuant to Article 25(1) concerning their introduction into the Union.

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

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, listing the plants, plant products and other objects, and the respective third countries, for which phytosanitary certificates are only required for their introduction into certain protected zones.

Those lists shall include at least:

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

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

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

#### *Article 58*

##### **Conditions for validity of phytosanitary certificate**

1. In the case of a third country which is party to the IPPC, the phytosanitary certificates shall only be valid if they have been issued by representatives of the official national plant protection organisation of that third country or, under their

responsibility, by other public officers who are technically qualified and duly authorised by the concerned official national plant protection organisation.

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

2. In addition to the requirements referred to in paragraph 1, the phytosanitary certificates shall only be valid if they have been issued pursuant to the following requirements:
  - (a) they have been issued in at least one of the official languages of the Union;
  - (b) they have been issued in compliance with the provisions of the IPPC;
  - (c) they are addressed to the Union or one of its Member States;
  - (d) they have been issued no more than 14 days before the date on which the plants, plant products or other objects covered by them have left the third country in which they were issued;
  - (e) where applicable they specify, under the heading 'Additional Declaration' and in accordance with the implementing acts adopted pursuant to Articles 37(2) and 43(2), which special requirement out of those listed as alternatives in the relevant provision of those acts have been complied with. This specification shall be given through reference to the relevant provision of those acts;
  - (f) where applicable, they attest compliance with the phytosanitary measures recognised pursuant to Article 38;
  - (g) they contain information in accordance with the relevant models specified in the Annex to the IPPC.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, specifying the conditions for the validity of phytosanitary certificates by third countries which are not a party to the IPPC.
4. The Commission may adopt, by means of implementing acts, the format of the phytosanitary certificates issued by third countries. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
5. Electronic phytosanitary certificates shall only be valid when provided through the computerised information management system referred to in Article [80 of revised Regulation 882/2004].

#### *Article 59*

#### **Cancellation of phytosanitary certificate**

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

**SECTION 2**  
**PLANT PASSPORTS REQUIRED FOR THE MOVEMENT OF PLANTS, PLANT PRODUCTS**  
**AND OTHER OBJECTS WITHIN THE UNION**

*Article 60*

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

1. The movement within the Union of certain plants, plant products and other objects shall only be allowed if they are accompanied by an official label attesting compliance with certain phytosanitary requirements of this Regulation (hereinafter: 'plant passport').
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, listing the plants, plant products and other objects, for which plant passports are required for their movement within the Union.

Those lists shall include at least:

- (a) plants for planting, other than seeds;
- (b) the plants, plant products and other objects listed in Annex V, Part A (I) of Directive 2000/29/EC, other than the plants for planting referred to in point (a);
- (c) other plants, plant products and other objects listed pursuant to Articles 37(2), or subject to the measures referred to in Articles 38(1) and 40(1);
- (d) seeds listed pursuant to Article 35(1);
- (e) plants, plant products and other objects for which measures have been adopted pursuant to Article 25(1) concerning their movement within the Union.

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

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, listing the plants, plant products and other objects, for which plant passports are only required for their movement into and within certain protected zones.

Those lists shall include at least:

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

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

4. The plant passport referred to in paragraph 1 shall attest, as applicable, compliance with the provisions of the Articles referred to in paragraphs 2 and 3, as well as with the provisions of Articles 5 and 7.

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

#### *Article 61*

##### **Exception for final users**

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

#### *Article 62*

##### **Exceptions for local movements**

1. No plant passport shall be required for the following movements, provided that there is no risk of spreading of quarantine organisms:
  - (a) the local movement of plants, plant products and other objects within specific limited parts of a Member State, originating from small operators whose entire production and sale of plants, plant products and other objects are destined for final users on the local market;
  - (b) the movements of plants, plant products and other objects between the premises of the same operator over short distances.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 81 setting out specified limits for the sizes of small operators, local markets and short distances.

#### *Article 63*

##### **Logo and information items**

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

#### *Article 64*

##### **Form and format**

1. The plant passport referred to in Article 60(1) and 60(3) shall contain the indication 'Plant Passport'.

The plant passports referred to in Article 60(2) shall in addition contain the indication 'ZP' (Zona Protecta) and the scientific name of the harmful organism relevant to the concerned protected zones and shall have a different colour than the plant passport referred to in the first subparagraph.

2. The plant passports referred to in Article 60(1), 60(2) and 60(3) shall be issued in the form of a distinct label, which may be printed in any legible size on any suitable substrate, provided that the plant passport is kept separate from the other information on that label.

The information referred to in Article 63(1) and in paragraph 1 shall be provided in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

3. The format of the plant passports referred to in Article 60(1), 60(2) and 60(3) shall be harmonised for the entire Union.

The Commission shall adopt, by means of an implementing act, a harmonised format for the plant passports referred to in subparagraph 1. That act shall set out the size and colour of the plant passports, the logo referred to in Article 63(1) as well as the font and font size to be used. Different sizes may be specified for specific types of plants, plant products or other objects.

That act shall be adopted within one year after the entry into force of this Regulation, in accordance with the advisory procedure referred to in Article 82(2).

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

#### *Article 65*

##### **Official label of plant reproductive material**

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

#### *Article 66*

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

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

#### *Article 67*

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

1. Plant passports for the entire Union territory shall be issued provided that the concerned plants, plant products and other objects and their packaging are

meticulously examined, either in their entirety or by representative samples of the plants, plant products and other objects concerned and it is concluded that:

- (a) they are free from Union quarantine organisms;
  - (b) they comply with the provisions of Article 35(1) concerning the presence of quality organisms on plants for planting;
  - (c) they comply with the requirements adopted concerning plants, plant products and other objects in accordance with Articles 37(2); and
  - (d) where applicable, they comply with the provisions of 38(1) and 40(1).
2. Plant passports for protected zones shall be issued provided that the concerned plants, plant products and other objects and their packaging are meticulously examined, either in their entirety or by representative samples of the plants, plant products and other objects concerned and it is concluded that:
- (a) they are free from the respective protected zone quarantine organisms;
  - (b) (they comply with the provisions of Articles 35(1) concerning the presence of quality organisms on plants for planting;
  - (c) they comply with the requirements concerning plants, plant products and other objects adopted in accordance with Article 43(2); and
  - (d) where applicable, they comply with the provisions of Articles 38(1) and 40(1) pursuant to Article 45.
3. The examinations of the plants, plant products and other objects referred to in paragraphs 1 and 2 shall be carried out by the operators, or where applicable by the competent authorities, who issue the plant passports pursuant to Article 66. Those examinations shall be carried out in accordance with the following conditions:
- (a) they shall be carried out regularly, at appropriate times and on the basis of the related risk;
  - (b) they shall be carried out in the premises of the operators and in their immediate vicinity;
  - (c) they shall extend to the relevant plants for planting or plant products grown, produced or used by the producer, or otherwise present on its premises, as well as to the growing medium used there; and
  - (d) they shall be made at least by visual observation, without prejudice to any specific examination requirements or measures adopted in accordance with Article 25(1), 27(2), 37(2), 38(1), 40(1), 42(1) and 43(2).
4. The Commission may adopt, by means of implementing acts, modalities concerning the methods for and frequency and timing of the examinations referred to in paragraph 3, with regard to specific plants, plant products and other objects, and on the basis of the particular phytosanitary risks they may present. Those implementing acts shall take into account the technical and scientific knowledge and developments. Those implementing acts shall be adopted, and where appropriate amended, in accordance with the examination procedure referred to in Article 82(3).

### *Article 68*

#### **Examinations as parts of certification schemes for plants for planting**

1. The Commission may adopt, by means of implementing acts, specific modalities for the examination methods during the production of certain plants for planting and, where appropriate, their number of generations, hybrids or subdivision of categories into grades satisfying different conditions. Those modalities may include the methods referred to in Article 67(4) and shall take into account the technical and scientific knowledge and developments.

Those implementing acts shall be adopted, and where appropriate amended, in accordance with the examination procedure referred to in Article 82(3).

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

### *Article 69*

#### **Conditions for authorisation of operators to issue plant passports**

1. Operators shall be authorised by the competent authorities to issue plant passports only where they comply with the following conditions:
  - (a) they possess the necessary knowledge to carry out the examinations referred to in Article 67 and 68 concerning the quarantine and quality organisms that could affect the relevant plants, plant products and other objects and their signs and symptoms;
  - (b) they shall possess the necessary knowledge concerning the means to prevent the presence and spread of those organisms, the means to eradicate them and provide the relevant training to their personnel;
  - (c) they identify and monitor the critical points of the production process as concerns compliance of those plants with the provisions referred to in Article 67(1, 2), and keep records of this;
  - (d) they ensure that the risks of infestation by the organisms concerned are adequately mitigated;
  - (e) they have in place systems and procedures enabling them to fulfil their obligations concerning traceability pursuant to Article 56, immediately and on a permanent basis.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, setting out qualification and training requirements to be fulfilled by the operators in order for them to comply with the conditions of paragraph 1(a) and (b).

### *Article 70*

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

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

The information on the supplies as contained in those systems and procedures shall be made available to the competent authorities on request.

#### *Article 71*

##### **Withdrawal of authorisation**

1. Competent authorities shall immediately investigate any actual or suspected non-compliance by authorised operators with the conditions in Article 69 and impose corrective measures on those operators as necessary.
2. Competent authorities shall without delay withdraw the authorisation referred to in Article 69(1) of an authorised operator if it no longer complies with the conditions set out in that Article and does not apply the corrective measures imposed by the competent authorities within the requested period of time.
3. Competent authorities shall without delay withdraw the authorisation referred to in Article 69(1) to issue plant passports for the entire Union territory, if an authorised operator is located within a restricted area as referred to in Article 17. That withdrawal shall only concern the plants, plant products and other objects likely to host the Union quarantine organism for which the restricted area was established.
4. Competent authorities shall without delay withdraw the authorisation referred to in Article 69(1) to issue plant passports for certain protected zones, if an authorised operator is located within a restricted area as referred to in Article 31(1). That withdrawal shall only concern the plants, plant products and other objects likely to host the protected zone quarantine organism for which the restricted area was established.
5. By way of derogation to paragraphs 3 and 4, the respective withdrawals may not take place, or may be revoked, where the competent authorities ensure by intensified control and appropriate measures that the provisions concerning examinations referred to in Article 67(1, 2) are complied with.

#### *Article 72*

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

1. In case a lot of plants, plant products or other objects, for which a plant passport has been issued, is divided up, or several of such units or parts thereof are combined into a single lot, the concerned registered operator shall replace the plant passport through the issuance of another plant passport (replacing plant passport).
2. The replacing plant passport shall only be issued if the unaltered identity and origin of the product concerned is guaranteed and it is concluded that that product, since dispatch by the producer, continues complying with the provisions referred to in Article 67(1, 2).

#### *Article 73*

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

In the case where plants, plant products and other objects, introduced into the territory of the Union from a third country accompanied with a phytosanitary certificate, require a plant passport for movement within the Union pursuant to Article 60(2, 3), that plant passport shall be issued to replace the phytosanitary certificate.

That issuance shall take place on the condition that the checks at introduction into the territory of the Union have been completed and the plants, plant products and other objects concerned have been found, where applicable, in compliance with the provisions referred to in Article 67.

#### *Article 74*

##### **Prohibition of use of plant passport**

1. The operator shall remove the plant passport from the plants, plant products and other objects concerned, in case it is proven that the requirements of Articles 63 and 64 concerning the logo, information items, form or format of the plant passport, or the requirements referred to in Article 67(1, 2) are not fulfilled.

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

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

### **SECTION 3**

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

#### *Article 75*

##### **Certification of wood packaging material**

1. Requirements adopted pursuant to Articles 25(1), 27(2), 37(2), 38(1), 40(1) and 43(2) may concern the application of a mark in accordance with Annex II to the FAO International Standard for Phytosanitary Measures No 15 on Guidelines for regulating wood packaging material in international trade<sup>15</sup>, certifying that wood packaging material has been treated in accordance with the specifications in Annex II to that standard. In that case, that mark shall only be placed by operators registered in accordance with Article 52.
2. The Commission shall be empowered, in accordance with Article 81, to adopt delegated acts setting out requirements for the authorisation, supervision and withdrawal of authorisation by the competent authorities of operators applying that mark.

### **SECTION 4**

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

#### *Article 76*

##### **Phytosanitary certificates for export and re-export**

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

---

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

contain information in accordance with the relevant models specified to the Annex of IPPC.

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

2. The Commission may adopt, by means of implementing acts, the format of the phytosanitary certificates for export and re-export. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
3. Electronic phytosanitary certificates shall only be valid when provided through the computerised information management system referred to in Article [80 of revised Regulation 882/2004].

#### *Article 77*

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

1. The Member State from which the plants, plant products and other objects referred to in Article 76(1) are exported from the Union and the Member State where the plants, plant products and other objects originated shall exchange information as necessary to ensure that the export certification is completed without delay.

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

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

Those implementing acts shall be adopted, and where appropriate amended, in accordance with the examination procedure referred to in Article 82(3).

**SECTION 5**  
**DOCUMENTS FOR TRANSIT OF PLANTS, PLANT PRODUCTS**  
**AND OTHER OBJECTS THROUGH THE UNION**

*Article 78*

**Phytosanitary transit**

1. Plants, plant products and other objects may be moved in phytosanitary transit through the Union territory provided that the following conditions are met:
  - (a) they are packed and moved in such a way that there is no risk of spreading of quarantine organisms during their transit;
  - (b) they are accompanied by a signed attestation of the operator that those plants, plant products or other objects originate outside the Union territory, are destined for a third country and are packed and moved in such a way that there is no risk of spreading of quarantine organisms during their transit;
  - (c) they are moved under official control by the competent authorities.
2. The provisions in paragraph 1 concerning the transit of plants, plant products and other objects through the Union territory shall apply accordingly to their transit through protected zones.
3. Without prejudice to Article 51, plants, plant products and other objects that do not comply with the provisions referred to in Article 67(1) may be exported to third countries, or Union territories listed in Annex I, provided that the following conditions are met:
  - (a) they are packed and moved in such a way that there is no risk of spreading of quarantine organisms during their transit until the point of exit from the Union territory;
  - (b) they are accompanied by a signed attestation of the operator that those plants, plant products or other objects originate inside the Union territory, do not comply with the Union phytosanitary requirements, are destined for third countries and are packed and moved in such a way that there is no risk of spreading of quarantine organisms during their transit;
  - (c) they are moved under official control by the competent authorities.
4. The Commission shall be empowered, in accordance with Article 81, to adopt delegated acts setting out the contents of, and a harmonised format for, the attestation referred to in paragraph 1.

## **Chapter VII**

### **Measures supporting the implementation of this Regulation**

#### *Article 79*

##### **Establishment of a team of Union phytosanitary experts**

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

#### *Article 80*

##### **Establishment of application system for notification and reporting**

The Commission shall establish an electronic application system for the notification and reporting on the measures set out in Chapters II, IV and VI. That system shall be connected to and compatible with the computerised information system referred to in Article 80(1) of Regulation [official controls].

Member States shall notify any case of non-compliance with the provisions of those Chapters through that electronic application system.

NON-PAPER

## **Chapter VIII**

### **Final provisions**

#### *Article 81*

##### **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 20, 21(4), 30(3), 32(1), 52, 57(2), 57(3), 58(5), 60(2), 60(3), 62(2), 69(2), 75(2), 76(4) and 78(4) shall be conferred on the Commission for an indeterminate period of time from the entry into force of this Regulation.
3. The delegation of power referred to in this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to this Regulation shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

#### *Article 82*

##### **Committee procedure**

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.
5. Any references in Directive 2000/29/EC, Council Directive 69/464/EEC, Council Directive 93/85/EEC, Council Directive 98/57/EC and Council directive 2007/33/EC to the Standing Committee on Plant Health, and the acts adopted in accordance with the provisions of those Directives, shall be construed as references to the Standing Committee referred to in paragraph 1.

### *Article 83*

#### **Penalties**

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

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

### *Article 84*

#### **Repeals**

1. Council Directive 2000/29/EC and the acts referred to in Annex IV are repealed.
2. References to the repealed Directives and Regulations shall be construed as references to this Regulation and shall be read in accordance to the correlation table set out in Annex V.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 81, setting out that one or more of the acts referred to in Annex IV shall be repealed at a specific date after the date from which this Regulation shall apply. In case of conflict between the provisions of those acts and the provisions of this Regulation, the provisions of this Regulation shall prevail.

### *Article 85*

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

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

This Regulation shall apply from [date x].

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 excluded from the scope of the Regulation**

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

**Annex II**  
**Criteria for the qualification of harmful organisms according  
to their risk to the Union**

**SECTION 1**

**CRITERIA TO IDENTIFY HARMFUL ORGANISMS WHICH QUALIFY AS A QUARANTINE ORGANISM AS  
REFERRED TO IN ARTICLE 3(1), 4(2), 6(2), 26(3) AND 29**

(1) Identity of the harmful organism

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

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

(2) Presence of the harmful organism in the Union

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

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

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

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

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

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

The organism shall be capable of establishment in the Union, or the specific part(s) of the Union territory where it is not present, because:

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

(c) *Probability of spread within the Union*

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

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

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

The entry, establishment and spread in the Union [or parts of it] of the organism shall have unacceptable economic, social and/or environmental impacts for the Union in one or several of the following areas:

(a) Direct effects on potential hosts in the endangered area:

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

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

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

- changes to producer costs or input demands, including control costs and costs of eradication and containment;
- effects on producer profits that result from changes in production costs, yields or price levels;
- changes to domestic or foreign consumer demand for a product resulting from quality changes;
- effects on domestic and export markets and prices paid, including effects on export market access and likelihood of phytosanitary restrictions imposed by trading partners;

- resources needed for additional research and advice;
- environmental and other undesired effects of control measures;
- effects on plant communities and biodiversity;
- effects on designated environmentally sensitive or protected areas;
- changes in ecological processes and the structure, stability or processes of an ecosystem, including further effects on plant species, erosion, water table changes, fire hazards, nutrient cycling;
- costs of environmental restoration;
- effects on food security;
- effects on employment;
- effects on water quality, recreation, tourism, animal grazing, hunting, fishing.

NON-PAPER

## SECTION 2

### CRITERIA TO IDENTIFY QUARANTINE ORGANISMS WHICH QUALIFY AS A PRIORITY ORGANISM AS REFERRED TO IN ARTICLE 5(2)

(1) Presence of the quarantine organism in the Union

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

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

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

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

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

- (a) Economic impacts: the organism shall have the potential to cause major losses in terms of the direct and indirect effects referred to in point (4)(b) of Section I for crops with a total annual production value for the Union of at least EUR 1 billion.
- (b) Social impacts: the organism shall have the potential to cause one or more of the following effects:
  - (i) a significant employment decrease in the agriculture, horticulture of forestry sector concerned;
  - (ii) risks to food security;
  - (iii) the disappearance of or permanent large-scale damage to certain main tree species growing or cultivated in the Union.
- (c) Environmental impacts:
  - (i) reduction, displacement or elimination of keystone plant species, plant species that are major components of ecosystems and endangered native plant species in relation to protected areas covered under the provisions of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora<sup>16</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>17</sup>;
  - (ii) major and permanent increases of the use of plant protection products on the crops concerned.

---

<sup>16</sup> OJ L 206, 22.7.1992, p. 7

<sup>17</sup> OJ L 20, 26.1.2010, p. 7

### SECTION 3

#### CRITERIA TO IDENTIFY HARMFUL ORGANISMS WHICH PROVISIONALLY QUALIFY AS A QUARANTINE ORGANISM REQUIRING TEMPORARY MEASURES AS REFERRED TO IN ARTICLES 26(1), 27(1) AND 29

(1) Identity of the harmful organism

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

(2) Presence of the harmful organism in the Union

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

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

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

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

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

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

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

## SECTION 4

### CRITERIA TO IDENTIFY HARMFUL ORGANISMS WHICH QUALIFY AS A QUALITY ORGANISM AS REFERRED TO IN ARTICLE 34(1) AND 35(2)

(1) Identity of the harmful organism

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

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

(2) Relevance of the harmful organism to the Union territory

The organism shall be present in the Union territory and shall not qualify as a quarantine organism for the entire Union territory.

(3) Probability of spread in the Union of the harmful organism

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

The assessment shall include as appropriate the following aspects:

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

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

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

(a) Direct effects:

- crop losses in terms of yield and quality;
- extra costs of control measures;
- extra costs of harvesting and grading;
- costs of replanting;
- losses due to the necessity of growing substitute crops;
- effects on existing production practices;
- effects on other host plants at the place of production;
- capacity of the organism to act as a vector for other harmful organisms.

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

(b) Indirect effects:

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

## SECTION 5

### CRITERIA TO IDENTIFY PLANTS FOR PLANTING WHICH ARE LIKELY TO POSE PREVIOUSLY UNIDENTIFIED PHYTOSANITARY RISKS, AS REFERRED TO IN ARTICLE 42(2)

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

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

**Annex III**  
**Principles for the management of the risks of quarantine organisms and risk management measures that may be applied**

**SECTION 1**

**MEASURES TO MANAGE THE RISKS OF QUARANTINE ORGANISMS AS REFERRED TO IN ARTICLES 16(1), 25(4), 27(5), 28(1), 37(3), 39(2), 40(1) AND 44(2)**

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

(1) Measures targeting prevention and elimination of infestation of cultivated and wild plants

- (a) Restrictions on the identity, nature, origin, ancestry, provenance and production history of cultivated plants;
- (b) Restrictions on the cultivation, harvesting and use of plants;
- (c) Restrictions on the use of plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects;
- (d) Surveillance, inspection, sampling and laboratory testing of plants, plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects for the presence of quarantine organisms;
- (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 organism 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 organisms;
- (g) Destruction of plants, plant products and other objects, infested or potentially infested with quarantine organisms or for preventive purposes;
- (h) Information, data recording, communication and reporting obligations.

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

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

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

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

- (a) Restrictions on the identity, nature, origin, provenance, ancestry, production history and traceability of plants, plant products and other objects;

- (b) Restrictions on the use, handling, processing, packaging, storage, distribution and destination of plants, plant products and other objects;
- (c) Surveillance, inspection, sampling, laboratory testing of plants, plant products and other objects for the presence of quarantine organisms, 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 organisms;
- (e) Information, data recording, communication and reporting obligations.

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

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

(3) Measures targeting other pathways for quarantine organisms

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

## SECTION 2

### PRINCIPLES FOR THE MANAGEMENT OF THE RISKS OF HARMFUL ORGANISMS AS REFERRED TO IN ARTICLES 16(1), 25(4), 26(2), 27(5), 28(1), 34(2), 37(3), 39(2), 39(3), 40(1), 42(2), 43(3), 44(2) AND 44(3)

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

(1) Necessity

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

(2) Proportionality

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

(3) Minimal impact

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

(4) Non-discrimination

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

(5) Technical justification

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

(6) Feasibility

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

**Annex IV**  
**Repealed acts referred to in Article 85(1)**

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

17. Commission Regulation (EC) No 1040/2002 of 14 June 2002 establishing detailed rules for the implementation of the provisions relating to the allocation of a financial contribution from the Community for plant-health control and repealing Regulation (EC) No 2051/97.

NON-PAPER

**Annex V**  
**Correlation table**  
**[to be completed]**

NON-PAPER